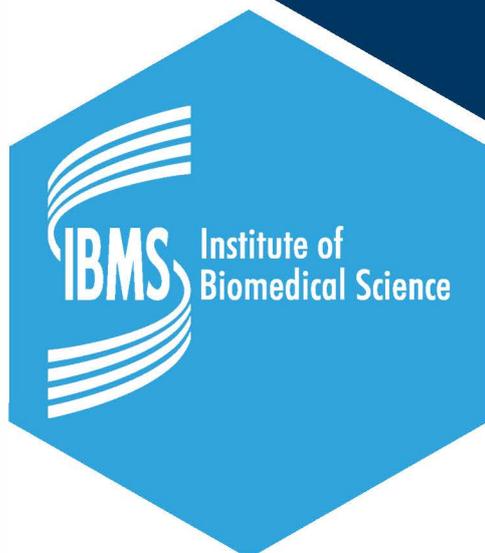


BLOOD TRANSFUSION PRACTICE DIGITAL SPECIALIST PORTFOLIO MODULES



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Blood Transfusion Practice Digital Specialist Portfolio Modules

- Quality Module
- Good Manufacturing Practice (GMP) Awareness in Transfusion
- Donor Selection and Testing
- Manufacturing and processing blood components
- Quality monitoring of blood components
- ABO and D typing
- Antibody Screening and Identification
- Resolving Samples Requiring Further Antibody Investigation
- Patient Blood Management (PBM) and appropriate use of blood
- Red cell phenotyping
- Compatibility Testing
- Selection of blood components and products
- Release of blood components and products
- Blood stock management and emergency planning
- Antenatal Screening and Haemolytic Disease of the Foetus and Newborn
- Investigation of serious adverse reactions and events
- Investigation of ABO and D anomalies

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	Quality Module
Module code	7045
Rationale/ Aims	<p>The aim of this module is to ensure candidates understand the role and application of quality management practices in the laboratory.</p> <p>The candidate will understand how quality management processes relate to laboratories and pathology departments, including POCT and how this contributes to healthcare in general and improves patient outcomes.</p> <p>The candidate will understand the principles of quality management including internal and external quality control and external quality assessment and be able to demonstrate this in practice, they will be able to perform audits and understand the processes that follow from the audit.</p> <p>They will be able to apply quality processes in their laboratory to ensure the quality of their own practice as well as that of the department.</p>
Learning outcomes	<ol style="list-style-type: none"> 1. Describe the elements of the laboratory quality management systems (including management of documents and data) and how they relate to patient outcomes. 2. Discuss, relevant to your practice, pre-analytical factors that influence sample acceptance criteria, test results and examples of how process failures are actioned. 3. Discuss the principles of internal quality control, including the use of third-party quality control and alternatives if these are not available, and monitoring for trends and bias. Include the use in comparison of equipment and operators. 4. Discuss internal quality control processes, including the use of appropriate materials, establishing acceptance criteria, use of IQC rules, detection of different types of error conditions and actions undertaken if internal quality controls fail. Use examples from practice where appropriate. 5. Discuss the processes for establishing metrological traceability of tests/targets as applicable and their influence on results. 6. Discuss the principles of external quality assessment (EQA), what to do if no EQA schemes are available for a test, and how to investigate unsatisfactory performance including understanding the UK EQA governance structure, and the escalation of laboratories to the National Quality Assurance Advisory Panel. Use examples from practice where appropriate. 7. Discuss the role of audit in pathology quality processes and explain, using an example from the candidates practice, the audit processes including identifying, investigating, and resolving non-conformances. 8. Explain the potential uses of measurement uncertainty data in pathology and give an example of how this has been calculated in the candidates workplace. 9. Investigate unusual results (e.g. EQA, IQC) and take appropriate action, explain the rationale for the actions taken, demonstrate relevant documentation has been completed appropriately. 10. Discuss the role of quality management in the training and competency of laboratory staff and how it contributes to the accreditation process.
Indicative Content	Candidates must be familiar with laboratory accreditation processes, the role and scope of practice of regulatory and accreditation bodies in pathology (UKAS, MHRA, HTA etc), relevant pathology ISO standards, and the role of independent health regulators relating to medical laboratories.

	<p>Candidates should understand quality management in their workplace and how this relates to patient care.</p> <p>Candidates should be aware of different types of audit, e.g. horizontal, vertical, clinical, examination.</p> <p>Candidates should know how to follow up on quality issues and how they may be resolved.</p> <p>Candidates should understand their scope of practice for investigating and reporting incidents.</p> <p>Candidates should be able to recognise and respond to pre-analytical, analytical and post-analytical errors as applicable to practice.</p> <p>Candidates should understand laboratory risk identification and management and how this relates to patient care.</p> <p>Candidates must be familiar with the principles of In vitro diagnostic medical devices (IVD) selection appropriate for clinical needs.</p>
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Module Title	Good Manufacturing Practice (GMP) awareness in transfusion
Module code	Allocated on Brightspace
Rationale/ Aims	The candidate will recognise and apply the Good Manufacturing Practice guidelines as part of their fitness to practice and as a requirement of the Blood Safety and Quality Regulations, as enforced by Medicines and Healthcare products Regulatory Agency (MHRA).
Learning outcomes	<p>On completion of the module, the candidate is expected to be able to:</p> <ol style="list-style-type: none"> 1. Explain the history of the Blood Safety and Quality Regulations and how they are relevant to Blood Transfusion laboratory practices. 2. Describe the principles and practice of Good Manufacturing Practice (GMP) as detailed in the indicative content shown below. 3. Demonstrate, with examples, the principles and practice of Good Documentation Practice (GDP). 4. Explain the principles of Good Distribution Practice, providing examples of how the cold chain can be maintained and the actions to be taken when the cold chain is breached. 5. Discuss the following requirements and reasons for; <ul style="list-style-type: none"> • Qualification and validation of equipment • Processes for change control • Risk assessment 6. Demonstrate with examples how the laboratory maintains the ongoing validated state of equipment, consumables and reagents. 7. Discuss the relevance of each of the key reference material shown below to blood transfusion laboratory practice; <ul style="list-style-type: none"> • MHRA orange guide • European Directorate for the Quality of Medicines and Healthcare (EDQM) • Good Practice Guidelines • British Society of Haematology (BSH) guidelines
Indicative Content	<p>Candidate should understand the principles and practice of GMP relating to:</p> <p>Quality Management Personnel and Organisation Premises and Equipment Documentation Production Quality Control Contract Manufacture and Analysis Complaints and Product Recall Self Inspection</p> <p>Knowledge for the requirements of qualification/validation of equipment/processes and for change control including: Validation of blood component storage environment Validation of the 'cold chain' Validation of testing equipment Validation of IT systems Validation and on-going stability of reagents and consumables</p>

Module Title	Donor selection and testing
Module code	Allocated on Brightspace
Rationale/ Aims	<p>The candidate will be able to understand and apply, where relevant, the Donor Selection Guidelines and testing rationale for blood donations, as described in the Guidelines for Blood Transfusion Services in the United Kingdom, and in compliance with the Blood Safety and Quality Regulations (BSQR) 2005.</p> <p>The candidate will be able to describe the use of additional tests for specific patient cohorts and understand both the availability of and issues surrounding screening tests for current and future infectious agents.</p> <p>This module also aims to enhance the candidate's knowledge of 'look back' procedures following a suspected transfusion transmitted infection.</p>
Learning outcomes	<ol style="list-style-type: none"> 1. Describe the criteria for blood donor selection, and when donors may be excluded 2. Describe the process of whole blood collection and blood component collection, for example by apheresis 3. Explain the rationale for both mandatory and additional screening tests 4. Describe the aetiology and pathophysiology of transfusion transmitted infections including viral, parasitic, bacterial or prion. 5. Identify the tests required for both new and repeat donors giving examples of test methodologies, including: <ul style="list-style-type: none"> • Immunohaematology tests eg: ABO/D typing, phenotyping • Microbiology screening • Virology tests 6. Describe the use of additional tests for transfusion in specific patient cohorts e.g., paediatric patients, sickle cell patients 7. Describe the actions required following the discovery of an anomalous test result eg: weak/D variant 8. Explain the principle and practice of a 'look back' when a transfusion transmitted infection is suspected 9. Discuss the issues surrounding current screening tests, including the risk of emerging infectious diseases
	<p>Candidates should understand and apply the following where relevant:</p> <p>Understand Donor Selection Guidelines, including the Donor Health Check, it's purpose and content</p> <p>Knowledge of collection practices of whole blood and component donations.</p> <p>Requirements for mandatory and additional screening tests.</p> <p>Aetiology and pathophysiology of all transfusion transmitted infections.</p> <p>Tests and testing methodologies on new and repeat donors.</p> <p>Product recall when a transfusion transmitted infection is suspected.</p>

Module Title	Manufacturing and processing blood components
Module code	7064
Rationale/ Aims	The candidate will be able to demonstrate a working understanding of the technical requirements for blood component manufacturing and processing as described in the Guidelines for Blood Transfusion Services in the United Kingdom, and in compliance with the Blood Safety and Quality Regulations (BSQR) 2005.
Learning outcomes	<ol style="list-style-type: none"> 1. Describe the methods used for manufacturing and processing routine blood components: <ul style="list-style-type: none"> • red cells • platelets • fresh frozen plasma (FFP) • cryoprecipitate 2. Describe the methods used for manufacturing and additional processing of specialist blood component preparation: <ul style="list-style-type: none"> • neonatal use • intrauterine transfusion • washed components • granulocytes 3. Explain the rationale for leucodepletion and irradiation of blood components 4. Explain the principles and methodologies of pathogen inactivation/reduction of blood components 5. Discuss the process and criteria for blood component validation. 6. List and explain the rationale for the specifications and minimum requirements for component labels. 7. Describe the criteria for storage of blood components and demonstrate, with examples, the validation and maintenance of the cold chain. 8. Explain the therapeutic benefits for the following components: <ul style="list-style-type: none"> • red cells (adult and neonatal) • platelets • fresh frozen plasma (FFP) • Cryoprecipitate • granulocytes
Indicative Content	<p>The candidate should understand and be able to apply the following where applicable.</p> <p>The principles and practice of GMP using the key reference material available; MHRA orange guide, EDQM Good Practice Guidelines, BSH guidelines.</p> <p>Manufacture and preparation of blood components from whole blood or apheresis donation.</p> <p>Manufacture and preparation of specialist blood components from whole blood or apheresis donation.</p> <p>Performance of tests and procedures in accordance with standard operating procedures.</p> <p>Management of component storage failure, requirements for quarantine,</p>

	<p>and maintenance of the cold chain. Completion of documentation in accordance with quality control and audit requirements.</p>
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Module Title	Quality monitoring of blood components
Module code	7065
Rationale/ Aims	The candidate will be able to demonstrate a working understanding of the technical requirements for quality monitoring of blood components as described in the Guidelines for Blood Transfusion Services in the United Kingdom, and in compliance with the Blood Safety and Quality Regulations (BSQR) 2005. They will be able to describe the principles of haemopoiesis and coagulation pathways as well as the importance of cell counting. Candidates will gain an underpinning knowledge of the requirement for validation and statistics to ensure the quality of a component is not compromised as well as how to handle a recall following an incident.
Learning outcomes	<ol style="list-style-type: none"> 1. Describe the principles of haemopoieses and coagulation pathways. 2. Describe the principles of cell counting using automated haematology analysers and flow cytometers. 3. Describe the criteria and provide examples for quality monitoring of blood components 4. Describe the principles and practice of environmental monitoring. 5. Describe the principles and practice of bacterial monitoring of blood components. 6. Demonstrate, with examples, the recall procedure following an incident. 7. Discuss the importance of calibration and traceability to UK standards and give examples of applications from your practice. 8. Discuss the importance of internal quality control specific to manufacturing of blood components. 9. Discuss the benefits of using statistical process control methods for ensuring the quality of a component, including statistical terminology (accuracy, precision, CV, tolerance, range, uncertainty of measurement).
Indicative Content	<p>Candidates should be able to understand and apply the following where relevant:</p> <p>The principles and practice of GMP using the key reference material available; MHRA orange guide, EDQM Good Practice Guidelines, BSH guidelines.</p> <p>Quality Monitoring of blood components.</p> <p>Detection of non-conforming blood components and actions required.</p> <p>Management of component storage failure, requirements for quarantine, and maintenance of the cold chain.</p> <p>Quality control and audit requirements.</p> <p>Statistical Process Control.</p>

Module Title	ABO and D typing
Module code	7066
Rationale/ Aims	The candidate will gain the underpinning knowledge and skills required for blood transfusion staff involved in the transfusion process within the laboratory. The candidate will be able to perform blood grouping tests and interpret results for the safe transfusion of compatible blood components.
Learning outcomes	<p>On completion of the module, the candidate is expected to be able to:</p> <ol style="list-style-type: none"> 1. Explain the basis of the ABO and D blood group systems – genes, antigens and antibodies and their clinical significance in transfusion medicine. 2. Describe factors affecting antigen-antibody reactions in vitro. 3. Discuss national and local sample acceptance criteria, actions to be taken when the criteria has not been met and the associated risks. 4. Describe how to interpret reaction strengths in ABO/D typing (both in forward and reverse grouping). 5. Discuss the principles of serological tests used in manual and automated blood grouping, their appropriate use, and potential sources of error. 6. Discuss the application of quality controls required for blood grouping and provide an example of when a quality control has failed and what further actions were required. 7. Discuss the increased security afforded by the electronic transfer of ABO/D results from automation to the laboratory information management system (LIMS). 8. Demonstrate, using examples from your practice how to interpret patient blood groups (both full group and confirmatory) using manual and automated methods. 9. Discuss the minimum specifications for blood grouping in emergency situations, prior to the issue of group compatible blood and explain the rationale behind the two-sample rule according to BSH guidance.
Indicative Content	<p>Candidates should understand the following as relating to ABO and D typing:</p> <p>Major blood group systems Antigen and antibody reactions Principles of manual and automated blood grouping Sample acceptance criteria Internal quality control and external quality assurance procedures Provision of blood components in emergency situations</p>

Module Title	Antibody Screening and Identification
Module code	7063
Rationale/ Aims	<p>The candidate will be able to demonstrate a working understanding of the mechanisms of antigen: antibody reactions and the significance of red cell antibodies. They will be able to perform antibody screening and subsequent antibody identification by employing various techniques and reagents. They will acquire the skills to systematically exclude and confirm the presence of an antibody(s).</p> <p>The candidate will be able to demonstrate their knowledge of how to request/perform further testing and investigations when an antibody cannot be identified locally or when dealing with multiple or complex antibodies.</p>
Learning outcomes	<ol style="list-style-type: none"> 1. Describe the major blood group systems and the characteristics of red cell antigens within each system. 2. Describe the mechanisms of antigen: antibody reactions and their role in <i>in vivo</i> red cell destruction. 3. Explain the clinical significance of red cell antibodies in pre-transfusion testing and antenatal scenarios. 4. Describe the principles of the indirect antiglobulin test (IAT) and the importance of grading reactions. 5. Discuss the specifications of reagents for patient antibody screening and identification, the rationale behind their selection depending on the testing system and methods used. 6. Demonstrate with examples how to positively identify and systematically exclude antibody specificities using British Society for Haematology (BSH) guidance on inclusion/exclusion. Include both IAT and enzyme techniques. 7. Explain the relevance of dosage reactivity of red blood cell antibodies in relation to homozygous/heterozygous antigen expression. 8. Explain the relevance of red cell phenotyping in antibody identification. 9. Demonstrate with examples how to interpret results, and recognise and describe when samples require further investigations
Indicative Content	<p>Candidates will have knowledge of the following :</p> <p>Techniques for performing an antibody screen and identification. Interpretation of results and next steps. Identify samples requiring additional testing and possible referral and/or clinical advice. Employ a range of further tests to elucidate alloantibody mixtures. Identify whether there are any underlying clinically significant alloantibodies in cases with autoantibodies.</p>

Module Title	Resolving Samples Requiring Further Antibody Investigation
Module code	7062
Rationale / Aims	<p>The candidate will recognise local limitations for antibody identification and understand the process for referral to a specialised laboratory. The candidate will understand the principles and practice of various techniques used in further/complex antibody investigations together with the interpretation and management of the results reported.</p> <p>Candidates will gain knowledge in the provision of red cells for patients with complex or unresolved antibodies.</p>
Learning outcomes	<ol style="list-style-type: none"> 1. Discuss your local procedure for referral to a specialised laboratory for follow-up testing when scope of practice is reached. 2. Discuss the inclusion of an auto control to aid in the investigation of an antibody. 3. Describe the application of the underlying principles and practice of follow up / complex antibody identification testing techniques including the following; <ul style="list-style-type: none"> • Direct antiglobulin test (DAT) (including poly and monospecific antiglobulin reagents) • Allo / auto adsorption processes • Elution techniques • Modified versions of routine techniques (eg: IAT, enzyme etc) • Neutralisation (e.g., Chido/Rogers) • Inhibition (e.g., Knopps) • Rare cell panel (including the storage, validation and testing of reagents) • Donath Landsteiner Test • Dithiothreitol treatment (DTT) (eg: monoclonal antibody therapy) • Red cell genotyping 4. Demonstrate with an example from your practice your involvement with one of the techniques listed above and explain how this impacted patient treatment 5. Discuss the requirements for providing blood for a patient with an unresolved pan-reactive antibody. 6. Describe the requirements for regulation, assessment and audit of follow-up specialised tests to ensure compliance with MHRA and UKAS. 7. Discuss the challenges for maintaining staff competence when performing non-routine complex identifications. 8. Discuss, using a report and results provided following a referral to a specialised laboratory, how you would ensure the patient receives appropriate blood in the future.
Indicative Content	<p>Candidates should have knowledge of the following testing techniques and surrounding processes:</p> <p>DAT (including monospecific)</p> <p>Allo / auto adsorption processes</p> <p>Elution techniques</p> <p>Modified versions of routine techniques (IAT, enzyme etc)</p> <p>Neutralisation (e.g., Ch/Rg)</p> <p>Inhibition (e.g., KNIR)</p>

	<p>Rare cells (High and low incidence / storage / validation / testing)</p> <p>Other tests (e.g., Donath Landsteiner Test)</p> <p>Genotyping</p> <p>QC</p> <p>EQA</p> <p>Audit</p> <p>Guidelines</p> <p>External Regulation</p> <p>Training / competency</p> <p>Reagent use / storage</p> <p>Referral of samples</p>
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Module Title	Patient Blood Management (PBM) and appropriate use of blood
Module Core	Allocated on Brightspace
Rationale/ Aims	The candidate will be able to demonstrate a working understanding of the principles of PBM including its role in consent, appropriate use, and blood conservation strategies. The candidate will be able to discuss how a multidisciplinary approach involving education and patient involvement supports best practice and improves patient outcomes and experiences.
Learning outcomes	<p>On completion of the module, the candidate is expected to be able to:</p> <ol style="list-style-type: none"> 1. Describe the 3 pillars of PBM and discuss the benefits to patient safety and outcome. 2. Discuss the diagnosis and treatment of anaemia in the following clinical situations. <ul style="list-style-type: none"> • Obstetric patients • Perioperative • Chronic illness 3. Discuss the use alternatives to transfusion, providing examples of when and how they would be appropriate. 4. Discuss the importance of consent in patients requiring a transfusion by considering the following: <ul style="list-style-type: none"> • Shared decision making • Legal requirements, recommendations, and guidance • Ethics 5. Define and discuss appropriate use of components e.g., include the use of transfusion triggers and/or indication codes. 6. Discuss the requirement to authorise (prescribe) a transfusion. 7. Demonstrate or provide an example of when patient blood management may be used in laboratory practice.
Indicative Content	<p>Candidate will need to understand the following:</p> <p>Patient Blood Management as a concept Core PBM initiatives and clinical approaches Principles of shared decision making and consent The relationship between transfusion, PBM, and patient safety The benefits of PBM to patients care and the healthcare system</p>

Module Title	Red cell phenotyping
Module code	7061
Rationale/Aims	<p>The candidate will gain the underpinning knowledge of the principles, practice and application of red cell phenotyping. The candidate will be able to perform red cell phenotyping by various techniques and interpret the results.</p> <p>The candidate will gain knowledge in the frequencies of red cell antigens and how this can influence the availability of donated blood and subsequent patient care.</p>
Learning outcomes	<ol style="list-style-type: none"> 1. Describe the underlying principles of various phenotyping techniques that can be employed. 2. Explain the following types of phenotyping, providing examples: <ul style="list-style-type: none"> • Single • Extended (Rh/K) • Full 3. Describe situations where Rh/K and extended phenotyping and/or genotyping may be employed, for the following; <ul style="list-style-type: none"> • Donor/donation testing • Pre-transfusion compatibility testing • Antenatal testing • Haemoglobinopathy patients • Other patients requiring long-term transfusion support 4. Explain the reasons why patients' red cells may produce a 'mixed field' phenotyping result. 5. Demonstrate with an example a situation where further referral to a specialist laboratory may be required when considering phenotyping / genotyping. 6. Discuss, following a referral, how would you capture the results to ensure the patient receives phenotyped red cells in the future. 7. Explain the term 'antithetical' in relation to phenotyping and subsequent transfusion support. 8. Discuss the frequencies of red cell antigens and how this can influence the availability of donated blood.
Indicative Content	<p>Candidates should have knowledge of the following and how it applies to their practice:</p> <p>Automated v manual phenotyping testing</p> <p>Occasions where phenotyping is inappropriate</p> <p>Donor v patient phenotyping</p> <p>IgM v IgG antisera used in phenotyping</p> <p>Gel card v tube phenotyping</p> <p>Reporting of incomplete / unresolved testing</p> <p>Genotyping technology used in your laboratory or a referral laboratory</p> <p>Selection of 'clinically significant' phenotyping testing</p> <p>QC</p> <p>EQA</p> <p>Audit</p> <p>Guidelines</p> <p>External Regulation</p> <p>Training / competency</p> <p>Reagent use / storage</p>

Module Title	Compatibility Testing
Module code	7070
Rationale/ Aims	<p>The candidate will be able to perform essential pre-transfusion checks, compatibility testing and interpretation of the results to provide safe, compatible/suitable blood components to patients. The candidate will also gain knowledge in the principles, practice and criteria for electronic and remote issue and the role IT has in the safe delivery of blood components.</p> <p>The candidate will understand the importance of concessionary release when routine compatibility testing has not been completed and a delay in blood provision must be avoided.</p>
Learning outcomes	<p>On completion of the module, the candidate is expected to be able to:</p> <ol style="list-style-type: none"> 1. Explain the importance of historical records in pre-transfusion procedures. 2. Explain the reasons behind suitable sample timings including recent transfusions and obstetric history. 3. Discuss the role that IT and automation has in providing safe, secure and accurate results in all pre-transfusion and compatibility testing. 4. Describe the principles and practice of serological compatibility testing including the investigation of an incompatible unit. 5. Describe the principles, practice and criteria for 'electronic' and 'remote' issue of blood components. 6. Discuss the limitations and effects of sample storage and why samples should be stored appropriately. 7. Describe scenarios where 'group compatible' red blood cells would be issued via a concessionary release procedure without the completion of routine compatibility testing.
Indicative Content	<p>Candidates should understand how the following are applied in compatibility testing:</p> <p>Sample integrity and demographic checks.</p> <p>Patient history.</p> <p>Determining suitability for electronic issue.</p> <p>Additional testing and investigation when required.</p> <p>Concessionary release procedures and national guidelines.</p>

Module Title	Selection of blood components and products
Module code	7071
Rationale/ Aims	<p>The candidate will understand the difference between a blood component and product and how they are used therapeutically. The candidate will be able to demonstrate the selection criteria for blood components based on the urgency and type of request and patient cohort, including those with special requirements.</p> <p>The candidate will have the ability to evaluate and apply local trust/service policies for the selection and issue of blood components and demonstrate knowledge of other disciplines test results in a clinical context (e.g. haematology and coagulation).</p>
Learning outcomes	<ol style="list-style-type: none"> 1. Describe how the tests and result interpretation from other areas/disciplines of pathology (e.g., Haematology and Coagulation), in a clinical context, can determine the transfusion requirements for a patient using examples from your practice. 2. Explain the importance of communication with all staff groups involved in effective provision of transfusion support in routine and emergency situations. 3. Describe how the appropriate selection of red cells is important regarding the urgency of request and unit expiry. 4. Describe the criteria and provide examples for the selection of blood components for patients with clinical conditions, giving rise to special requirements. 5. Discuss the consequences of not providing specific requirements to a patient. How would this be captured and reported? 6. Describe how national guidelines relating to the provision of specialised components have been implemented within your local service/trust. 7. Discuss the selection of blood components for patients with regards to major haemorrhage. 8. Define the term 'blood product' and explain how it is different from a blood component. 9. Describe with examples the therapeutic uses of blood products.
Indicative Content	<p>Candidates should understand and be able to apply the following where appropriate:</p> <p>Tests and result interpretation in clinical context which influence the transfusion decisions for a patient e.g. Full blood count Prothrombin time Activated Partial Thromboplastin Time (APTT) Fibrinogen Platelet function test</p> <p>Selection and provision of blood components in an emergency Red cell specification for emergency use Fresh Frozen Plasma (FFP) specification for emergency use Platelet specification for emergency use</p>

	<p>Transfusion support during a major haemorrhage Pretransfusion testing Blood component provision Effective communication</p> <p>Selection criteria for red cells and components in different patient groups such as Haematopoietic stem cell transplantation (HSCT) Intrauterine transfusion Exchange transfusion Neonates Autoimmune Haemolytic Anaemia Solid organ transplants Haematology Patients Red cell antibodies</p> <p>Rationale for the provision of specialist components in different patient groups Cytomegalovirus (CMV) negative Irradiated components Phenotyped red cells HbS negative red cells K negative red cells</p> <p>Alternatives to allogeneic transfusion such as: Cell salvage (intraoperative and post operative) Erythropoiesis stimulating agents such as Erythropoietin, Iron, Tranexamic acid</p>
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Module Title	Release of blood components and products
Module code	7072
Rationale/ Aims	<p>The candidate will be able to demonstrate the safe issue and release of blood components and products with regards to labelling and integrity checks. They will be able to discuss the rationale and governance behind traceability, including procedures for issuing components during laboratory information management system (LIMS) 'downtime'.</p> <p>Candidates will be able to describe the recall process and prompt actions required to avoid the transfusion of an unsuitable unit.</p>
Learning outcomes	<p>On completion of the module, the candidate is expected to be able to:</p> <ol style="list-style-type: none"> 1. Describe the procedures for safe issue and secure labelling of blood components and products for patient use. 2. Discuss the minimum labelling requirements for compatibility labels, attached to an issued component. 3. Explain the rationale for visually inspecting blood components prior to release and describe any actions that you would take upon a compromised unit. 4. Describe the importance of 'line clearance' in accordance with Good Manufacturing Practice. 5. Define the term "traceability" with regards to regulatory bodies who oversee blood transfusion and describe your local procedure for achieving 100% traceability. 6. Discuss how a laboratory safely issues blood components during laboratory information management system (LIMS) 'downtime' and subsequently fulfils the traceability requirements. 7. Discuss the rationale for changing the expiry time on post thawed plasma components. 8. Discuss the reasons, both internal and external, why a component might be recalled, and the prompt actions required to avoid transfusion of an unsuitable unit. 9. Demonstrate, using examples from your practice, how to manage a component recall appropriately.
Indicative Content	<p>Candidates should understand and be able to apply the following where appropriate:</p> <p>Storage requirements, expiry times and transport criteria for blood and blood components, prior to and after issue.</p> <p>Administration of blood and blood components.</p> <p>Procedures for traceability, restocking and disposal of blood and blood components in order to ensure full audit trails.</p> <p>Internal and external recall procedures of blood components.</p> <p>Local policies and national guidance regarding issuing and management of blood and blood components.</p>

Module Title	Blood stock management and emergency planning
Module code	6875
Rationale/ Aims	<p>The candidate will be able to demonstrate good inventory management practice, ensuring efficient rotation and selection of components to reduce wastage and conserve blood. The candidate will be able to identify the role of the Blood Stock Management Scheme or other inventory data management systems and evaluate the data analysis provided.</p> <p>The candidate will be able to demonstrate an understanding of the importance of national policies available for blood shortages and emergency planning as well as be able to evaluate their local emergency blood management plans.</p>
Learning outcomes	<ol style="list-style-type: none"> 1. Discuss the risks associated with inappropriate care and handling of blood components and products, with respect to their storage, rotation, and selection. 2. Describe how to achieve good stock management to reduce wastage, using examples from practice where relevant. 3. Describe how and why you would perform a stock level review and discuss how overstocking contributes toward wastage. 4. Describe the role of the Blood Stocks Management Scheme and discuss how data can drive improvement. 5. Demonstrate, using an example from your practice, the submission of data to the Blood Stocks Management Scheme (or local reporting system) to help identify trends and improve wastage. 6. Discuss the importance of highlighting close to expiring stock and the methods available to achieve this. 7. Discuss the importance of emergency blood management plans for all components. 8. Discuss the actions blood transfusion laboratories can take to contribute towards blood conservation during normal periods and during a potential shortage situation. Discuss your local policies and national guidance for managing stocks during a shortage.
Indicative Content	<p>Candidates should have an understanding of the following:</p> <p>Blood stock management scheme and its function</p> <p>The impact of laboratory practice on national stock</p> <p>The effectiveness of stock rotation and appropriate selection to support patient care and reduce wastage.</p> <p>Emergency Planning and conservation of the blood supply chain.</p> <p>Location of national guidance and resources available for emergency blood management planning during a shortage or threat to the blood supply.</p>

Module Title	Antenatal Screening and Haemolytic Disease of the Fetus and Newborn
Module code	7137
Rationale/ Aims	The candidate will be able to demonstrate an understanding of the transfusion care pathway for antenatal patients with regards to blood grouping, antibody screening, antibody identification, and quantification/titration. The candidate will gain knowledge of the current guidance for monitoring the patient as well as the techniques available to reduce the risk of haemolytic disease of the fetus and newborn.
Learning outcomes	<ol style="list-style-type: none"> 1. Describe the transfusion care pathway for antenatal patients with regards to sampling requirements, pre and postnatal. 2. Explain the clinical significance of red cell antibodies and discuss how the patient and fetus are monitored and follow up samples are managed according to national guidance. 3. Describe the importance of differentiating between prophylactic and immune anti-D. 4. Describe the process for referral or analysis of samples requiring titration or quantification, interpret the results and communicate them effectively to the wider team. 5. Discuss the aetiology of haemolytic disease of the fetus and newborn (HDFN) and describe the principles and benefits of the following techniques available to reduce the risk of HDFN <ul style="list-style-type: none"> • Cell free fetal DNA screening • Paternal testing • Fetal genotyping • Routine antenatal anti-D prophylaxis (RAADP) 6. Explain the principles of acid-elution/staining and flow cytometric methods for measuring fetal maternal haemorrhage (FMH) and interpret the results. 7. Discuss how to determine the correct dose of anti-D immunoglobulin following a potentially sensitizing event and describe how this advice would be delivered according to your laboratory's procedure. 8. Describe routine post-natal testing required for the mother and infant and discuss how a potential case of HDFN would be recognised. 9. Discuss the criteria for the selection of red cells for intrauterine transfusion (IUT), exchange and top-up transfusions for the fetus/infant in cases of HDFN due to red cell antibodies. 10. Discuss the criteria for the selection of red cells for the mother during and after pregnancy.
Indicative Content	<p>Candidates require knowledge and understanding of:</p> <p>Routine antenatal testing including booking bloods, follow up and postnatal samples.</p> <p>Recognition of red cells antibodies in the context of haemolytic disease of the fetus and newborn (HDFN) and appropriate follow up tests.</p> <p>Differentiation between immune and prophylactic anti-D</p> <p>The aetiology of haemolytic disease of the fetus and newborn (HDFN).</p> <p>Perform/discuss how to investigate a case of suspected HDFN</p> <p>Applying the criteria for the selection of blood for intrauterine transfusion (IUT), exchange and top-up transfusions</p>

	Compatibility testing for mother and infant when required to provide appropriate, safe blood components Eluate on a cord blood sample and interpreting the results
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Module Title	Investigation of serious adverse reactions and events
Module code	7073
Rationale/ Aims	The candidate will be able to demonstrate an understanding of adverse reactions and events, how they happen, how to recognise them and how to complete appropriate laboratory investigations. The candidate will be able to identify the role of haemovigilance and discuss the importance of reporting such reactions/events both locally and externally.
Learning outcomes	<p>On completion of the module, the candidate is expected to be able to:</p> <ol style="list-style-type: none"> 1. Describe the classification and characteristics of serious adverse reactions and serious adverse events in transfusion. 2. Describe how you would respond to a suspected adverse reaction/event in accordance with your local procedures. 3. Discuss the rationale for performing repeat tests on pre- and post-transfusion samples in a case of a suspected haemolytic transfusion reaction. 4. Explain the laboratory investigations required for a suspected transfusion reaction, including sample types and details of any further testing to be performed. 5. Discuss the principles of root cause analysis and how they are applied when completing an incident report. 6. Explain the importance of haemovigilance and assess the need to report to Serious Hazards of Transfusion (SHOT) and / or Serious Adverse Blood Reactions and Events (SABRE). 7. Explain how the recommendations from the current British Society for Haematology (BSH) guidance on the investigation of acute transfusion reactions can be included in your laboratory's standard operating procedure.
Indicative Content	<p>Candidates will understand the following and their importance in laboratory practice:</p> <p>Classification and characteristics of adverse reactions and events, to include both non-infectious and infectious hazards.</p> <p>Laboratory transfusion reaction investigations.</p> <p>Haemovigilance.</p> <p>Internal and external recall procedures.</p> <p>Local quality procedures and root cause.</p> <p>SHOT and SABRE reporting schemes.</p> <p>BSH guidance on the investigation of acute transfusion reactions</p>

Module Title	Investigation of ABO and D anomalies
Module code	7069
Rationale/ Aims	<p>The candidate will be able to demonstrate how they interpret blood groups and recognise anomalous results. They will be able to describe both the laboratory and clinical factors that may lead to anomalous results and why it is significant to the patient's treatment.</p> <p>Candidates will be able to discuss the importance of grading reactions as well as the management of a suspected ABO subgroup or weak/variant D. They will gain an understanding of the further actions required to obtain a result and how to safely select blood components following the identification of an anomalous result.</p>
Learning outcomes	<ol style="list-style-type: none"> 1. Demonstrate with examples laboratory factors that may lead to anomalous results of ABO and D typing including; <ul style="list-style-type: none"> • Sample integrity • Potential 'wrong blood in tube' • Reagents • Equipment • Manual techniques 2. Discuss the investigation of blood group anomalies in specific patient groups including: <ul style="list-style-type: none"> • Paediatrics/neonates • Elderly patients • Immunosuppressed patients • Post haemopoietic stem cell transplantation • Patients on monoclonal antibody therapies • Post transfusion 3. Explain the scientific basis and clinical significance of ABO subgroups and weak/D variants in both donors and patients. 4. Discuss the importance of grading reactions with regards to a weak/variant D type. 5. Discuss the rationale for further testing or referral before a blood group can be assigned. 6. Discuss how a blood group would be assigned to a patient following the identification of a blood grouping anomaly. 7. Describe how the safe and appropriate selection of components can be carried out following the identification of an anomalous result.
Indicative Content	<p>Candidates should understand the following and how they related to the investigation of ABO and D anomalies:</p> <p>Major blood group systems Antigen and antibody reactions Principles of manual and automated blood grouping Sample acceptance criteria Internal quality control and external quality assurance procedures Provision of blood components in emergency situations</p>

About this document

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