IBMS Certificate of Attainment for Clinical Scientist Registration

(Experiential Route)

HAEMATOLOGY

CURRICULUM HANDBOOK

Version 5

Contents

Introduction

1. Eligibility and Experience

The Programme Handbook for the Clinical Scientist Certificate of Attainment (Experiential Route) states that in Section 4 paragraph 4.1.3 that "Applicants will be required to provide a statement confirming that they currently work with a high level (M level) professional practice in health or scientific settings that equates to a role of a clinical scientist. The information and guidance in this handbook is specific for those applying for, and accepted onto, the Haematology pathway.

1.1 Applicants will be expected to have an MSc degree or equivalent academic level of qualification **and high-level experience of autonomous professional practice and expertise in Haematology***, or in a relevant science that includes haematology as the major specialism.

**High-level experience of autonomous professional practice and expertise" equates to an HCPC registered Biomedical Scientist or Clinical Scientist working at a minimum of agenda for change Band 7 or SEO (PHE) or private laboratory equivalent grade. As an indication of autonomy and expertise, the majority of the evidence presented should reflect experience gained at this level or above, over a minimum of 24 months.*

1.2 To meet the minimum educational requirement of M Level, in addition to "pure" clinical haematology MScs, other M level qualifications will be considered provided that there is a haematology component that forms the major specialism within the qualification, i.e. the educational component would be expected to include haematology practice with a research project specific to haematology. We also recognise individuals may have gained their modality expertise at this level with a different qualification e.g. an RCPath qualification.

1.3 Examples of qualifications that underpin the ability to practice at a high level are: haematology MSc degrees, MSc in Biomedical Science that include haematology as the major specialism, as a minimum an IBMS specialist portfolio in Haematology, the IBMS Higher Specialist Diploma in Haematology, STP in the Blood Sciences modality, a medical degree with an intercalated Medical / Haematology MSc.

1.4 Applicants admitted onto the programme will be expected to demonstrate **t**heir qualifications **and experience in Haematology** at a level that enables them to evidence decision-making in complex and unpredictable situations; and the independent learning ability required for continuing professional development.

They will be expected to show how they:

- deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences;
- demonstrate self-direction and originality in tackling and solving problems, and act autonomously in planning and implementing tasks at a professional or equivalent level;
- continue to advance their knowledge and understanding, and to develop new skills to a high level;

1.5 In order to be able to demonstrate they have met the Health and care professions (HCPC) standards of proficiency for clinical scientists (December 2014) applicants must be able to provide evidence that they meet the core areas of practice for a clinical scientist in their specialty. The vehicle for doing this is the IBMS Clinical Scientist Certificate of Attainment (Experiential Portfolio).

1.6 As the HCPC standards of proficiency are standards that apply to an individual's scope of practice assessment against the standards is contextualized by the role the individual undertakes. Some standards will therefore need to be interpreted according to the applicant's specific role.

1.7 To demonstrate the HCPC standards of proficiency have been met by the individual applicant for this modality they will need to provide evidence that their professional practice is directly related to, and involves contact with, patients and other healthcare professional for the assessment, diagnosis and treatment of patients from a haematology perspective.

1.8 Applicants for the programme are expected to be working in a role that supports their ability to evidence education, training and assessment in these areas. Examples are HCPC registered biomedical scientists; those defined by the QAA subject benchmark for clinical science as clinical scientists in haematology who analyse the cellular components of blood and blood-producing tissues such as the bone marrow. The results are used in the diagnosis and management of patients with anaemia, clotting disorders, haematological cancer and genetic disorders. Some scientists specialise in blood transfusion. Also included are those that come under the umbrella definition of clinical scientist by the HCPC as someone who "oversees specialist tests for diagnosing and managing disease. They advise doctors on tests and interpreting data, and carry out research to understand diseases". Applicants such as scientists/academics who are working within the field of haematology and meet this definition, but are not currently on the HCPC register, are also eligible to apply.

1.9 As a major responsibility of a clinical scientist is within the acquisition of evidence-based guidance based on their own research or that of the peer reviewed

literature, extensive expertise, some evidence may fall solely within a sub-specialisms. The candidate is required to provide evidence that they can meet HCPC standards of proficiency and para 3.4 in the Guidance to Candidates lists the following examples:

- Evidence of academic and vocational qualifications where relevant to the standards of proficiency for clinical scientists.
- Evidence of prior structured training and competence assessment appropriate to their current scope of practice, including how their learning has involved other learners (e.g. learning from medical students)
- Evidence of experiential learning and CPD in their current practice
- Evidence of their scope of practice (e.g. witness testimonies, case studies, presentations, audits, clinical case work, research projects or collaborations)
- Evidence must demonstrate that they have been assessed in the specialty by appropriately qualified individuals (clinical scientist or medical practitioner).

1.10 It is recognised that some applicants may also have experience in disciplines other than haematology. This should not be a barrier provided their current haematology experience meets the stated criteria.

2. Core Areas of Practice for a Clinical Scientist

Professional Practice

Professional practice must meet the professional standards of conduct, performance and ethics defined by professional bodies (e.g. IBMS) and the regulator (HCPC), and is safe, lawful and effective, and within the scope of practice for the role undertaken, while maintaining fitness to practise.

Personal qualities must encompass communication skills, self-management, self-awareness, acting with integrity and the ability to take responsibility for self-directed learning, maintaining their own health and wellbeing, critical reflection and action planning to maintain and improve performance.

Applicants must demonstrate the ability to be an independent self-directed learner acting autonomously in a non-discriminatory manner when planning and implementing tasks at a professional level, contributing to the education and training of colleagues and providing mentoring, supervision and support as appropriate.

Applicants must demonstrate the ability to work, where appropriate, in partnership with other professionals, often as part of a multidisciplinary team, supporting staff, service users and their relatives and carers while maintaining confidentiality. Similarly, they must demonstrate the ability to work with the public, service users, patients and their carers as partners in their care, embracing and valuing diversity.

Scientific and Clinical Practice

Applicants must demonstrate a systematic understanding of relevant knowledge, and a critical awareness of current problems, future developments and innovation in health and healthcare science practice, much of which is at, or informed by, the forefront of their professional practice in a healthcare environment.

Research, Development and Innovation

Applicants must demonstrate a comprehensive understanding of the strengths, weaknesses and opportunities for further development of healthcare and healthcare science as applicable to their area of clinical practice, research, audit, innovation and service development, which either directly or indirectly leads to improvements in patient experience, clinical outcomes and scientific practice.

A conceptual understanding and advanced scholarship in their specialism will enable them to critically evaluate and critique current research and innovation methodologies and, where appropriate, propose new research questions and hypotheses.

Clinical Leadership

Applicants must be able to demonstrate scientific and clinical leadership based on the continual advancement of their knowledge, skills and understanding through the independent learning required for continuing professional development.

Crucial to this is the ability to critique, analyse and solve problems, define and choose investigative and scientific and/or clinical options, and make key judgements about complex facts in a range of situations.

3. Generic Curriculum for Clinical Scientists

3.1. The purpose of the curriculum for the Certificate of Attainment for Clinical Scientist Registration (Experiential Route) is to clearly set out the academic and professional knowledge and skills that applicants are expected to have achieved for their professional scope of practice. Additionally, its purpose is to demonstrate parity with other routes that give eligibility to apply for registration with the HCPC as a clinical scientist. The curriculum will therefore be subject to review in line with changes introduced to these other routes.

3.2. The HCPC standards of proficiency for clinical scientists have been intrinsic to the development of the curriculum and correlate the learning outcomes of the curriculum for haematology. The candidate is expected to provide evidence that these have been met in their scope of practice in haematology through academic and professional qualifications together with experiential learning from a broad range of activities working as a qualified professional in haematology.

Applicants should consider how they have managed their own learning and exercised initiative and personal and professional responsibility to enable them to gain the skills in haematology necessary to meet the learning outcomes of this programme. They should also consider how they can demonstrate that their competence assessment at this level has been carried out by appropriate staff, e.g. a registered clinical scientist or medical practitioner.

The range of activities is likely to have included:

- Advanced library study
- Case study/discussions
- Debate/discussion forum
- Expert briefings
- Individual tutoring
- Interactive lectures
- Interaction with patients
- Multi-professional team meetings
- Opportunities to enable interprofessional and interdisciplinary learning
- Personal critical reflection and action planning
- Problem-based learning
- Role play
- Seminars
- Skills teaching
- Simulation
- Self-assessment
- Self-directed learning activities

- Team projects
- Tutor-led small group learning

3.3. The level of assessment is informed by the Framework for Higher Education in England, Wales and Northern Ireland (QAA 2008) level 7 descriptor. Applicants will be expected to demonstrate that they have achieved:

- High-quality clinical and scientific practice that applies basic, core scientific knowledge, skills and experience in a healthcare setting, places the patient and the public at the centre of care, prioritising patient safety and dignity and reflecting NHS/health service values and the NHS Constitution.

- The ability to perform quality assured appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and skilfully, adhering to applicable legislation and in compliance with local, national and international guidelines.

- The ability to deal with complex scientific and clinical issues both systematically and creatively, make sound judgements in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences, including patients and the public.

- The ability to define and choose investigative and scientific and/or clinical options, and make key judgements about complex facts in a range of situations.

- Originality in the application of knowledge, together with a practical understanding of how established techniques of research and enquiry are used to create and interpret diagnostic procedures.

3.4. The curriculum for each specialty is defined by the following parameters (taken from the QAA subject benchmark statement for clinical sciences):

A broad understanding of:

- The structure and function of the human body, as relevant to practise, together with a knowledge of health, disease, disorder and dysfunction, and pathology
- The role of other professions in health and social care;
- The theoretical basis, and the variety of approaches to, assessment and intervention
- The legislation and professional and statutory codes of conduct that affect health and social care practice

- Philosophy and policy of health and social care and its translation into ethical and evidence-based practice
- The need to establish and maintain a safe practice environment

A detailed knowledge of:

- The principles and applications of scientific enquiry, including the evaluation of treatment efficacy and the research process
- The basic science underpinning the specialty in which the registrant practices, relevant basic clinical medicine and the fundamental principles of clinical practice
- The wider clinical situation relevant to the patients presenting to the specialty
- The ways in which professional principles are translated into action through a number of different diagnostic, monitoring, treatment and management approaches, and how to select approaches to meet the needs of an individual
- The clinical applications of the specialty and the consequences of decisions made upon actions and advice
- The evidence base that underpins the use of the procedures employed by the service
- The principles associated with a range of techniques employed in the specialty
- The standards of practice expected from techniques

The ability to:

- Identify the clinical decision which the test/intervention will inform
- Make judgement on the effectiveness of procedures
- Provide interpretation of data and a diagnostic (therapeutic) opinion, including any further action to be taken by the individual directly responsible for the care of the patient
- Understand the wider clinical situation relevant to the patients presenting in the specialty
- Develop/devise an investigation strategy taking into account the complete clinical picture
- Supervise others as appropriate to areas of practice
- Respond to enquiries regarding the service provided when dealing with clinical colleagues
- To communicate with patients, carers and relatives, the public and other healthcare professionals as appropriate
- Communicate the outcome of problem solving and research and development activities

It is recognised that some of the learning for these areas that will have taken place may not have been at master's level (as is permitted in university regulations for MSc qualifications). However, this provides the foundation for further development to enable the application of knowledge for the specialist to be at master's level, therefore fulfilling the requirements for demonstrating the HCPC standards of

proficiency for clinical scientists have been met. For example: the IBMS Specialist Portfolio in Haematology is a postgraduate vocational qualification which does not have a formal taught M-level academic component but would be recognised as providing suitable knowledge and practical experience of laboratory investigations and diagnosis.

4 Specialty Specific Academic Curriculum: HAEMATOLOGY

4.1 Clinical and Laboratory Management

4.1.1 Governance: audit, list generation, maintaining audit trails for quality assurance and improvement programmes (TQM, NEQAS), multidisciplinary team meetings.

4.1.2 Disease classification.

4.1.3 Legislation: Human Tissue Act (2004), and the Human Tissue (Scotland) Act (2006), Storage and Retention of Specimens, Medicines and Healthcare products Regulatory Agency (MHRA), UK's Bloody Safety and Quality Regulations.

4.1.4 Patient management: ethical and legislative processes; reporting in relation to clinical management of patient and wider clinical situation relevant to service users including the application of investigative protocols and diagnostic tests in the assessment of haematological disorders; and the integration and interpretation of haematology parameters with other relevant diagnostic algorithms in the overall clinical assessment of the patient

4.1.5 Communicating results with patients, their representatives and the multi-disciplinary team.

4.1.6 Communication techniques: taking into account factors such as age, capacity, learning ability and physical ability, characteristics and consequences of verbal and non-verbal communication and how this could be affected by factors such as age, culture, ethnicity, gender, socio-economic status and spiritual or religious beliefs, assist communication (use of interpreter).

4.1.7 Multidisciplinary team working: taking into account factors such as personal scope of practice as a clinical scientist, relationship to other professionals, sustaining professional relationships, contributing effectively.

4.1.8 Maintain records: taking account relevant legislation on recording, sharing, storing and accessing information.

4.2 Clinical Physiology and Pathology

4.2.1 Normal haemopoiesis (including erythropoiesis, leucopoiesis and thrombopoiesis) in the neonate, child, adult and elderly patient. Includes:

- Sites of haemopoiesis and the processes of cellular maturation and differentiation, recognising the importance of the full blood count, and other haematological investigations, in the patient pathway such that appropriate interpretation of the results can be made, both in the context of the clinical details available and in the absence of complete clinical information

- Application of investigative protocols and diagnostic tests in the assessment of haematological disorders
- Integration and interpretation of haematology parameters with other relevant diagnostic parameters in the overall clinical assessment of the patient

4.2.2 WBC as an assessment of inflammation, infection and neoplasia and their exclusion. Includes:

- Normal morphological features of leucocytes and their progenitors in peripheral blood and bone marrow
- Leucocytes and their benign disorders
- The biological and clinical effects of infectious mononucleosis and laboratory methods utilised for its diagnosis

4.2.3 RBC as an assessment of acute, chronic, inherited and acquired anaemias and their exclusion. Includes:

- The production of haemoglobin and its structure/function relationship in health
- Classification of anaemias
- Commonly encountered inherited and acquired haemoglobin variants and their effects on erythropoiesis and haemoglobin function
- Homozygous, heterozygous and compound heterozygous inheritance of abnormal haemoglobins (including HbS, HbSC, HbC, alpha and beta-thalassaemias, HbH and HbBarts) their molecular biology, laboratory features, clinical manifestations and options for therapeutic intervention
- National screening programmes for sickle cell disease and thalassaemias, and their impact on patient care
- Other common inherited and acquired abnormalities of erythropoiesis and red cell survival, their morphological characteristics and relationship with red cell indices
- Red cell enzymopathies, clinical manifestations, and methods of laboratory diagnosis
- The role of micronutrients iron, B12 and folate in haemopoiesis, their individual biochemical pathways and sites/mechanisms of storage
- Clinical manifestations and causes of iron, B12 and folate deficiency and the clinical and laboratory procedures used for their identification
- Clinical strategies used for the correction of iron, B12 and folate deficiency and their impact on haemopoiesis
- Disorders of iron overload, clinical manifestations, laboratory investigations and therapeutic interventions
- Intracellular parasites, methods employed for their identification, diagnosis, treatment and monitoring

4.2.4 PLT as a measure of platelet sufficiency and the investigation and exclusion of disorders of primary haemostasis, evaluation of the risk of bleeding, and the assessment of inflammation, infection and neoplasia. Includes:

- Methods of platelet enumeration and causes of pseudo-thrombocytopenia
- Investigation of the thrombocytopenic patient and protocols for reporting low platelet results

4.2.5 Malignancy: to understand and apply a range of laboratory procedures to the investigation of patients suspected of malignancy or to those requiring monitoring and to recognise the need for further investigation to achieve a satisfactory clinical outcome. Includes:

- World Health Organization criteria for the classification of haematological malignancies and its impact on laboratory practice and reporting
- The breadth of haematological malignancy including: Acute myeloid and lymphoblastic leukaemias and their subtypes, Chronic myeloid and lymphoid leukaemias, myelodysplastic syndromes, myeloproliferative neoplasms and their overlapping disorders, plasma cell dyscrasias
- The clinical features associated with commonly encountered primary and secondary malignancies and their laboratory manifestations including full blood count, blood film, bone marrow (including cytochemical) appearance, immunophenotypical and cytogenetic features
- Clinical and laboratory markers of prognosis and their utility in informing clinical practice
- Measurement of minimal residual disease, sensitivity to therapeutic intervention and markers of relapse
- The effects of therapeutic intervention on haemopoiesis and haemopoietic tissue

4.2.6 Haemostasis to apply a series of laboratory-based investigations to determine the sufficiency of haemostasis for the screening, monitoring and diagnosis of its disorders, organ dysfunction (including liver and kidney) and for the prevention of bleeding and thrombosis. Includes:

- Primary haemostasis and the impact of commonly encountered primary haemostatic disorders
- Laboratory methods used to determine the nature of commonly encountered primary haemostatic disorders
- Synthesis, secretion and port-translational modification of clotting factors, von Willebrand factor, and their roles in haemostasis
- *In vivo* and *in vitro* haemostatic pathways
- Routine coagulation tests and their interpretation. Further tests to investigate abnormal results and the rationale underpinning their selection
- Coagulation abnormalities associated with haemophilia A, B and C, von Willebrand disease and other factor deficiencies.

- Coagulation abnormalities associated with acquired defects
- Thrombotic risks associated with reduced levels of inhibitors and co-factors and defects that are detected using genetic analysis, including Factor V Leiden and prothrombin gene mutation
- Commonly employed therapeutic interventions (for example replacement therapy and anticoagulation) to manage a range of disorders of haemostasis
- Clinical significance of antiphospholipid antibodies

4.2.7 Transfusion for the assessment of blood cell serology in the pre-, peri- and post-operative settings, antenatal and postnatal care and for the provision of safe and compatible blood products according to clinical need. Includes:

- Manual and automated techniques for ABO/D typing, serological cross-matching, red cell phenotyping, antibody screening and identification
- Major blood group systems – genes, antigens and antibodies and their clinical significance in transfusion medicine
- Laboratory methods and protocols for the investigation of transfusion complications

4.3 Investigative Techniques and Procedures

4.3.1. Basic laboratory procedures and techniques

- Pre- and post-analytical laboratory processes that can be automated either as standalone automation or integrated with the analysers, for example with tracking systems
- Clinical sensitivity and specificity of methods, problems with cross reactivity and prozone effects
- Principles and limitations of analytical methods and sample requirements for laboratory investigation and diagnosis. To include:
  - spectrophotometry
  - immunoassay
  - immunoelectrochemistry
  - colourimetry
  - high performance liquid chromatography
  - flow cytometry
  - capillary electrophoresis
  - isoelectric focusing
  - mass spectrometry
  - Maintenance and calibration
- Range of samples that may be analysed on general haematology and immunoassay analysers
  - Structure of the instrument software/ user interface

    - Function and design of the basic instrument and haematology parameters
- Factors affecting sample integrity and specific risks associated with the reagents or method of investigation
    - Internal quality control and the interpretation of the QC data
- Reference ranges for stated analytes and understand the significance of abnormal results individually and as part of a multi-analyte profile

4.3.2. Immunochemical techniques

- Specific fixatives and their characteristics and their compatibility with subsequent immunostaining procedures
- Potential problems associated with prolonged section storage and loss of tissue antigenicity
- Importance of accurate and appropriate antigen retrieval and commonly used methodologies: including proteolytic enzyme digestion, heat mediated methods, optimal digestion, and assessment in stained preparations
- Methods for the production of monoclonal and polyclonal antibodies, for the preparation of conjugated antisera
- Methods for the preparation and validation of different substrates
- Methods for validation of primary antibodies before introduction into a diagnostic procedure and the requirement for assessment of batch to batch variation when in use
- Concepts of sensitivity, specificity, avidity and affinity and their significance to the quality assurance of immunostaining
- Problems of non-specific and inappropriate staining; their causes, and methods for their reduction or elimination
- Quality control and quality assurance procedures
- Principles, advantages/disadvantages and clinical application of diagnostic techniques including:
    - Chemiluminescence assays
    - Electrophoresis
    - ELISA
    - Haemagglutination
    - Immunofluorescence
    - Immunodiffusion
    - Immunoblotting
    - Multiplex technologies
    - Radioimmunoassay

4.3.3. Light microscopy

- Principles of light microscopy

- Microscopic recognition of normal and abnormal immunochemical staining patterns.
- Clinical applications of light microscopy in diagnostic techniques
- Limitations of light microscopy

4.3.4. Fluorescent microscopy

- Principles of fluorescence microscopy
- Properties of different fluorescent compounds
- Microscopic recognition of normal and abnormal immunofluorescence patterns
- Clinical applications of fluorescent microscopy in diagnostic techniques

4.3.5. Image Capture

- principles of recording photographic images.
- storage of images under the terms of the Data Protection Act.
- process for image back-up via IT networks or discs.
- principles of semi quantitative methods of microscopic analysis and when their use is appropriate.

4.4. Primary Investigations of Blood and its Components

4.4.1. Cell Counting and haemoglobin concentration measurement

- automated cell counting methods for:
  - Leucocytes
  - Erythrocytes
  - Platelets
  - Reticulocytes
  - White cell differentials

4.4.2. Erythrocyte Sedimentation Rates (ESR)/plasma viscosity

- ESR measurement and environmental effects on the accuracy of results
- Measurement of plasma viscosity
- Reference values and the significance of abnormal results for diagnosis of disease

4.4.3. Identification and enumeration of peripheral blood cells by microscopy

- Staining blood cells by Romanowsky staining

- Pre-analytical variables that will affect appearance of blood cells
- Significance of abnormal or immature white blood cells on the peripheral blood film
- Normal reference values and the significance of abnormal results
- Referral mechanisms for abnormal results

4.4.4. Infectious Mononucleosis

- Screening test for infectious mononucleosis (IM)
- Blood count, serological and morphological features of IM
- Limitations of IM screening tests.

4.5. Abnormal haemoglobins and thalassaemia

4.5.1. Sickle cell

- Screening test for HbS disorders
- Blood count and morphological features of sickle cell disorders
- Limitations of sickle cell screening tests

4.5.2. Haemoglobin variants (HbS, C, D, E)

- Detection and investigation of abnormal haemoglobin using HPLC, capillary electrophoresis, isoelectric focusing, mass spectrometry
- Reference values and the significance of abnormal results

4.5.3. Imbalanced globulin chain production

- Detection and investigation of imbalanced globin chain production (abnormal haemoglobin using HPLC, capillary electrophoresis, isoelectric focusing, DNA chain analysis)
- Reference values and the significance of abnormal results

4.5.4. Unstable haemoglobin

- Detection of unstable haemoglobin
- Significance of abnormal results

4.5.5. Investigation of enzymopathies

- Detection of abnormal red cell enzymes
- Clinical significance of abnormal results

4.5.6. Haemolytic anaemia

4.5.6.1. Haemolytic anaemia screening tests

- Peripheral blood morphology features associated with haemolytic anaemia
- Screening tests to identify the occurrence of haemolysis, including:
  - Reticulocyte count
  - Serum haptoglobin
  - Urinary haemosiderin
  - Methaemoglobin
  - Serum haemopexin
  - pre-analytical variables, normal reference values and the significance of abnormal results.

4.5.6.2. Inherited and acquired haemolytic anaemia

- Identification of membrane abnormalities (e.g. osmotic fragility, flow cytometry), enzyme deficiencies (e.g. G-6-PD, pyruvate kinase), acquired immune haemolytic anaemia (e.g. DAT, presence of cold or warm reacting antibodies)
- Acquired non-immune haemolytic anaemia (e.g. PNH, malaria)
- Pre-analytical variables, normal reference values and the significance of abnormal results

4.6. Micronutrients

4.6.1. Functional iron deficiency and iron overload

- Effect of iron deficiency and iron overload on red cell indices
- Assessment of iron status (serum ferritin, serum transferrin, serum iron, zinc protoporphyrin) and erythropoiesis (reticulocyte enumeration)
- Pre-analytical variables, normal reference values and the significance of abnormal results

4.6.2. Vitamin B12/folate deficiency

- Changes in blood cell indices and morphological features associated with B12 and folate deficiency.
- Measurement of vitamin B12, serum folate, methylmalonic acid and total homocysteine and their association with the clinical manifestations of deficiency
- Reference values and the significance of abnormal results
- Further investigations and therapeutic interventions

4.7. Malaria

4.7.1. Malaria parasites

- Geographical occurrence of malaria
- Risk assessment protocol for VHF assessment required prior to malaria request
- Screening techniques for malaria parasites, including:
  - Thick and thin blood films
  - Use of different stains
  - Immunochromatography
  - Parasitaemias and their significance
- Clinical symptoms of suspected cases and haematological changes
- Malaria parasites: types, life cycle and the stages found in the blood
- Effect of drug treatment on detection and limitations of techniques employed
- Referral pathways for positive result
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4.8. Malignancies

4.8.1. Haematological malignancies

- Know the changes in peripheral blood cell indices associated with malignancy, including:
  - erythrocytosis
  - leucocytosis
  - leucopenia
  - thrombocytopenia
  - thrombocytosis
  - anaemia
- Morphological indicators of malignancy including:
  - Leucoerythroblastic blood picture
  - Auer rods
  - Ring sideroblasts
  - Signs of dysplasia
- Techniques for the investigation of hematological malignancies including:
  - Cytochemistry
  - Bone marrow aspirate/trephine collection and examination
  - Immunophenotyping
  - Cytogenetics and molecular genetics
- Methods of investigating JAK2, or alternative molecular markers for the diagnosis of myeloproliferative neoplasms
- Limitations of tests, further investigations that may be required, reference values and significance of abnormal results
- Secondary malignancies and their effects on the haempoietic system

4.8.2. Haemostasis

4.8.2.1. Haemostasis function

- Components of the *in vivo* and *in vitro* haemostatic pathways and their modes of action
- Techniques for measuring prothrombin time (PT) and clotting factors involved
- Techniques for measuring activated partial thromboplastin time (APTT) and which clotting factors are measured
- Pre-analytical variables, normal reference values and the significance of abnormal results
- Effects of anticoagulant therapy including direct oral anticoagulants on PT and APTT measurement
- Relationship between abnormal PT and APTT and other laboratory tests, e.g. full blood count and liver function tests
- Technique for measuring thrombin time (TT) and reptilase time (RT)

4.8.2.2. Fibrinogen

- Laboratory investigation and clinical emergency of suspected disseminated intravascular coagulation (DIC)
- Fibrinogen estimation
- Difference between Clauss and derived fibrinogens and the limitations of the latter test
- Pre-analytical variables, normal reference values and the significance of abnormal results

4.8.3. D-Dimer measurement

- Estimation of fibrin degradation products
- Pre-analytical variables, normal reference values and the significance of abnormal results
- Use of D-dimer for the investigation of suspected cases of venous thromboembolism, derivation of cut-off values and how these may differ from reference ranges

4.8.4. Anticoagulant therapy

- Principles of heparin, vitamin K antagonist (VKA) and oral anticoagulant (OA) therapy
- Monitoring anticoagulant therapy, with unfractionated heparin (UFH) and low molecular weight heparin
- International normalised ratio (INR) system for monitoring VKA OA therapy
- Pre-analytical variables, therapeutic ranges and significance of out of range results

- Assessment of direct thrombin inhibitor (DTI) and direct factor Xa inhibitor (DFXaI) therapy with routine coagulation screening tests and specific assays for DTI and DFXaI

4.8.5. Bleeding disorders

- Screening tests for coagulation and the clotting factors, which are measured by the PT, APTT and TT.
- Techniques to assess specific coagulation factor deficiencies (e.g. one-stage clotting assays).
- Detection of coagulation factor inhibitors.
- Techniques to assess platelet function.
- Pre-analytical variables, normal reference values and the significance of abnormal results.
- Difference between assays used in the diagnosis of a deficiency and monitoring of treatment

4.8.6. Thrombotic disorders

- Techniques to investigate thrombotic risk associated with thrombosis, including:
  - Clotting i.e. protein C activity, protein S activity, activated protein C resistance screening
  - Chromogenic (i.e. antithrombin activity, protein C activity)
  - Immunoassays (i.e. free protein S antigen)
- Pre-analytical variables, normal reference values and the significance of abnormal results
- Interpretation and reporting of thrombophilia investigations

4.8.7. Lupus Anticoagulant

- Significance of the screening tests for coagulation and the potential influence of lupus anticoagulant on them
- Effect of lupus anticoagulant on clotting based tests (e.g. INR, one-stage factor assays)
- Techniques to demonstrate the presence of lupus anticoagulant i.e. screening, confirmatory and mixing tests for assays such as dRVVT and APTT
- Interpretive procedures for distinguishing lupus anticoagulants from other causes of elevated clotting times
- Pre-analytical variables, normal reference values and the significance of abnormal results
- Therapeutic interventions for patients demonstrating lupus anticoagulant

5 Programme Learning Outcomes for IBMS Clinical Scientist Certificate of Attainment Experiential Portfolio – Section 1: Professional Conduct

5.1 Module 1: Personal Responsibility and Development

To complete this section of the IBMS Clinical Scientist Certificate of Attainment Mapping Document you must be able to demonstrate you have worked in an environment that has enabled you to receive training and gain experience relevant to the learning outcomes for this specialty. You must provide evidence to demonstrate you meet the standards of proficiency required to practice as a clinical scientist.

You are required to demonstrate an understanding of contractual responsibilities and expected behaviour of a clinical scientist. The HCPC standards of conduct, performance, and ethics and the Institute of Biomedical Science Code of Conduct and Guide to Good Professional Practice are reference points, together with other organisational and national/international standards. As a registered clinical scientist you must be able to recognise the responsibilities you have for your own professional behaviour and its impact on others, the level of autonomy that comes with your responsibility for completing tasks and procedures, for using judgment within broad parameters and being able to reflect on this and other learning opportunities to inform self-development. Central to this is the contribution of healthcare science to patient care, patient safety, service delivery, research and innovation, often at the cutting edge of science. All clinical scientists must understand the impact of their work on patients and patient care and remember that their work has a direct or indirect impact on patient care.

In the context of service users there are three areas of practice that are considered appropriate when interpreting the standards of proficiency:

a. Patients or carers in clinics and/or wards where there is direct contact with biomedical and clinical scientists
b. Professional groups that have direct patient healthcare role which relies on pathology services including clinical laboratory investigation, advice, treatment evaluation and research
c. Service providers that employ biomedical and/or clinical scientists for services that contribute to the patient healthcare pathway

Aims

To demonstrate a detailed knowledge and experience base for the candidate's own professional behaviour and awareness of its impact on others. This includes the level

of autonomy that comes with responsibility for completing tasks and procedures, for using judgment within broad parameters and being able to reflect on this and other learning opportunities to inform self-development as a clinical scientist.

Indicative Curriculum

- Standards of proficiency for clinical scientists
- Structure and organisation of the department, its relationship to the local clinical setting and how this compares with other locations in the UK
- Basic understanding of financial accountability, budget control and resource management
- Principles of clinical governance including clinical audit, accreditation requirements relevant to the specialism including equality and diversity, confidentiality, informed consent and data security
- Management principles and structures
- European Community (EC) Working Time Directive (1996) and its principles
- The role of appraisal in staff management and development
- Principles of training and development of staff
- Principles of lifelong learning and continuing professional development

Learning Outcomes

To be able to:

a. *Describe the appropriate action and referral mechanisms available when personal limit of practice has been reached. (HCPC SoP 1, 1.1, 2, 4.5)*

b. *Show an understanding of the importance of financial accountability, budgetary control and resource management. (HCPC SoP 1.2)*

c. *Demonstrate a detailed knowledge of all aspects of the department's operations, of their inter-relationships and of the pre-, intra- and post-analytical factors that affect quality and service delivery and how it fits into the local clinical setting and the relationship of the service to the interests and needs of different service users. (HCPC SoP 2.1- 2.5)*

d. *Explain and critically evaluate the structures, processes and methodologies that underpin the quality of the service provided by their employer and quality improvement initiatives to promote high-quality patient care and enhance patient safety, and discuss the quality mechanisms relevant to your division/specialism. (HCPC SoP 2.1- 2.5)*

e. *Show an understanding of the way the specialty is structured and practiced in other locations within the UK. (HCPC SoP 2.1-2.5)*

f. *Demonstrate the competence, and therefore the potential, to provide leadership and support for staff continuity in the different aspects or areas of departmental activity, e.g. scientific, technical, research and development; quality assurance, audit, accreditation; reporting, clinical liaison; health and safety, staff training; IT, budget and management (management principles and tools used in the services and factors that influence access to and use of services available). (HCPC SoP 4, 4.1, 4.2, 4.3, 4.4, 4.5, 14.1)*

g. *Demonstrate the ability to conduct duties and responsibilities in accordance with local, professional and regulatory policies and practice to ensure there is a high standard of care and trust with service users even in circumstances of personal incompatibility (HCPC SoP 2.4, 2.6, 2.7, 3.1)*

h. *Describe how principles of self-management and time keeping are applied in relation to service delivery and prioritising the workload. (HCPC SoP 1.2)*

i. *Demonstrate an understanding of the role of the Health and Care Professions Council (HCPC) by describing its role and requirements for statutory regulation with specific reference to:*
   - *How HCPC standards of proficiency apply to professional practice.*
   - *How the HCPC standards of conduct, performance and ethics (2016) apply to professional practice.*
   - *Professional Indemnity Insurance and the relevance of this to their scope of practice*. (HCPC 2.2, 3)*

**To note: you must make sure that the professional indemnity arrangement you have in place provides appropriate cover, i.e. appropriate to your practice, taking into account the nature and extent of its risks. If you are a member of the IBMS your professional indemnity insurance covers you for your role whether you are a biomedical scientist or clinical scientist. If not a member you should check with your employer with respect to your employment role, i.e. as either a biomedical scientist or clinical scientist.*

j. *Demonstrate an understanding of the need to respect and uphold the rights, dignity, values, and autonomy of service users, including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing. (HCPC SoP 2.3)*

k. *Demonstrate how the principles of patient confidentiality are upheld by working in accordance with policies that protect the dignity, privacy and confidentiality of service users. (HCPC SoP 2.3, 2.4)*

l. *Demonstrate an understanding of the importance of maintaining physical and mental well-being and how to take appropriate action in response to one's own health issues. (HCPC SoP 3.2)*

m. *Demonstrate an understanding of the implications of the European Community (EC) Working Time Directive (1996) and its principles. Demonstrate how you comply with departmental time-keeping policy. (HCPC SoP 3.2)*

n. *Demonstrate an understanding of the principles of continuing professional development (CPD) in relation to responsibility for maintaining personal competence and that of staff being supervised. (HCPC SoP 3.3, 11,11.1)*

o. *Discuss and appraise the ethical foundations of professionalism, including critical reflection, and how these relate to the clinical scientist, the patient, the practice of healthcare science and the wider healthcare environment. (HCPC SoP 3.3, 11,11.1)*

p. *Demonstrate that active participation in the training and professional development of staff and work towards targets for personal, academic, professional and career development. (HCPC SoP 4.5, 4.7)*

Evidence for this module is expected to come from the following sources:

- Personal statement that summaries employment history and how specialty specific competences have been developed at postgraduate level. This should be supported copies of certificates of relevant postgraduate qualifications, competence assessment reports, reports on placements or secondments
- Involvement in management, supervision and/or training of staff within the laboratory
- Expert briefing/individual tutoring sessions
- Self-directed learning activities, personal critical reflection, personal development plan, CPD activities
- Evidence based (e.g. reflective statements) participation in local seminars and meetings, attendance at clinical audit meetings and clinical governance committees
- Personal involvement in recognition and solution of problems with laboratory or clinical scenarios that demonstrate the opportunity for experience-based learning and enhancement of self-development

5.2 Module 2: Equality and Diversity

To complete this section of the IBMS Clinical Scientist Certificate of Attainment Mapping Document you must be able to demonstrate you have worked in an environment that has enabled you to receive training and gain experience relevant to the learning outcomes for this specialty. You must provide evidence to demonstrate you meet the standards of proficiency required to practice as a clinical scientist.

You must be able to recognise and respect the equality culture and diversity of people and their rights and responsibilities. You are expected to be proactive against discrimination and act as a role model.

Aims

To demonstrate a detailed knowledge and experience base with respect to developing and maintaining an equality culture that recognises the diversity of people and their rights and responsibilities.

Curriculum

HCPC standards of conduct, performance and ethics (2016).
Equality and diversity policies and legislation and local and national level.
Principles of equality and diversity.

Learning outcomes

To be able to:

a. *Demonstrate an understanding of HCPC standards of conduct, performance and ethics (2016) by describing how it applies to equality and diversity. (HCPC SoP 5, 6)*

b. *Demonstrate they understand how local policies and national legislation on diversity and equal opportunities apply to your professional practice. (HCPC SoP 5.1)*

c. *Demonstrate they apply the principles of equality and diversity in their own practice and to those you supervise. (HCPC SoP 6)*

Evidence for this module is expected to come from the following sources:

- Local training and development courses
- Personal statement to demonstrate understanding and application in practice
- Witness statements

5.3 Module 3: Communication

To complete this section of the IBMS Clinical Scientist Certificate of Attainment Mapping Document you must be able to demonstrate you have worked in an environment that has enabled you to receive training and gain experience relevant to the learning outcomes for this specialty. You must provide evidence to demonstrate you meet the standards of proficiency required to practice as a clinical scientist.

You will be expected to apply a variety of communication methods and approaches, appropriate to others and the situation, in order to facilitate and promote constructive outcomes. You will be expected to be able to communicate effectively on difficult, complex and sensitive issues and demonstrate the ability to overcome barriers to communication. This must take into account factors such as age, capacity, learning ability and physical ability, characteristics and consequences of verbal and non-verbal communication and how this could be affected by factors such as age, culture, ethnicity, gender, socio-economic status and spiritual or religious beliefs, assisted communication (use of interpreter).

Aims

To demonstrate a detailed knowledge and experience base for responding to enquiries regarding the service provided when dealing with clinical colleagues and other healthcare professionals, to communicate with patients, carers and relatives, and to communicate the outcomes of problem solving and research and development activities.

Applicants who do not have English as their first language and do not have a UK degree are required to provide evidence of English language skills with a minimum International Language Testing System (IELTS) score of 7.0 with no element less than 6.5, or a Test of English as a Foreign Language (TTOEFL) Internet Based Test with a minimum score of 100/120. (HCPC SoP 8.2)

Curriculum

Application of a variety of communication methods and approaches in order to facilitate and promote constructive outcomes in different situations relative to the specialty.
Effective communication on difficult, complex and sensitive issues, including ethical aspects of communication with patients and the public.
Overcoming barriers to communication.
Presentation skills.

Learning outcomes:

To be able to:

a. *Demonstrate the ability to communicate clearly and with confidence to clinical and other professional colleagues both within and outside the profession of the specialism. (HCPC SoP 8, 8.1, 8.2, 8.3, 8.5). This includes the following:*
   - How communication should be modified to address and take account of factors such as age, capacity, learning ability and physical ability
   - How communication can be affected by factors such as age, culture, ethnicity, gender, socio-economic status and spiritual or religious beliefs
   - How communication needs of the service users can be assisted (e.g. through the use of an interpreter)

b. *Demonstrate the ability to appropriately summarise and present complex scientific ideas and information in order to educate and train others both within and outside the profession for the specialism. (HCPC SoP 8.10)*

c. *Demonstrate the use of correct clinical and medical language and terminology pertinent to the specialism. (HCPC 8.6)*

d. *Demonstrate the ability to communicate with patients, carers and relatives, the public and other healthcare professionals as appropriate. (HCPC 8.4, 8.7, 8.8)*

e. *Demonstrate the ability to receive and respond to a variety of sources of information and be able to solve problems by a variety of methods, including the use of appropriate software. (HCPC SoP 8.1)*

f. *Clearly convey information or results to the appropriate level of detail, demonstrate an understanding that different communication methods may be required to facilitate effective feedback and participation of others. (HCPC 8.9)*

g. *Explain the principles of effective written and verbal communication and feedback, considering the needs and dignity of patients, the public, health professionals and scientists. (HCPC SoP 8.4, 8.10)*

Evidence for this module is expected to come from the following sources:

- Presentations at scientific meetings, oral and written communications within and outside the department, through seminars, case presentations, posters, peer-reviewed publications in the specialty
- Representative appointments, e.g. committee membership, advisory panel, specialist interest groups

5.4 Module 4: Patient Records and Data Handling

To complete this section of the IBMS Clinical Scientist Certificate of Attainment Mapping Document you must be able to demonstrate you have worked in an environment that has enabled you to receive training and gain experience relevant to the learning outcomes for this specialty. You must provide evidence to demonstrate you meet the standards of proficiency required to practice as a clinical scientist.

You must be able to demonstrate the knowledge and skills needed to follow correct procedures for recording, sharing, storing and accessing information in the laboratory with respect to your role as a clinical scientist.

Aims

To demonstrate a detailed knowledge and experience base to follow and initiate correct procedures for recording, sharing, storing and accessing information in the laboratory with respect to the role of a clinical scientist.

Curriculum

Information governance, data security.
Legislation, protocols and guidance for managing records.
Information management systems and the use of information technology relevant to the specialism.

Learning outcomes

To be able to:

a. *Demonstrate an understanding of the data protection policies by describing the extent to which the Data Protection Act 1998, and other legislation and professional guidance covers patients, research and laboratory records. (HCPC SoP 7, 7.1, 7.3, 10.1, 10.2)*

b. *Apply knowledge of data security and apply due diligence to password strength, email attachments, downloading file, backup storage etc. (HCPC SoP 10.1, 10.2)*

c. *Demonstrate ability to maintain accurate, clear laboratory records in accordance with legislation requirements and local procedures for handling and recording clinical and other types of information. (HCPC SoP 10, 10.1)*

d. *Demonstrate ability to educate and train others in the purpose of accurate, clear laboratory records, and the need to follow standard operating procedures for*

handling and recording clinical and other types of information. (HCPC SoP 7.2, 10)

e. *Demonstrate an understanding of all aspects of information technology pertinent to service provision and a competence to use it for effective practice in the specialism. (HCPC SoP 7.2, 10)*

Evidence for this module is expected to come from the following sources:

- Personal statement to demonstrate understanding and use of IT pertinent to service provision and support of effective practice to the level required in the specialism
- Training certificates
- Witness statements

5.5 Module 5: Professional Relationships

You must demonstrate that you can sustain a consistent approach to work relationships in the context of the role of a clinical scientist in order to achieve the best results for service users. This is achieved by recognising and valuing the contributions of other team members and demonstrating the ability to work effectively with others and develop productive working relationships. This includes the building and sustaining professional relationships as an independent practitioner.

In the context of service users there are three areas of practice that are considered appropriate when interpreting the standards of proficiency:

a. Patients or carers in clinics and/or wards where there is direct contact with biomedical and clinical scientists
b. Professional groups that have direct patient healthcare role which relies on pathology services including clinical laboratory investigation, advice, treatment evaluation and research
c. Service providers that employ biomedical and/or clinical scientists for services that contribute to the patient healthcare pathway

Aims

To demonstrate a detailed understanding and experience base to contribute effectively to work undertaken as part of a multi-disciplinary team as a clinical scientist.

Curriculum

Role of clinical scientist.
Principles of team working.
Recognising and valuing the contributions of other team members.
Working effectively with others and develop productive working relationships.

Learning outcomes

To be able to:

a. *Demonstrate how the role of a clinical scientist impacts on other professional groups in the provision of patient focussed healthcare. (HCPC SoP 9, 9.1, 9.2, 9.3, 13.3, 13.4). These may include:*
   - Groups that have professional interactions with patients and carers relying on the output of pathology services and including:
     Other pathology disciplines
     Accident and Emergency
     Intensive Care Unit
     Theatres
     Wards (including specialist units)
     Outpatient clinics
     Mortuary
     General practitioners
     Health education
     Occupational health/Social Care services
     Public health/Epidemiology
   - Patients in clinics and wards (e.g. POCT, phlebotomy) where there is direct contact
   - Employers who interact with professional groups to which pathology services are provided and who therefore rely on the knowledge and skills of registrants for service delivery and improvement

b. *Demonstrate an understanding of how the role of a clinical scientist relates to their personal scope of practice and the relationship to other professionals, and the ability as an independent practitioner to build and sustain professional relationships in order to contribute effectively as part of a multi-disciplinary team. (HCPC 9.2, 9.4)*

c. *Demonstrate an understanding and application of the principles of team working with respect to leadership, individual contributions and differing opinions in the laboratory team. (HCPC SoP 9.2)*

Evidence for this module is expected to come from the following sources:

- Job description
- Self-statement (with examples) on how contributions to multi-disciplinary team meetings have been effective
- Evidence based examples of responsibility taken for supervision, team leadership
- Representative appointments, e.g. committee membership, advisory panel, specialist interest groups and evidence of professional contribution

Please note evidence must include a reflective report demonstrating an understanding of the importance of the experience gained by interaction with service users and carers, and the contribution this makes to professional development, for example in planning and evaluating diagnostics, treatments and interventions.

6 Programme Learning Outcomes for IBMS Clinical Scientist Certificate of Attainment Experiential Portfolio – Section 2: Professional Skills and Standards

6.1 Module 1: Professional Knowledge

To complete this section of the IBMS Clinical Scientist Certificate of Attainment Mapping Document you must be able to demonstrate you have worked in an environment that has enabled you to receive training and gain experience relevant to the learning outcomes for this specialty. You must provide evidence to demonstrate you meet the standards of proficiency required to practice as a clinical scientist.

This is the basis for statutory regulation as a clinical scientist and you must be able to demonstrate a strong knowledge base appropriate to specialty and to the investigations, therapeutic intervention strategies and to development and evaluation of new and current methods.

Aims

To demonstrate a detailed understanding and experience base to provide interpretation of data and a diagnostic opinion, including further action to be taken in the care of the patient. This includes demonstrating individual leadership responsibility for specific work of the laboratory service related to the specialty.

Curriculum

Fundamental principles for an understanding of the pathogenesis, clinical features and classification of the major categories of disorders investigated relevant to the specialism.
Basic principles and structures underpinning history taking, clinical examination and clinical decision making.
Clinical applications of the specialty.
Patient history and examination and development of clinical investigation and management plans.

Learning outcomes
To be able to:

a. *Explain fundamental principles for an understanding of the pathogenesis, clinical features and classification of the major categories of disorders investigated relevant to their specialism. (HCPC SoP 13, 13.1, 14)*

b. *Demonstrate accountability for individual leadership and team responsibilities for specific work of the laboratory service related to the specialty. (HCPC SoP 13.5)*

c. *Discuss, compare and contrast a range of leadership models, including those that underpin current NHS Leadership and Competency Frameworks, and identify and critically evaluate how your personal values, principles and assumptions affect your personal leadership style. (HCPC SoP 13.5).*

d. *Describe and evaluate the basic principles and structures underpinning history taking, clinical examination and clinical decision making and show the application of this in the context of their role in their specialty through the integration of specialty parameters with other diagnostic parameters in the overall clinical assessment of the patient. (HCPC SoP 14, 14.8, 14.9, 14.13)*
History taking, clinical examination should cover:
- *Importance of patient-centred care, treating patients with respect, honesty and compassion, maintaining patient dignity and confidentiality and putting the patient first*
- *Duty of candour and the importance of this in healthcare*
- *Informed consent*
- *Principles, guidance and law with respect to informed consent*
- *Introduction to the patient, including role of the clinical scientist*
- *Explanation to the patient*
- *Structured models for presenting a patient history*
- *Process of patient-centred interviewing and the features of a good consultation with respect to: initiating the session, gathering information, building the relationship, explaining and planning, closing the session*
- *Link between the patient history and examination and development of clinical investigation and management plans*
- *Shared clinical decision making*
- *How information from a history and examination is used to develop clinical management plans*

e. *Demonstrate an experience-based understanding of all aspects of the diagnostic process and the wider clinical situation relevant to the service user including:*
- *comprising history-taking;*
- *clinical examination;*
- *formulation of differential diagnosis;*
- *the role of pathology and other clinical service investigations;*

and the consequent integration of knowledge relevant to the clinical situation of individual patients, including how practice may change to take account of new developments or changing contexts such as the effect of drugs or

treatments. (HCPC SoP 13.2, 13.6, 13.8, 13.9, 14, 14.1, 14.8, 14.10, 14.12, 14.17, 14.22)

f. *Recognise the need to be aware of emerging technologies and new developments in order to demonstrate the application of evidence-based investigation and clinical management of the patient. (HCPC SoP 12.10)*

g. *Demonstrate the application of evidence-based professional knowledge to interpret data in order to provide diagnostic and therapeutic opinions, including any further action which the individual directly responsible for the care of the patient or service user should take. (HCPC SoP 12.10, 14.9, 14.17, 14.22)*

h. *Demonstrate an experience-based understanding of the clinical relevance of the results of specialty specific investigations for the patient, and where appropriate, family members, and the ability* identify the clinical decision which the test/intervention will inform. *(HCPC SoP 14.11)*

Evidence for this module is expected to come from the following sources:

- Employer reference
- Evidence of training
- Job description
- Case studies
- Research
- Reporting of laboratory investigations, clinical interpretation/advice
- Examples of clinic leadership
- Participation in scientific meetings
- Notes from clinical liaison meetings
- Attendance at ward rounds, clinical audit and governance meetings
- Clinical report authorisation
- Witness testimonies

6.2 Module 2: Health and Safety

To complete this section of the IBMS Clinical Scientist Certificate of Attainment Mapping Document you must be able to demonstrate you have worked in an environment that has enabled you to receive training and gain experience relevant to the learning outcomes for this specialty. You must provide evidence to demonstrate you meet the standards of proficiency required to practice as a clinical scientist.

Aims

To ensure a detailed understanding and experience base to work in accordance with national legislation and organisational policy for health and safety, and contribute to the evaluation and improvement of procedures in the specialty.

Curriculum

Requirements and obligations of Health and Safety, including infection control.
Health and safety legislation/policies at local and national level applicable to the specialism.
Procedures for risk assessments and reporting of injuries, diseases, dangerous occurrences regulations (RIDDOR).
Immunisation requirements.

Learning outcomes

To be able to:

a. *Demonstrate an understanding of how the laboratory health and safety policies, controlling legislation and appropriate procedures of risk assessment (e.g. RIDDOR, clinical governance) for the specialty. (HCPC SoP 15, 15.2, 15.3)*

b. *Demonstrate an understanding of the potential hazards associated with the handling of tissue and other biological products in the specialty. (HCPC SoP 15, 15.2, 15.6)*

c. *Demonstrate the ability to establish safe environments for practice, which minimise risks to service users, those treating them and others, including the use of hazard control and infection control. (HCPC SoP 15, 15.1, 15.2, 15.5,)*
   This includes:
   - *determining when it is not possible to work safely and take remedial action in order to work in accordance with laboratory safety protocols. (HCPC SoP 15.2)*

- *confirming that work is carried out with due respect to different types of hazards including fire, electrical, biological, chemical, radiation, moving and handling and the use of visual display units. (HCPC 15.3)*

- *knowing the correct use of personal protective equipment and how this applies to each biohazard category. (HCPC SoP 15.4)*

- *knowing the risks associated with specimens (fixed and unfixed), clinical waste and equipment and describe the correct procedure for handling samples that may contain hazard group 2, 3 and 4 pathogens. (HCPC 15.5)*

- *knowing the immunisation requirements for the laboratory staff and the role of occupational health. (HCPC SoP 15.7)*

- *knowing the principles and applications of disinfectants, methods for sterilisation and decontamination and for dealing with waste and spillages correctly. (HCPC SoP 15.8)*

Evidence for this module is expected to come from the following sources:

- Evidence of initiating and evaluating health and safety audits
- Writing/review of health and safety policies
- Evidence based attendance (e.g. reflective statements) of participation in health and safety training seminars
- Evidence of initiating and evaluating risk assessments
- Critical appraisal of laboratory practices
- Evidence based involvement in recognition and solution of problems with laboratory or clinical scenarios

6.3 Module 3: Quality

You must demonstrate experience of maintaining quality improvement programmes and improving the quality of your own work and that of others against the organisational and professional standards that are used to measure it.

In the context of service users there are three areas of practice that are considered appropriate when interpreting the standards of proficiency:

a. Patients or carers in clinics and/or wards where there is direct contact with biomedical and clinical scientists
b. Professional groups that have direct patient healthcare role which relies on pathology services including clinical laboratory investigation, advice, treatment evaluation and research
c. Service providers that employ biomedical and/or clinical scientists for services that contribute to the patient healthcare pathway

Aims

To ensure a detailed understanding and experience base for the application of internal and external quality control and assessment procedures, audit and accreditation procedures and performance criteria relevant to evaluating the provision and reproducibility of the laboratory testing service in the specialty.

Curriculum

- Patient safety
- Horizontal and vertical audit
- Clinical audit
- Pathology accreditation schemes
- National quality assurance programmes
- Quality methodologies
- Quality processes and procedures
- Clinical governance
- Current NHS quality management and improvement systems
- Quality assurance to protect patients and assure high-quality healthcare science services, and deliver safe and effective services

Learning outcomes

To be able to:

a. *Contribute effectively in case conferences and other methods of review and recognise the value of these in the clinical diagnosis of the patient. (HCPC SoP 11.2)*

b. *Demonstrate an understanding of the role of accreditation in pathology and the requirement for accreditation schemes relevant to the modality. (HCPC SoP 12.6)*

c. *Demonstrate an experienced based understanding of the sources of variation that can occur in the performance of the major categories of specific procedures in their specialism and through a continued awareness how they demonstrate, by example, a climate of quality management, assurance and maintenance of quality improvement programmes in the laboratory. (HCPC SoP 12)*

d. *Demonstrate an experience based understanding and application of maintaining different types of audit used to maintain a quality management system. (HCPC 12.1, 12.3, 12.4)*

e. *Demonstrate an understanding and experience in the use of quality control and quality assurance techniques including restorative action when performance deteriorates. (HCPC SoP 12.5)*

f. *Demonstrate an experienced base understanding (for example through active participation in seminars, discussion groups and training) of the application of the principles of quality assurance, clinical performance parameters, accreditation and clinical audit to evaluating and improving the reproducibility of the commonly requested investigations relevant to this modality. (HCPC 12.1, 12.2, 12.3, 12.4, 12.5, 12.7, 12.8, 12.9)*

g. *vii) Demonstrate the ability to make judgements on the effectiveness of common procedures relevant to the discipline used in the diagnosis and management of patients and revise an investigation strategy in conjunction with other service users taking into account the complete clinical picture. (HCPC SoP 12.7)*

Evidence for this module is expected to come from the following sources:

- Evidence-based participation in national quality schemes
- Evidence-based attendance (e.g. reflective statements) of participation in quality audits
- Examples of initiating and evaluating quality assessments
- Critical appraisal of laboratory practices
- Examples of involvement in recognition and solution of problems with laboratory or clinical scenarios

6.4 Module 4: Performing Standard Investigations

You must demonstrate you achieved a high level of competence in performing analytical techniques and procedures in common use in this specialty at a standard that produces consistently valid results.

You must be able to demonstrate an understanding of the requirements of accuracy and precision of a procedure in the context of diagnosis, prognosis, monitoring and treatment and the effects of pre- and post-analytical variables, including the effects of confounding factors such as age, pregnancy and drugs.

Aims

To ensure a detailed understanding and experience base for performing analytical techniques and procedures in common use in this specialty at a standard that produces consistently valid results.

Curriculum

Principles and application of common procedures/investigations/techniques used in the specialism.
Selection of appropriate diagnostic tests for individual patients and interpretation of results.
Collection, receipt, retention, storage and respectful disposal of human tissues and samples.
Troubleshooting problems that might arise during the routine application of techniques.
Use of quality control and quality assurance, including remedial action when performance deteriorates.

Learning Outcomes

To be able to:

a. *Demonstrate an understanding of the legal and professional requirements for the collection, receipt, retention, storage and respectful disposal of human tissues and samples. (HCPC SoP 13.7)*

b. *Demonstrate an understanding of the scientific, operational and outcomes associated with the range of techniques employed in the subject specific curriculum and be able to recognise, solve and minimise problems with standards of practice expected from these techniques. (HCPC SoP 13.7, 13.10, 13.11, 13.12, 14.3, 14.5, 14.6, 14.7, 14.16)*

c. *Demonstrate a high level of practical competence in any specialist techniques relevant to an intended or actual area of specialisation. (HCPC SoP 13.12, 14.2, 14.4)*

d. *Demonstrate the ability to* identify the clinical decision which the test/intervention will inform and *undertake or arrange investigations relevant to the clinical situation. (HCPC SoP 13.10, 14.14)*

e. *Demonstrate an understanding the requirements of accuracy and precision of a procedure in the context of diagnosis, prognosis, monitoring and treatment and the ability to make judgements on the effectiveness of procedures taking into account the effects of pre- and post-analytical variables (including the effects of confounding factors such as age, pregnancy and drugs) for the appropriate interpretation and assessment of diagnostic procedures, HCPC SoP 14.15)*

Evidence for this module is expected to come from the following sources:

- Evidence based statements on work experiences
- Participation of approved training programmes
- Formal training and competence assessment records at local or national
- Practical training and assessment of junior staff
- Employer statement on scope of practice

6.5 Module 5: Research and Development

To complete this section of the IBMS Clinical Scientist Certificate of Attainment Mapping Document you must be able to demonstrate you have worked in an environment that has enabled you to receive training and gain experience relevant to the learning outcomes for this specialty. You must provide evidence to demonstrate you meet the standards of proficiency required to practice as a clinical scientist.

You must demonstrate you have applied your knowledge and understanding of disease processes in the context of the study/investigation of those processes.
You should be able to generate ideas; assess, plan, conduct, evaluate, interpret and report research and innovation projects, which includes original research; and disseminate the findings and, where appropriate, the adoption of the findings. You should also be able to use research to improve practice by applying your knowledge and understanding from a professional, evidence-based approach to research into the pathogenesis and origins of disease processes, and the diagnosis and monitoring of disease.

Aims

To ensure a detailed understanding and practical experience base for the role of research, development and innovation in the NHS in improving patient care, including prevention, diagnostics, treatment and service delivery.

Curriculum

Ethics approval processes and research governance (e.g. Human Tissue Act).
Key statistical concepts and methods typically used in research.
Intellectual property issues and copyright.
Critical evaluations of scientific literature and writing up a literature review.
Presenting quantitative and qualitative data, publishing and communicating research results.

Learning outcomes

To be able to:

a. *Demonstrate the ability to design, plan, conduct and report on investigations which may bring new techniques into the laboratory. (HCPC SoP 14.21)*

b. *Discuss and justify the research, audit and innovation process from idea generation to dissemination/implementation, including patient/user. (HCPC SoP 14.21, 14.26)*

c. *Explain and justify current UK ethical and governance frameworks and processes spanning the conduct of human and animal research, innovation and audit. (HCPC SoP 14.21)*

d. *Critically evaluate the literature/evidence base in the light of existing knowledge to identify a research question and create a new approach or technique to improve patient care or service delivery. (HCPC SoP 14.20, 14.23, 14.27)*

e. *Demonstrate the ability to conduct experimental work, produce and present result of statistical analysis, give a clear and accurate account of a subject, marshal arguments, and engage in debate and dialogue both with specialists and non-specialists. (HCPC SoP 14.18, 14.19, 14.24, 14.25, 14.26)*

f. *Demonstrate the ability to present outcomes of research or development work at a standard suitable for presentation. (HCPC SoP 14.28)*

g. *Discuss and critically evaluate the context within which research, development, innovation and audit are undertaken to improve patient care, promote innovation and improve service delivery. (HCPC 14.29)*

Evidence for this module is expected to come from the following sources:

- Critical evaluation of literature to identify research question
- Grant applications
- Supervised or collaborative research project (abstract only required)
- Examples of participation on research and development projects
- Peer reviewed papers, posters/presentations
- Evidenced based participation in local research meetings

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