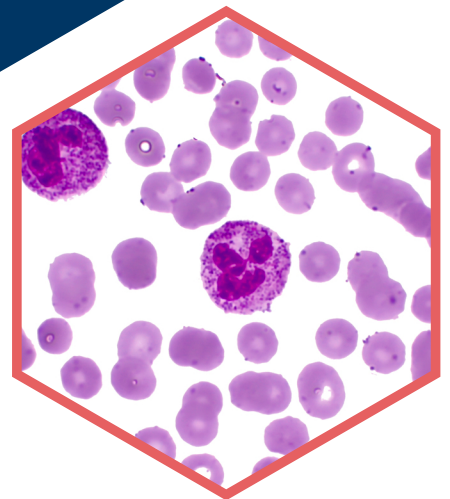




# BLOOD SCIENCE TRANSFUSION PRACTICE DIGITAL SPECIALIST PORTFOLIO MODULES



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Module Title	BS Good Manufacturing Practice (GMP) awareness and inventory management
Module code	26318
Rationale/ Aims	<p>Candidates will be able to 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).</p> <p>Candidates will be able to demonstrate good inventory management practice, ensuring efficient rotation and selection of components to reduce wastage and conserve blood. They will also be able to demonstrate an understanding of the importance of national policies available for blood shortages and emergency planning.</p>
Learning outcomes	<ol style="list-style-type: none"> <li>1. Describe the principles and practice of Good Manufacturing Practice (GMP) and how they apply to hospital transfusion practice.</li> <li>2. Demonstrate, with examples, the principles and practice of Good Documentation Practice (GDP).</li> <li>3. 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.</li> <li>4. Discuss the risks associated with inappropriate care and handling of blood components and products, with respect to their storage, rotation, and selection.</li> <li>5. Describe how to achieve good stock management to reduce wastage, using examples from practice where relevant.</li> <li>6. Discuss the importance of highlighting close to expiring stock and the methods available to achieve this.</li> <li>7. Discuss the importance of emergency blood management plans for all components.</li> <li>8. Discuss the following requirements and reasons for; <ul style="list-style-type: none"> <li>• Qualification and validation of equipment</li> <li>• Processes for change control</li> <li>• Risk Assessment</li> </ul> </li> <li>9. Demonstrate with examples how the laboratory maintains the ongoing validated state of equipment, consumables and reagents</li> </ol>
Indicative Content	<p>Candidates require knowledge and understanding of the principles and practice of GMP relating to:</p> <ol style="list-style-type: none"> <li>a) Quality Management</li> <li>b) Personnel and Organisation</li> <li>c) Premises and Equipment</li> <li>d) Documentation</li> </ol>

	<p>e) Production</p> <p>f) Quality Control</p> <p>g) Contract Manufacture and Analysis</p> <p>h) Complaints and Product Recall</p> <p>i) Self Inspection</p> <p>Candidates require knowledge and understanding of:</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>
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Module Title	BS Appropriate Use and Release of Components and Products
Module code	26314
Rationale/ Aims	<p>The candidate will be able to demonstrate a working understanding of the principles of Patient Blood Management (PBM) including its role in consent, and appropriate use of blood.</p> <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 discuss the rationale and governance behind traceability, including procedures for issuing components during laboratory information management system (LIMS) 'downtime'.</p> <p>Candidates will also describe the recall process and prompt actions required to avoid the transfusion of an unsuitable unit.</p>
Learning outcomes	<ol style="list-style-type: none"> <li>1. Discuss the use of alternatives to transfusion, providing examples of when and how they would be appropriate.</li> <li>2. Define and discuss appropriate use of components e.g., include the use of transfusion triggers and/or indication codes.</li> <li>3. Describe the procedures for safe issue and secure labelling of blood components and products for patient use.</li> <li>4. Discuss the minimum labelling requirements for compatibility labels, attached to an issued component.</li> <li>5. Explain the rationale for visually inspecting blood components prior to release and describe any actions that you would take upon a compromised unit.</li> <li>6. Define the term "traceability" with regards to regulatory bodies who oversee blood transfusion and describe your local procedure for achieving 100% traceability.</li> <li>7. Discuss how a laboratory safely issues blood components during laboratory information management system (LIMS) 'downtime' and subsequently fulfils the traceability requirements.</li> <li>8. Discuss the rationale for changing the expiry time on post thawed plasma components.</li> <li>9. 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.</li> <li>10. Demonstrate, using examples from your practice, how to manage a component recall appropriately.</li> </ol>
Indicative Content	<p>Candidates require knowledge and understanding of:</p> <p>The relationship between transfusion, PBM, and patient safety.</p> <p>The benefits of PBM to patients care and the blood supply.</p>

	<p>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. Local policies and national guidance regarding issuing and management of blood and blood components.</p>
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Module Title	BS Antenatal Screening and Haemolytic Disease of the Fetus and Newborn
Module code	26315
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"> <li>1. Describe the transfusion care pathway for antenatal patients with regards to sampling requirements, pre and postnatal.</li> <li>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.</li> <li>3. Describe the importance of differentiating between prophylactic and immune anti-D.</li> <li>4. Describe the process for referral of samples requiring titration or quantification.</li> <li>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"> <li>• Fetal maternal haemorrhage estimation (Kleihauer and flow cytometry)</li> <li>• Cell free fetal DNA screening</li> <li>• Paternal testing</li> <li>• Fetal genotyping</li> <li>• Routine antenatal anti-D prophylaxis (RAADP)</li> </ul> </li> <li>6. Describe routine post-natal testing required for the mother and infant and discuss how a potential case of HDFN would be recognized.</li> <li>7. 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.</li> <li>8. Discuss the criteria for the selection of red cells for the mother during and after pregnancy.</li> </ol>
Indicative Content	<p>Candidates require knowledge and understanding of:</p> <p>The aetiology of haemolytic disease of the fetus and newborn (HDFN).  Perform/discuss how to investigate a case of suspected HDFN.  Compatibility testing for mother and infant when required to provide appropriate, safe blood components.</p>

Module Title	BS Donor Testing and Selection of Components and Products for Patients
Module code	26312
Rationale/ Aims	<p>The candidate will be able to understand the Donor Selection Guidelines and testing rationale for blood donations. They will understand the difference between a blood component and product and how they are used therapeutically.</p> <p>The candidate will also 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. 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 (eg: Haematology and coagulation).</p>
Learning outcomes	<ol style="list-style-type: none"> <li>1. Describe the criteria for blood donor selection, and explain when donors may be excluded.</li> <li>2. Explain the rationale for both mandatory and additional screening tests for donors.</li> <li>3. Describe using examples from your practice 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.</li> <li>4. Explain the importance of communication with all staff groups involved in effective provision of transfusion support in routine and emergency situations.</li> <li>5. Describe how the appropriate selection of red cells is important regarding the urgency of request and unit expiry.</li> <li>6. Describe the criteria and provide examples for the selection of blood components for patients with clinical conditions, giving rise to special requirements.</li> <li>7. Discuss the selection of blood components for patients with regards to major haemorrhage.</li> <li>8. Define the term 'blood product' and explain how it is different from a blood component.</li> <li>9. Describe, with examples, the therapeutic uses of blood products.</li> </ol>
Indicative Content	<p>Candidates require knowledge and understanding of:</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.</p> <p>Selection and provision of blood components in an emergency.</p>

	<p>Solid organ transplants</p> <p>Selection criteria for red cells and components in different patient groups such as</p> <p>Haematopoietic stem cell transplantation (HSCT)</p> <p>Intrauterine transfusion</p> <p>Exchange transfusion</p> <p>Neonates</p> <p>Autoimmune Haemolytic Anaemia</p> <ul style="list-style-type: none"> <li>○ Haematology Patients Red cell antibodies</li> </ul> <ul style="list-style-type: none"> <li>• Rationale for the provision of specialist components in different patient groups <ul style="list-style-type: none"> <li>○ Cytomegalovirus (CMV) negative</li> <li>○ Irradiated components</li> <li>○ Phenotyped red cells</li> <li>○ HbS negative red cells</li> <li>○ K negative red cells</li> </ul> </li> <li>• Alternatives to allogeneic transfusion such as: <ul style="list-style-type: none"> <li>○ Cell salvage (intraoperative and post operative)</li> <li>○ Erythropoiesis stimulating agents such as Erythropoietin,</li> <li>○ Iron</li> <li>○ Tranexamic acid</li> </ul> </li> </ul>
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Module Title	BS ABO and D Typing
Module code	26319
Rationale/ Aims	The candidate will gain underpinning knowledge of ABO and D blood group systems and their significance in transfusion medicine. They will be able to demonstrate their skills in performing and interpreting blood groups for the safe transfusion of compatible blood components as well as understand the principles behind each technique. Candidates will understand the security provided by automated systems as well as the rationale behind national guidance for sampling and testing.
Learning outcomes	<ol style="list-style-type: none"> <li>1. Explain the basis of the ABO and D blood group systems – genes, antigens and antibodies and their clinical significance in transfusion medicine.</li> <li>2. Describe factors affecting antigen-antibody reactions in vitro.</li> <li>3. Discuss national and local sample acceptance criteria, actions to be taken when the criteria has not been met and the associated risks.</li> <li>4. Describe how to interpret reaction strengths in ABO/D typing (both in forward and reverse grouping).</li> <li>5. Discuss the principles of serological tests used in manual and automated blood grouping, their appropriate use, and potential sources of error.</li> <li>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.</li> <li>7. Discuss the increased security afforded by the electronic transfer of ABO/D results from automation to the laboratory information management system (LIMS).</li> <li>8. Demonstrate, using examples from your practice how to interpret patient blood groups (both full group and confirmatory) using manual and automated methods.</li> <li>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.</li> </ol>
Indicative Content	<p>Candidates require knowledge and understanding of:</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	BS Antibody Screening and Identification
Module code	26313
Rationale/ Aims	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). The candidate will also 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.
Learning outcomes	<ol style="list-style-type: none"> <li>1. Describe the major blood group systems and the characteristics of red cell antigens within each system.</li> <li>2. Describe the mechanisms of antigen: antibody reactions and their role in in vivo red cell destruction.</li> <li>3. Explain the clinical significance of red cell antibodies in pre transfusion testing and antenatal scenarios.</li> <li>4. Describe the principles of the indirect antiglobulin test (IAT) and the importance of grading reactions.</li> <li>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.</li> <li>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 and the use of an auto control.</li> <li>7. Explain the relevance of dosage reactivity of red blood cell antibodies in relation to homozygous/heterozygous antigen expression.</li> <li>8. Explain the relevance of red cell phenotyping in antibody identification.</li> <li>9. Discuss your local procedure for referral to a specialised laboratory for follow up testing when scope of practice is reached.</li> </ol>
Indicative Content	<p>Candidates require knowledge and understanding of:</p> <p>Techniques for performing an antibody screen and identification.</p> <p>Interpretation of results and next steps.</p> <p>Identify samples requiring additional testing and possible referral and/ or clinical advice.</p>

	Identify whether there are any underlying clinically significant alloantibodies in cases with autoantibodies.
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Module Title	BS ABO and D Anomalies and Samples Requiring Further Investigation
Module code	26316
Rationale/ Aims	<p>The candidate will be able to 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. Candidates will understand 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> <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. Candidates will also gain knowledge in the provision of red cells for patients with complex or unresolved antibodies.</p>
Learning outcomes	<ol style="list-style-type: none"> <li>1. Demonstrate with examples laboratory factors that may lead to anomalous results of ABO and D typing including; <ul style="list-style-type: none"> <li>• Sample integrity</li> <li>• Potential 'wrong blood in tube'</li> <li>• Reagents</li> <li>• Equipment</li> <li>• Manual techniques</li> </ul> </li> <li>2. Discuss the investigation of blood group anomalies in specific patient groups including: <ul style="list-style-type: none"> <li>• Paediatrics/neonates</li> <li>• Elderly patients</li> <li>• Immunosuppressed patients</li> <li>• Post haemopoietic stem cell transplantation</li> <li>• Patients on monoclonal antibody therapies</li> <li>• Post transfusion</li> </ul> </li> <li>3. Explain the scientific basis and clinical significance of ABO subgroups and weak/D variants in both donors and patients.</li> <li>4. Discuss the importance of grading reactions with regards to a weak/variant D type.</li> <li>5. Discuss the rationale for further testing or referral before a blood group can be assigned.</li> <li>6. Discuss how a blood group would be assigned to a patient following the identification of a blood grouping anomaly.</li> </ol>

	<ol style="list-style-type: none"> <li>7. Describe how the safe and appropriate selection of components can be carried out following the identification of an anomalous result.</li> <li>8. Discuss the requirements for providing blood for a patient with an unresolved pan-reactive antibody.</li> <li>9. Discuss how the laboratory ensures the patient receives appropriate blood in the future.</li> </ol>
Indicative Content	<p>Candidates require knowledge and understanding of the following and how they relate to the investigation of ABO and D anomalies:</p> <ul style="list-style-type: none"> <li>• Major blood group systems</li> <li>• Antigen and antibody reactions</li> <li>• Principles of manual and automated blood grouping</li> <li>• Sample acceptance criteria</li> <li>• Internal quality control and external quality assurance procedures</li> <li>• Provision of blood components in emergency situations</li> <li>• How to interpret a referral report</li> </ul>

Module Title	BS Red Cell Phenotyping
Module code	26320
Rationale/ Aims	Candidates will gain underpinning knowledge of the principles, practice and application of red cell phenotyping. Candidates will be able to perform red cell phenotyping and interpret the results. Candidates will gain knowledge in the frequencies of red cell antigens and an understanding of how this can influence the availability of donated blood and subsequent patient care.
Learning outcomes	<ol style="list-style-type: none"> <li>1. Describe the underlying principles of various phenotyping techniques that can be employed.</li> <li>2. Explain the following types of phenotyping, providing examples: <ul style="list-style-type: none"> <li>• Single</li> <li>• Extended (Rh/K)</li> <li>• Full</li> </ul> </li> <li>3. Describe situations where Rh/K and extended phenotyping and/or genotyping may be employed, for the following; <ul style="list-style-type: none"> <li>• Donor/donation testing</li> <li>• Pre-transfusion compatibility testing</li> <li>• Antenatal testing</li> <li>• Haemoglobinopathy patients</li> <li>• Other patients requiring long-term transfusion support</li> </ul> </li> <li>4. Explain the reasons why patients' red cells may produce a 'mixed field' phenotyping result.</li> <li>5. Demonstrate, with an example, a situation where further referral to a specialist laboratory may be required when considering phenotyping / genotyping.</li> <li>6. Discuss, following a referral, how would you capture the results to ensure the patient receives phenotyped red cells in the future.</li> <li>7. Explain the term 'antithetical' in relation to phenotyping and subsequent transfusion support.</li> </ol>
Indicative Content	<p>Candidates require knowledge and understanding of:</p> <p>Automated v manual phenotyping testing</p> <p>Occasions where phenotyping is inappropriate</p> <p>Donor v patient phenotyping</p> <p>Reporting of incomplete / unresolved testing</p> <p>Genotyping technology used in your laboratory or a referral laboratory</p>

Module Title	BS Compatibility Testing and Transfusion Reactions
Module code	26317
Rationale/ Aims	<p>Candidates 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. Candidates will also gain knowledge of the principles, practice and criteria for electronic and remote issue and the role IT has in the safe delivery of blood components. The candidate will gain understanding of the importance of concessionary release when routine compatibility testing has not been completed and delays in blood provision must be avoided.</p> <p>The candidate will be able to demonstrate an understanding of adverse reactions and events. The candidate will understand the requirement for haemovigilance and discuss the importance of reporting reactions/events both locally and externally.</p>
Learning outcomes	<ol style="list-style-type: none"> <li>1. Explain the importance of historical records in pre-transfusion procedures.</li> <li>2. Explain the reasons behind suitable sample timings including recent transfusions and obstetric history.</li> <li>3. Discuss the role that IT and automation has in providing safe, secure and accurate results in all pre-transfusion and compatibility testing.</li> <li>4. Describe the principles and practice of serological compatibility testing including the investigation of an incompatible unit.</li> <li>5. Describe the principles, practice and criteria for 'electronic' and 'remote' issue of blood components.</li> <li>6. Discuss the limitations and effects of sample storage and why samples should be stored appropriately.</li> <li>7. Describe scenarios where 'group compatible' red blood cells would be issued via a concessionary release procedure without the completion of routine compatibility testing.</li> <li>8. Describe how you would respond to a suspected adverse reaction/event in accordance with your local procedures.</li> <li>9. Discuss the rationale for performing repeat tests on pre- and post-transfusion samples in a case of a suspected haemolytic transfusion reaction.</li> <li>10. Explain the laboratory investigations required for a suspected transfusion reaction, including sample types and details of any further testing to be performed.</li> </ol>

Indicative Content	<p>Candidates require knowledge and understanding of:</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> <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>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>
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## About this version

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