SYLLABUS FOR THE EUROPEAN SPECIALISATION IN HISTOCOMPATIBILITY AND IMMUNOGENETICS (ESHI) CERTIFICATE

The ESHI Certificate Syllabus is split into a number of grouped areas of study.

The sections require different levels of knowledge. If the section is one for which the candidate only needs ‘awareness’ then this means that the candidate must show evidence that during their experience/training they have been exposed to the concept mentioned, either within their own lab or through reading textbooks/papers.

Upon completion of training, it is expected that the candidate will be able to form a clinically relevant opinion on Histocompatibility and Immunogenetics (H&I) related issues based upon an applied, contemporary, scientific understanding. This informed opinion will underpin the ability to give clinically relevant advice in all aspects of H&I.

1. Legislation and Regulations
   Is aware of relevant European and Local Statutes, Regulations and Guidance pertaining to:
   a. Transplantation practice
   b. Health and Safety
   c. Biological, chemical and mechanical hazards
   d. Confidentiality
   e. Consent
   f. Specimen handling and transport
   g. Specimen storage and disposal

2. Quality Management
   Knows the requirements of national and international standards relating to quality management systems, including:
   a. Accreditation
   b. Internal and External Quality Assurance
   c. Quality Control
   d. Introducing new technology / effective change control
   e. Audit
   f. Incident monitoring and root cause analysis
   g. Principles of Good manufacturing Practice

3. Laboratory Management
   Is aware of the principles involved in the following:
a. Budget planning and handling  
b. Recruitment  
c. Disciplinary and grievance procedures  
d. Performance Review  
e. The role of Trade Unions / Partnership working  
f. Communication skills  
g. Leadership Skills  
h. Delivering training  
i. Clinical Governance

4. Innate and adaptive immunity  
Knows the physiological processes and the clinical relevance of the following in relation to H&I services:  
a. Haemopoiesis in health and disease  
b. The roles of different leukocyte populations  
c. PRRs and PAMPs in innate immunity; TLRs etc  
d. The Complement system  
e. Antigen Presentation and MHC restriction  
f. Structure, function and biological distribution of MHC Antigens  
g. T and B cell activation  
h. Regulatory cell subsets  
i. NK cell activation  
j. Inflammation  
k. The action of immunosuppressive therapies  
l. Autoimmunity

5. Transplant immunology  
Knows the physiological processes and the clinical relevance of the following in relation to H&I services:  
a. Direct and indirect T cell activation  
b. Role of passenger leukocytes  
c. Immune processes leading to hyperacute, acute, accelerated and chronic allograft rejection  
d. Immune processes leading to GvHD  
e. GvL  
f. Relevance of HLA antibodies in rejection  
g. Non-HLA immunity  
h. Tolerance and regulatory cell populations
i. NK cells in rejection and GvHD/GvL
j. Minor histocompatibility antigens
k. Non inherited maternal antigens (NIMA)

6. The Major Histocompatibility Complex
Knows the relevance of the following in relation to H&I services:
a. International Histocompatibility Workshops
b. Anthropological studies
c. The HLA Complex: gene location
d. HLA gene and protein nomenclature
e. HLA haplotypes
f. HLA gene polymorphism
g. Non-HLA genes in the extended HLA Complex; MIC, HFE, C’ (=Complement)

7. Relevant techniques in H&I Services
Knows the limitations of the following and can provide clinical interpretation, recommending additional testing where appropriate:
a. Principles of HLA typing techniques including CDC, SSP, SSO, SBT & NGS (Next Generation Sequencing)
b. Assays for the detection and definition of HLA-specific antibodies
c. Techniques employed for donor/recipient cross-matching and assessment of risk at the time of transplant
d. Omission of the pre-transplant crossmatch
e. Post-transplant monitoring
f. Principles involved in the management of a Registry or Cell Bank, including aseptic technique, cell culture, cryopreservation, cataloguing, storage and retrieval.
g. Cellular assays used within H&I

8. Genetics and Molecular Genetics
Knows the principles of the following in relation to H&I:
a. DNA based technologies used in H&I services
b. Transcription and translation of genes
c. Generation of HLA polymorphism
d. Potential mechanisms underlying HLA and disease associations
e. Potential mechanisms underlying HLA and pharmacogenetic associations
f. NK cell receptor gene families
9. Biostatistics and Bioinformatics
Is aware of basic analyses and can advise upon the relevance of statistical analyses including:
- Survival analysis
- Population genetics
- Database Management
- International Genetics Databases
- Data storage and processing
- Epitope prediction

10. Clinical Relevance of H&I in solid organ transplantation
(Required for Module 1 H&I in solid organ transplantation, Module 3 H&I in disease association, and Module 4 H&I in transfusion)
Is experienced with the following aspects of H&I and can provide interpretive advice on the following:
- Selection of appropriate donors or recipients for transplantation
- Assessment of risk at the time of transplant
- Factors influencing transplant outcome
- Post-transplant monitoring
- Biological variation in requirement for HLA matching in different forms of solid organ transplantation

11. Clinical Relevance of H&I in haematopoietic stem cell transplantation
(Required for Module 2 H&I in HSC transplantation, Module 3 H&I in disease association, and Module 4 H&I in transfusion)
Is experienced with the following aspects of H&I and can provide interpretive advice on the following:
- Selection of appropriate donors for transplantation
- Searching for donors on local and international registries/cord banks
- Factors influencing transplant outcome
- Post-transplant monitoring
- Biological variation in requirement for HLA matching when using different sources of donors for transplantation

12. Clinical Relevance of H&I in transfusion
(Required for Module 4: H&I in Transfusion only)
Is aware of the following aspects of H&I and can provide interpretive advice on the following:
- Selection of appropriate donors or recipients for treatment with HLA and/or HPA selected blood products and assessment of risk
13. Clinical Relevance of H&I in disease, cancer and pharmacogenetic testing
(Required for Module 3: H&I in Disease Association only)
Is aware of the following aspects of H&I and can provide interpretive advice on the following:
  a. Clinical relevance of HLA in autoimmune and infectious disease
  b. Clinical relevance of HLA in cancer and immunotherapy
  c. Clinical relevance of HLA in pharmacogenetic testing

14. Organ allocation and enhancing donation rates
(Required for Module 1 H&I in solid organ transplantation only)
Knows the principles of the following in relation to H&I:
  a. Deceased donor organ allocation locally and within Europe
  b. Heart beating and non-heart beating donation
  c. Opt in and opt out programmes for donation after death
  d. Living donation
  e. Paired exchange schemes
  f. Altruistic donation
  g. Antibody incompatible transplantation

15. Research and Development
Is aware of the principles involved in and can provide documented evidence of experience in the following:
  a. Requirements and Procedures for gaining ethical approval
  b. Research Governance
  c. Good Clinical Practice
  d. Data Analysis
  e. Data Presentation