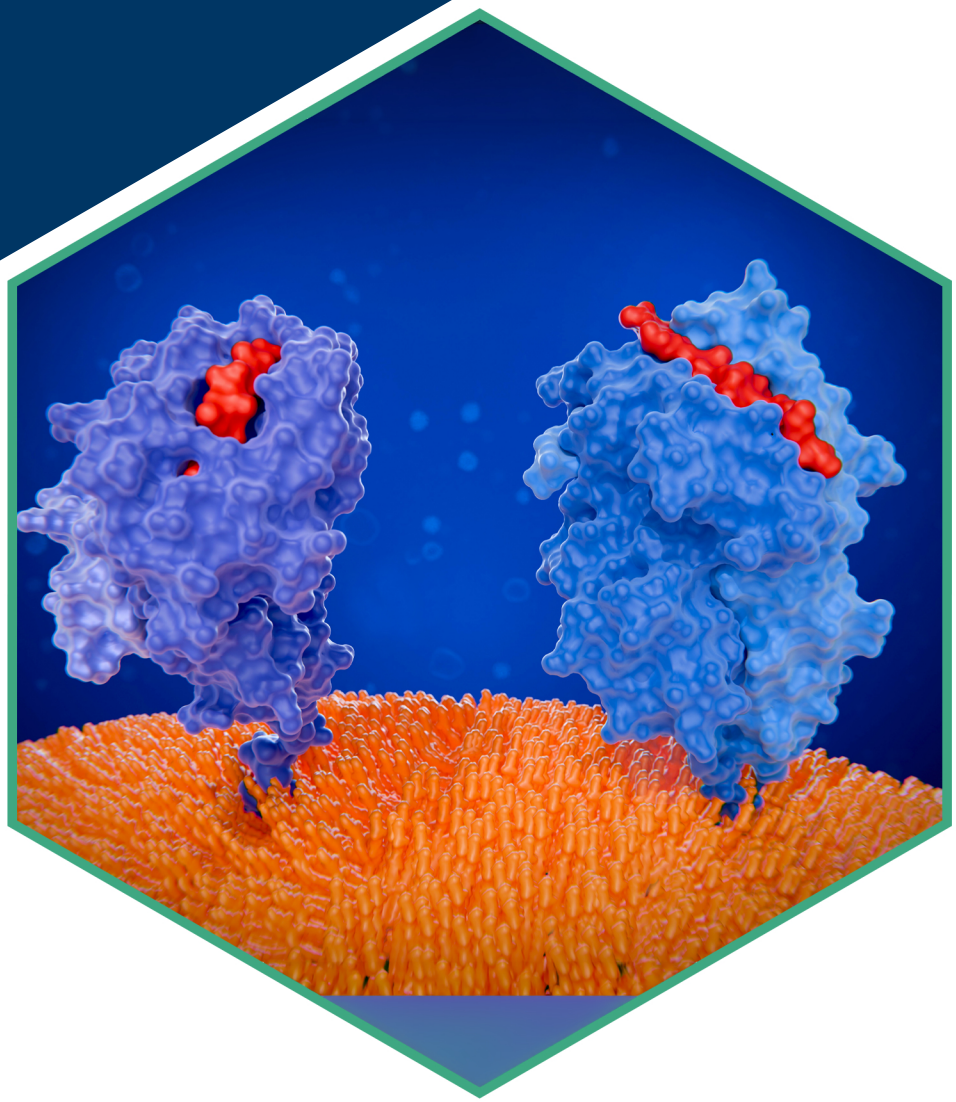
HISTOCOMPATIBILITY AND IMMUNOGENETICS DIGITAL SPECIALIST PORTFOLIO MODULES

IBMS Institute of Biomedical Science



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Histocompatibility and Immunogenetics Specialist Portfolio Modules

- Quality (please see separate booklet for learning outcomes)
- Foundations of Immunology in Histocompatibility and Immunogenetics
- The Major Histocompatibility Complex (MHC)
- Mechanisms of Rejection and Immunosuppression in Solid Organ Transplantation
- DNA extraction & Polymerase Chain Reaction (PCR)
- H&I Next Generation Sequencing (NGS)
- Non-Transplant Clinical Applications of Human Leukocyte Antigens (HLA)
- Antibody Screening and Identification
- Crossmatching
- Solid Organ Transplantation
- Principles of Haematopoietic Stem Cell Transplant
- HLA Matching, Donor Selection and Transplant Monitoring
- Transfusion
- Histocompatibility and Immunogenetics Quality

Please note
All learning outcomes (LOs) are met through two pieces of evidence, Q&A as agreed with a training officer and an additional piece of work as selected by the candidate.

A statement of work and reflective statement on each module will be required which will include sign off by the trainer stating that the candidate works in accordance with laboratory procedures, the competence for which should be evidenced in-house and is not part of the portfolio submission.

Indicative Content outlines background knowledge that may be required to meet the LOs and/or knowledge and competences expected to be demonstrated across multiple modules. Knowledge of areas highlighted in the indicative content may be examined during the viva.

Module Title	Foundations of Immunology in Histocompatibility and Immunogenetics
Module code	40766
Rationale/ Aims	This module will enable the candidate to acquire an in-depth understanding of the immunological processes and effector molecules central to transplantation science. This knowledge will enable the candidate to comprehend the evolution of transplantation practices, particularly regarding the significance of histocompatibility and testing methodologies, the generation and implications of antibodies, targets for immunosuppression, and factors contributing to organ damage.
Learning outcomes	1. Describe innate and adaptive immunity and their interaction 2. List and define the major characteristics and functions of cells of the immune system 3. Explain the concept of self and non-self, including the theories of T and B cell tolerance 4. Describe the structure, function and genetic organisation of Immunoglobulins, T-cell receptors and Killer-cell Immunoglobulin-like Receptors (KIR) 5. Discuss mechanisms for Immunoglobulin and T-cell receptor diversity, including mechanisms for Immunoglobulin class switching 6. Describe the roles of cytokines and chemokines in immune responses with transplant examples 7. Explain the role of the lymphatic system and the morphology of lymph nodes, MALT, Pals and Peyer's patches 8. Describe the role of professional and non-professional antigen presenting cells with reference to the processing of exogeneous and endogenous peptides, the role of MHC Class I and II, presentation and cross-presentation of antigens, the role of co-stimulatory molecules (CD3, CD4/CD8, CD28,B7) and the activation of T cells 9. Describe the mechanisms of HLA polymorphisms and their significance in antigen presentation, and the implications of this for patients in your laboratory 10. Discuss with examples disorders that can arise from faulty haematopoiesis.
Indicative Content	Candidates require knowledge and understanding of: Different branches of the immune system, including cellular characteristics and functions of the following: Granulocytes, Macrophage, dendritic cells, other antigen presenting cells, Th0, Th1, Th2, Th17, Tc1, Tc2, regulatory cells, T and B cells, NK cells, endothelial cells and platelets.

	and effector processes such as: • Necrosis • Apoptosis • Inflammation The candidate should be able to define the following terms: • Antigen • Super Antigen • Antigen Epitope • Idiotope The candidate should know the differences between primary and secondary immune responses, and humoral and cellular Immunity. Candidates should understand the complement cascade including Classical and Alternative pathways.

Module Title	The Major Histocompatibility Complex (MHC)
Module code	40759
Rationale/ Aims	The candidate will gain an understanding of the structure, function and nomenclature of the Major Histocompatibility Complex (MHC), including theories on MHC evolution and variation.
Learning outcomes	1. Explain the genomic organisation of the MHC region on chromosome 6, highlighting the locations and clinical functions of classical HLA genes, non-classical HLA genes (e.g., HLA-DO, HLA-DM), and associated genes such as TAP, LMP, TNF, C2, C4, Bf, and HFE 2. Describe the structural features, key functions and differences of the MHC Class I and II molecules 3. Explain the WHO nomenclature for serological and molecular HLA typing with examples from your practice. Include numeric principles, locus identifiers, specificity, broad/split, and null and other variants. 4. Discuss the concept of public and private epitopes with reference to Bw4/Bw6, shared amino acid sequences and cross-reactivity 5. Explain Linkage Disequilibrium and discuss, with examples, its implications. 6. Describe, with examples, theories of selective pressure responsible for MHC variation. 7. Describe statistical methods commonly used in population genetics and explain how they are applied and their clinical relevance. 8. Demonstrate assigning haplotypes in a family pedigree
Indicative Content	Candidates require knowledge and understanding of: Mode of inheritance of HLA genes The terms phenotype, genotype and haplotype Organisation and mechanisms of gene control, e.g. recombination, crossover and mutations

Module Title	Mechanisms of Rejection and Immunosuppression in Solid Organ Transplantation
Module code	40764
Rationale/ Aims	The candidate will gain a comprehensive understanding of various types of grafts and will be able to define the different forms of rejection, along with the underlying immune mechanisms. Additionally, the candidate will acquire knowledge of immunosuppressive therapies and their respective modes of action.
Learning outcomes	1. Discuss the role of the H&I laboratory in minimising rejection 2. Describe the principles behind the different types of rejection 3. Discuss laboratory actions taken when investigating suspected rejection including collation of clinical information required 4. Discuss different categories of immunosuppressive therapies and their mode of action, e.g. calcineurin inhibitors, steroids, antiproliferative's and biological agents 5) Discuss the potential impact of immunosuppressive therapies on assays within your laboratory 6) Discuss, with examples, immunosuppressive regimes used in solid organ transplantation 7) Define the following terms: mono, triple, quadruple therapy and discuss the scenarios in which they may be used 8) Discuss emerging or novel therapies and their possible applications
Indicative Content	Candidates require knowledge and understanding of: The different forms of graft, and how these are used in practice Immunological process behind graft rejection including the following: cytotoxic T cells, antibody formation, ADCC, inflammation and complement activation. Different immunosuppressive therapies, including: Prophylactic Induction Maintenance Rejection An awareness of the criteria used to assess allograft rejection e.g. Banff criteria

Module Title	DNA extraction & Polymerase Chain Reaction (PCR)
Module code	40761
Rationale/ Aims	The candidate will gain a comprehensive understanding of the theoretical principles and practical methodologies involved in DNA extraction and quantitation within the H&I laboratory. This includes familiarity with various extraction techniques, the importance of sample quality, and methods used to assess DNA concentration and purity, and an understanding of how DNA quality and concentration can directly influence the reliability and sensitivity of downstream molecular assays. The candidate will also develop a sound theoretical and practical understanding of the application of Polymerase Chain Reaction (PCR) and real-time PCR (qPCR) in H&I testing and be able to demonstrate the ability to optimise and troubleshoot PCR-based assays in line with laboratory quality standards and clinical requirements.
Learning outcomes	1. Discuss, with examples from your lab, the different types of samples which DNA can be extracted from, and the handling of the samples post DNA extraction. 2. Explain the principles of DNA extraction techniques including cell lysis, purification, precipitation and washing and discuss the method of DNA extraction used in your laboratory, in addition to other methodologies available. 3. Explain how DNA concentration and purity are measured, why these measurements are essential before carrying out an assay, and the potential impact that inaccurate DNA quantification or purity assessment can have on assay performance and results. 4. Demonstrate the techniques used in your lab to reduce cross-contamination, the use of negative controls and the importance and principles of wipe testing. 5. Define the underlying principles of PCR and its application to HLA typing. 6. Explain the different applications of various PCR-based typing systems including SSO/SSP/qPCR, low/medium/high resolution, turnaround times and advantages/disadvantages of PCR-based typing systems. 7. Explain the principles of gel electrophoresis, the use of a DNA molecular weight marker, how data is interpreted and quality controls. 8. Discuss what remedial/repeat actions may be required where an individual assay is suboptimal and demonstrate with examples from practice. 9. Discuss the factors to be considered when developing and optimising a new PCR assay. Consider reagents, primer design, equipment, target, set up, workflow, and end point analysis.

	10. Demonstrate interpretation of PCR results using examples from candidate's practice
Indicative Content	Candidate requires knowledge and understanding of: Principles of DNA extraction from blood, tissue or buccal swabs. The importance of quantifying DNA and be able to adjust DNA concentration accordingly. The various types of contamination and risk of sample errors/mix-ups which can be encountered, and how they can be prevented and monitored for. DNA amplification techniques, with particular focus on the principles, setup, and applications of Polymerase Chain Reaction (PCR) across a range of analytical platforms. This should include: • Appropriate setup and optimisation of PCR reactions, considering factors such as template quality, primer concentration and cycling parameters. • The importance of having separate pre and post areas to avoid contamination. • Primer design strategies, including how to address challenges such as high GC content and minimising primer-dimer formation. • The function and importance of key reagents used in molecular typing, such as primers, DNA polymerases, probes, and necessary cofactors. • The differing resolutions and limitations of methods used. • How methods involving RT-PCR work. • The principles of gel electrophoresis and the use of molecular weighted markers. Candidates must be able to: Interpret PCR results relevant to laboratory scope of practice

Module Title	H&I Next Generation Sequencing (NGS)
Module code	40762
Rationale/ Aims	The candidate will gain a detailed understanding of the principles and clinical applications of Next Generation Sequencing (NGS) for HLA typing within the H&I laboratory setting. This includes both theoretical knowledge and practical experience of the NGS workflow, from sample preparation, library construction, sequencing, and data analysis through to result interpretation and reporting. The candidate will develop an understanding of the core bioinformatics principles underpinning HLA sequence analysis, including read alignment, variant calling, phasing, and allele assignment, with an emphasis on how these are applied in the context of polymorphic HLA genes. The candidate will also gain an understanding of the quality control metrics and data validation used to assess NGS assay performance.
Learning outcomes	1. Discuss the relevance of NGS in the laboratory and its importance in the wider setting of Histocompatibility and Immunogenetics. 2. Define the underlying principles of a range of NGS technologies, for example Sequencing by Synthesis, Semiconductor Sequencing, Single Molecular Real-Time sequencing. 3. Explain the importance of each major component of an NGS assay (e.g. sample preparation, library preparation, target enrichment, sequencing, data analysis and data storage etc.). 4. Discuss the strengths and limitations of each NGS method and how it compares to Sanger sequencing; consider the detection of copy number variation, single nucleotide variation, loss of heterozygosity and structural variants. 5. Discuss possible errors which can occur during NGS and propose relevant troubleshooting. Use an example of practice where relevant. 6. Demonstrate the acceptance of a run, and how failures are managed. 7. Discuss the benefits of using NGS in patient management. 8. Demonstrate interpretation of NGS results from candidate's practice 9. Discuss the procedure for managing International ImMunoGeneTics® Information System (IMGT) updates within candidate's laboratory and explain the importance
Indicative Content	The candidate requires knowledge and understanding of: DNA replication processes and theoretical principles and practical applications of key NGS platforms, including library preparation, clonal amplification and sequencing by synthesis. Sanger sequencing. The candidate should understand the core bioinformatics principles relevant to HLA analysis, including:

	• Mapping sequencing reads to the IMGT/HLA reference database. • Assessing sequencing read quality and identifying low quality or ambiguous regions. • Performing base and variant calling. • Evaluating read/depth coverage • Using software to interrogate/visualise variant calls. • Relevant guidelines

Module Title	Non-Transplant Clinical Applications of Human Leukocyte Antigens (HLA)
Module code	40767
Rationale/ Aims	The candidate will acquire a thorough knowledge and understanding of diseases associated with specific HLA alleles; including the up to date understanding of the mechanisms of the HLA associations and application of the patient's HLA type in the context of their clinical condition. The candidate will acquire a thorough knowledge and understanding of HLA alleles associated with adverse outcomes in the use of specific therapeutic drugs; including an up to date understanding of the mechanisms of the HLA association and application of the patient's HLA type in the context of their clinical condition.
Learning outcomes	1. Identify common and uncommon HLA disease associations used clinically and tested for in the H&I laboratory. 2.Discuss, with examples, proposed common mechanisms for HLA disease associations, including the extent of the association. 3. Discuss, with examples, the clinical implication and relative risk of positive/negative or presence/absence of the associated HLA for the patient. 4. Identify HLA alleles associated with adverse drug reactions commonly tested for in the H&I laboratory. 5. Discuss, with examples, proposed mechanisms for the association of drug reactions with HLA alleles, including the extent of the association. 6. Discuss, with examples, the relative risk of positive/negative or presence/absence of the HLA associated allele with the adverse drug reaction and the clinical implication for the patient. 7. Discuss how a sample with an unusual request for disease association/pharmacogenetic testing would be managed within your laboratory. 8. Demonstrate interpretation and reporting of disease association and pharmacogenetic testing in line with current guidelines.
Indicative Content	The candidate requires knowledge and understanding of: The use of HLA typing for disease association testing, including the selection of the appropriate HLA typing test with consideration of the degree of resolution, turnaround time required and the clinical reporting of the result. The role of specific HLA alleles the diagnosis of diseases, including, but not limited to, Ankylosing Spondylitis, Rheumatoid Arthritis, Coeliac Disease, Narcolepsy, Bechet's Disease, Birdshot Retinopathy and Actinic Prurigo.

	The use of HLA typing for adverse drug reactions, including the selection of the appropriate HLA typing test with consideration to the degree of resolution, turnaround time required and the clinical reporting of the result. The role of specific HLA alleles in adverse drug reactions including HLA B*57:01, B*58:01, A*31:01, B*15:02, A*02:01 EQA schemes for disease association and pharmacogenetic testing Associated mechanisms for a variety of diseases including, but not limited to, coeliac disease and ankylosing spondylitis

Module Title	Antibody Screening and Identification
Module code	40765
Rationale/ Aims	The candidate will acquire an in-depth understanding of the theory and practice involved in the identification of HLA and Non-HLA antibodies that are relevant within a histocompatibility and immunogenetics laboratory setting. This knowledge will enable the candidate to comprehend the advantages and disadvantages of each technique and how these techniques can be used to generate an antibody profile for the patient and the impact this profile will have on their access to a solid organ or haemopoietic stem cell transplantation.
Learning outcomes	1) Explain the principles of antibody screening and identification techniques include advantages and disadvantages. The following should be included: • Cytotoxicity • Solid phase immunoassays 2. Discuss sample pre-treatment methods for antibody testing used within your laboratory and explain the rationale for when these are used. 2) Discuss acceptance criteria of the assays used in candidate's practice and demonstrate what actions may be taken if results are outside accepted criteria. 3) Demonstrate how trends in QC parameters are monitored within the lab and explain their importance. 4) Discuss criteria used in assessing which HLA antibodies within solid organ transplantation are clinically significant, including antibody class, listing strategy and risk stratification. 5. Discuss the clinical significance of non-HLA antibodies in transplantation. 6. Describe differences between screening and identification techniques for HLA antibodies within histocompatibility and immunogenetics laboratories, including how you determine cut-offs 7. Demonstrate identification of HLA or Non-HLA antibodies for a patient relevant to your practice and discuss, with examples where relevant, how to troubleshoot inconclusive or unexpected results. 8. Explain the impact of the antibody profile on the patient's ability to receive a solid organ or hematopoietic stem cell transplant. 9. Discuss routes to sensitisation and discuss how this might influence interpretation of results
Indicative Content	Candidates require knowledge and understanding of: The principles and practice of HLA and Non-HLA antibody screening within the histocompatibility and immunogenetics laboratory setting, this would include:

	• Principles, advantages and limitations of techniques used to identify HLA and Non-HLA Antibodies. • The importance or IQA and EQA as applied to HLA and Non-HLA antibody detection. • Clinical application of HLA and Non-HLA Antibody Detection • The detection and generation of HLA Antibody profiles. • The impact of HLA and Non-HLA antibody detection on the patients access to transplantation. • ELISA • Flow Cytometry – Cellular and Bead based assays The role of HLA Class, antibody isotypes and auto-antibody roles in this setting. The tools available within analysis software that aid interpretation of results

Module Title	Crossmatching
Module code	40768
Rationale/ Aims	The candidate will gain a detailed understanding of the principles and applications of flow cytometric crossmatching (FCXM) as performed in the Histocompatibility & Immunogenetics (H&I) laboratory. This will include the theoretical basis of the assay, its clinical relevance in transplantation, and the technical aspects involved in developing, optimising and troubleshooting both the FCXM assay and the flow cytometer itself. The candidate will be able to interpret assay results and understand the limitations and potential sources of error. Additionally, the candidate will gain a comprehensive understanding of virtual crossmatching (vXM). This will include its principles, clinical use, and limitations. Candidates will be able to demonstrate how to perform and interpret a vXM using HLA typing and antibody specificity data and understand how vXM supports donor-recipient compatibility assessment in both deceased and living donor transplant scenarios.
Learning outcomes	1. Explain the principles of flow cytometric crossmatching including the selection and preparation of cells and patient sera, use of controls, selection of conjugate(s) and differentiation between T-cell and B-cell reactivity 2. Explain the importance of running QC checks on the flow cytometer to verify instrument performance and define the metrics validated as part of the acceptance criteria, such as PMT voltages and fluorescence intensity 3. Explain the importance of tracking QC trends over time and demonstrate how deviations are documented and investigated 4. Explain the principles of colour compensation and spectral overlap in flow cytometry and describe how improper compensation can impact assay accuracy and data interpretation 5. Discuss the clinical significance of HLA and non-HLA antibodies in flow cytometric crossmatching and their potential impact on transplant outcomes 6. Describe the gating strategy and analytical workflow used in flow cytometric crossmatching, including how fluorescence shifts are measured and assessed 7. Explain how you would interpret T-cell and B-cell flow cytometric crossmatch results, including the application and validation of laboratory cut-off values 8. Demonstrate troubleshooting a flow cytometric crossmatch 9. Demonstrate virtual crossmatching and explain how it differs from a physical crossmatch

	10. Explain the advantages and limitations of using a virtual crossmatch
Indicative Content	The candidate requires knowledge and understanding of: Applications of flow cytometry crossmatching including: • Clinical application • Laboratory practice and quality assurance • Assay limitations and challenges The candidate should understand the principles of virtual crossmatching including: • Use of HLA antibody profiles and donor HLA types • Advantages in deceased donor allocation • Limitations and risk assessment The candidate should be able to: Set up and run flow cytometric crossmatch Maintaining quality of assay performance Analyse flow crossmatch results

Module Title	Solid Organ Transplantation
Module code	40760
Rationale/ Aims	The candidate will gain an understanding of histocompatibility as applied to solid organ transplantation including patient eligibility and registration for transplantation, the allocation policies for organs, including paired exchange for live kidney donation. They will also be able to perform donor-recipient compatibility assessment. In addition, the candidate will develop understanding of post-transplant monitoring techniques to support effective patient outcomes and identify factors that impact re-transplantation. The candidate will be able to explain the legal and regulatory frameworks governing solid organ transplantation.
Learning outcomes	1. Explain the criteria for patient registration onto a transplant waiting list, using local examples if applicable 2. Discuss the national allocation policies for solid organs, including the importance and relevance of the following: • ABO Blood groups • Waiting time • HLA A, B – DR hierarchy • Homozygocity • Geographical regions • Donor and recipient risk index • Tier A/B, Level 4 • Donor Size/weight • Virology testing 3. Demonstrate candidates' ability to determine suitability of donor offers with reference to ABO grouping, HLA typing, HLA antibodies and crossmatch result, consider risk stratification 4. Explain the purpose of the U.K. Living Kidney Sharing Scheme, include types of donors and patients entered, transplant cycles and transplant chains 5. Compare methods used for antibody removal in cases of ABO and HLA incompatible transplantation 6. Describe procedures in place in your laboratory to ensure compliance with the Human Tissue Act, include handling, storage and disposal of human tissues and give examples of how these are applied in practice 7. Explain the application of post-transplant monitoring and the significance of these antibodies if detected, use examples from clinical practice if relevant 8.Discuss factors which may affect re-transplantation in solid organ recipients

	9. Discuss methods/strategies employed by transplant laboratories to aid prevention sensitisation
Indicative Content	The candidate requires knowledge and understanding of: Organ sources utilised for solid organ transplantation. The candidate will be aware of methods utilised to prevent sensitisation such as HLA matching, listing of unacceptable antigens, selected products for transfusion. The candidate will know legislation and regulations that govern deceased and living transplantation.

Module Title	Principles of Haematopoietic Stem Cell Collection and Transplantation
Module code	40763
Rationale/ Aims	The candidate will acquire a good understanding of haematopoiesis, cell lineages and biological properties of haematopoietic stem cells (HSC) and non-HSCs of the human blood system. Including knowledge of how haematopoiesis can go awry and develop into diseases requiring treatment by HSCT. The candidate will also understand the principles of HSC transplantation including the sourcing and collecting of HSCs, indications for HSCT, success factors and complications of HSCT.
Learning outcomes	1. Describe the classification, lineage pathways, cellular components, regulation and clinical use of haematopoiesis 2. Explain the principles and mechanisms of haematopoietic stem cell transplantation in the treatment of malignant and non-malignant blood diseases and disorders 3. Identify common diseases and conditions encountered in patients referred for testing in the H&I laboratory treatable by HSCT, explain the mechanisms and stages of those diseases. Reference UK and international guidelines for indications and disease stages treatable by HSCT 4. Discuss the principles of the methods of collection and the laboratory processing of stem cells for HSCT, including sources of stem cells, cryopreservation and pretreatment of stem cells 5. Describe the different sources of haematopoietic stem cells and donors used for transplant, including the advantages, disadvantages and influence on the outcomes of HSCT 6. Describe the mode of action and types of pre-transplant conditioning regimens and explain their influence on HSCT outcomes 7. Describe the potential post-transplant complications of HSCT, including GvHD, rejection, infection and secondary malignancies 8. Discuss the mechanisms and impact of post HSCT therapies on the outcome of transplant including post-transplant Cyclophosphamide, donor lymphocyte infusions, Letermovir, Cyclosporine A, Tacrolimus 9. Describe the impact of non-HLA factors on the outcomes of HSCT including disease stage, type of donor, CMV status, ABO, age and sex of the donor and recipient
Indicative Content	The candidate requires knowledge and understanding of: The need and rationale for HSCT, including the biology of the cells of the haematopoiesis system involved, the commonly encountered disease indications and outcomes of HSCT.

	The pathways involved in the workup of patients to HSCT including the timelines of treatment and the role of the H&I laboratory at different stages of workup, including liaising with the HSCT clinical team. The importance and management of non-HLA clinical factors in the outcome of HSCT including CMV and other IDMs, ABO, donor age and sex etc. The drugs and therapies, including modes of action, used in the pre-transplant and post-transplant treatment of transplant patients. Methods of stem cell collection, processing and storage, including relevant guidelines. Candidates must be aware of UK and international guidelines for indications and disease stages treatable by HSCT.

Module Title	HLA Matching, Donor Selection and Transplant Monitoring in Haematopoietic Stem Cell Transplant
Module code	40770
Rationale/ Aims	The candidate will acquire a good understanding of the role of H&I laboratory, and the role of HLA and antibodies, in sourcing, testing, identifying, matching and mismatching the most appropriate and safest HSCs for transplantation, and the processes of pre-transplant and post-transplant monitoring of the transplant in accordance with national and international standards
Learning outcomes	1. Describe, with examples, the process and criteria involved in the identification of related and unrelated donors including the choice of donor source, HLA matched and mismatched donors, non-HLA factors, the role of the donor registries and the use of in silico tools to assist the process including DPB1 TCE, B Leader Matching, PIRCHE, Peptide Binding Motif) 2. Explain, with examples, how pre-transplant treatment could impact laboratory testing 3. Explain, with examples, the importance and impact of the degree of HLA matching and mismatching permissible in the selection of donors and the outcome of HSCT 4. Explain the importance and impact, and the role of the laboratory, in the mitigation of HLA antibodies in the outcome of HSCT 5. Describe, with examples, the role of the laboratory in post-transplant monitoring of engraftment including the use of chimerism analysis 6. Describe the principles of alternative therapies to allogeneic HSCT stem cell transplantation including gene therapy, CAR-T cells, autologous stem cell transplantation, immunotherapy, and pharmacological treatments 7. Discuss the mechanism and importance of the Graft versus Leukaemia/Tumour effect 8. Describe the biological function, laboratory investigation and clinical relevance of other immunogenetic systems including KIR, MICA/MICB and minor histocompatibility antigens in the outcomes of HSCT 9. Explain how a H&I laboratory complies with standards, guidelines and legislation relating to HSCT
Indicative Content	The candidate requires knowledge and understanding of: The analytical tasks performed in the H&I laboratory including HLA typing, HLA antibody identification and crossmatching and they use relevant to the requirements for HSCT.

	The technical problems and laboratory issues encountered in testing HSCT patients undergoing treatment for HSCT, and how to mitigate and overcome these problems. The sources and hierarchies of HSCs for transplant, and the benefits of each source type in the outcome of transplant. The use of bioinformatic tools and local and national protocols and standards to appropriately investigate the patient, relations and unrelated donor registries to identify the best HSC donor for the patient. The impact of the UK and international guidelines, protocols and standards on stem cell transplant, stem cell processing and donor selection. Candidates must be aware of UK and international guidelines for indications and disease stages treatable by HSCT, and for the selection of the most appropriate and safest stem cell donor. Including: guidelines from BSHI, ASHI, EBMT, MHRA, HTA & JACIE Methods and modes of action of HLA antibody reduction pre-transplant and post-transplant, and how the H&I laboratory works with the transplant team to reduce the effects of HLA antibodies Other biological systems that affect clinical outcomes and may be used for improving selection of donors including the genetics, mechanisms, testing methods and application of these tests in clinical use, including MICA, MICB, KIR and minor histocompatibility antigens. Chimerism testing methods, analysis and application in HSCT. The availability and application of a range of bioinformatics tools used for improving HSCT outcomes.

Module Title	Transfusion
Module code	40769
Rationale/ Aims	The candidate will develop comprehensive knowledge of the techniques used for Human Platelet Antigen (HPA) and Human Neutrophil Antigen (HNA) genotyping, as well as antibody testing relevant to transfusion. They will gain an understanding of the clinical indications and rationale for requesting platelet and donor typing, antibody investigations, and the principles involved in the provision of HLA/HPA matched platelet transfusions for patients with immune-mediated platelet disorders. The candidate will acquire an understanding of the management and selection of apheresis platelet panels, and the role of H&I laboratories in supporting transfusion practice. Additionally, the candidate will learn about the investigation and management of conditions such as Foetal Neonatal Alloimmune Thrombocytopenia (FNAIT)**,** Transfusion-Related Acute Lung Injury (TRALI), Idiopathic Thrombocytopenia Purpura (ITP) and Post-Transfusion Purpura (PTP)**.**
Learning outcomes	1. Explain the principles of molecular techniques used for HPA and HNA genotyping 2. Discuss the major platelet and leukocyte antigen systems, their nomenclature and relevance to transfusion 3. Explain the principles behind antibody screening assays (e.g. MAIPA) for HPA and HNA. Discuss the advantages and disadvantages of these methodologies 4. Discuss the clinical significance of platelet and leukocyte antibodies in conditions such as PTP, FNAIT, TRALI, ITP and refractoriness to platelet transfusion 5. Explain how typing and antibody results are used in the investigation and management of FNAIT, TRALI, and PTP 6. Discuss the testing of apheresis platelet donors and the management of donor panels in relation to the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book) 7. Discuss the provision of HLA/HPA matched platelets for patients with suspected platelet transfusion refractoriness, the importance of post-transfusion increment data, and the selection of appropriate blood products 8. Describe the role of H&I laboratories in supporting transfusion, including the rationale for testing and the impact on patient care
Indicative Content	The candidate requires knowledge and understanding of: Theoretical principles and practical applications of HPA, and HNA genotyping and antibody screening. Investigation and transfusion requirements for patients with PTP, FNAIT, TRALI, ITP and platelet transfusion refractoriness.

	Management of apheresis platelet donor panels and provision of matched platelets as described in the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book). Overview of H&I laboratory testing, including why tests are performed and how results guide the provision of blood products. Candidates should be able to: Maintain, run and troubleshoot assays performed.

Module Title	Histocompatibility and Immunogenetics Quality
Module code	40771
Rationale/ Aims	The candidate will gain a thorough understanding of the application of quality management in an H&I setting. This will include an introduction to key components such as Internal and External Quality Assurance (IQA/EQA), the purpose and process of risk assessment, and the role of accreditation standards (e.g. UKAS/ISO 15189) and national guidelines in ensuring compliance and continuous improvement. Candidates will understand the difference between verification and validation and apply this in practice.
Learning outcomes	1. Describe the range of external quality assurance (EQA) schemes available to H&I laboratories and explain how performance criteria are established and assessed within each scheme 2. Explain the difference between validation and verification and discuss, using examples from practice, their significance in ensuring the reliability and accuracy of laboratory processes 3. Demonstrate acceptance of new lots and shipments of reagents/kits 4. Describe the key principles of change management and how they apply to the implementation of new procedures within the laboratory setting 5. Discuss the role of accreditation bodies such as EFI, UKAS, JACIE, HTA and MHRA in ensuring quality and compliance in H&I laboratories and explain how accreditation impacts laboratory practice and patient safety 6. Discuss the core principles of incident management within the laboratory, including the roles of risk assessment, root cause analysis and effective incident documentation 7. Identify National guidelines relevant to H&I laboratories and summarise how they apply to laboratories
Indicative Content	The candidate requires knowledge and understanding of: External Quality Assurance schemes to support inter-laboratory consistency through defined performance criteria Validation and verification to ensure accuracy and reliability of laboratory methods The principles of change management The role of accreditation bodies in relation to maintaining compliance and enhancing patient safety Incident management The use of National guidelines to standardise practices

About this version

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