IBMS Certificate of Attainment for Clinical Scientist Registration (Experiential Route)

CLINICAL BIOCHEMISTRY

CURRICULUM HANDBOOK

Version 4

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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 Clinical Biochemistry 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 Clinical Biochemistry***, or in a relevant science that includes medical/clinical biochemistry 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 biochemistry MScs, other M level qualifications will be considered provided that there is a clinical biochemistry component that forms the major specialism within the qualification, i.e. the educational component would be expected to include clinical biochemistry practice with a research project specific to clinical biochemistry. 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: clinical biochemistry specific MSc degrees, MSc in Biomedical Science that include clinical biochemistry as the major specialism, as a minimum an IBMS specialist portfolio in Clinical Biochemistry, the IBMS Higher Specialist Diploma in Clinical Biochemistry, STP in the Blood Sciences modality, a medical degree with an intercalated Medical / Clinical Biochemistry MSc.

1.4 Applicants admitted onto the programme will be expected to demonstrate **t**heir qualifications **and experience in Clinical Biochemistry** 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 clinical biochemistry 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 biochemists who provide clinical interpretation of biochemical or toxicological data and advise on the diagnosis of disease and monitoring of treatments. 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 clinical biochemistry 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-specialism. 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 clinical biochemistry. This should not be a barrier provided their current clinical biochemistry 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 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 clinical biochemistry. The candidate is expected to provide evidence that these have been met in their scope of practice in clinical biochemistry through academic and professional qualifications together with experiential learning from a broad range of activities as a qualified professional working in clinical biochemistry.

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 clinical biochemistry 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 appropriate staff, e.g. by 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 they 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 speciality 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 practice, 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 speciality 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 speciality;
- 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 speciality;
- 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 speciality;
- 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 Clinical Biochemistry 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: CLINICAL BIOCHEMISTRY

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 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 clinical biochemical disorders; and the integration and interpretation of biochemical parameters with other relevant diagnostic algorithms in the overall clinical assessment of the patient.

4.1.4 legislation: Human Tissue Act (2004) and the Human Tissue (Scotland) Act (2006), Storage and Retention of Specimens, Medicines and Health Regulatory Authority (MHRA).

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 multi-disciplinary 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

- physiology of water and electrolyte control with specific reference to:
  - role of anti-diuretic hormone;
  - the renin-angiotensin-aldosterone system;
  - associated regulatory mechanisms.
- homeostasis and physiological significance of buffer systems.
- normal acid-base balance including bicarbonate readsorption and hydrogen ion excretion, transport of carbon dioxide and oxygen.
- link between disturbances of hydrogen ion homeostasis and other disease states.
- acid-base disturbances (including anion gap). To include examples of:
  - non respiratory (metabolic) acidosis;

- respiratory acidosis;
- respiratory alkalosis.

- anatomy and physiology of normal kidney function and common pathologies that may arise including acute kidney injury (AKI) and chronic kidney disease (CKD).
- indicators of glomerular filtration rate (GFR), specifically plasma or serum creatinine, urea and cystatin C, and their analytical and clinical limitations.
- derivation of a calculated/estimated GFR, including creatinine clearance, CKD-epi equation, MDRD equation and other equations that may be applied locally, including those appropriate to children.
- additional analyses, measures and variables that are required in the calculation of GFR, for example urine creatinine, timed urine volume, subject age, gender, ethnicity, height and weight depending on the GFR calculation applied.
- role of the liver in: carbohydrate, fat, protein and hormone metabolism; storage; the metabolism and excretion of bilirubin; and detoxification of drugs and foreign compounds.
- common disease processes affecting the liver and their management including: cholestasis; hepatitis; cirrhosis; malignancy.
- causes of pancreatitis, and the importance of the laboratory in providing differential diagnosis and ongoing support for the patient.
- epidemiology of liver disease according to race, age and sex and the role of liver disease in pregnancy
- metabolism and breakdown of haemoglobin; the excretion and physiological importance of total and direct bilirubin.
- significance of abnormal bilirubin in plasma/serum/urine.
- synthesis of albumin in the liver and its use to indicate functional capacity of the organ.
- major causes of jaundice, including pre-hepatic, post hepatic and hepatic.
- inherited abnormalities of bilirubin metabolism, including Gilbert's syndrome.
- aetiology and pathophysiology of diabetes and know the difference between Type 1, Type 2 and secondary diabetes.
- pathways of gluconeogenesis, glycogen synthesis, glycogen breakdown and metabolic effects of insulin.
- role and transport of the major lipids in the blood to include: fatty acids; triglycerides; cholesterol; and phospholipids.
- classification of lipoproteins, their composition, metabolism and principle function.
- epidemiology of cardiovascular disease according to all associated risk factors.
- influence of sex, age, exercise, obesity, alcohol and extraneous oestrogens on lipoproteins.
- causes of primary and secondary hyperlipidaemia, and treatment (NICE guidelines)
- structural and physiological role of the troponins.

- mechanisms of calcium, magnesium and phosphate homeostasis and their inter-relationship
- role of these minerals in bone formation and resorption in bone disorders and the consequences of treatment.
- role of calcium, phosphate and magnesium in various disease states.
- relationships and roles of PTH, PTHrp, Vitamin D and calcitonin in calcium regulation, and when and how these hormones may be measured.
- role of the kidneys in regulation of calcium levels in blood.
- relationship and physiological significance of ionised and total calcium and the calculations used to correct calcium results.
- types of tumour and the disorders in biochemistry they can cause.
- staging of tumour growth and the implications for the patient biochemically.
- biochemical consequences of tumour growth such as ectopic hormone production.
  roles of faecal occult blood, PSA, CEA, CA125, CA153, CA19-9, AFP, HCG, HIAA, catecholamines and metadrenalines
- chemical and physical properties of protein molecules.
- relationship between serum, plasma, urine, CSF and other fluid type proteins.
- immunoglobulin synthesis and function of the five classes of Immunoglobulin (IgG, IgA, IgM, IgD, IgE) and the difference between “heavy” and “light” chains.
- Hyperviscosity Syndrome.
- Function of: Beta2 microglobulin; CRP; Alpha-1-Antitrypsin; Ceruloplasmin; IgE; Complement; Cryoglobulins; Carbohydrate Deficient Transferrin.
- biochemistry of purine synthesis and degradation.
- biological requirement (including recommended daily amounts) for the different vitamins and vitamers in the human body.
- clinical effect of vitamin deficiency or excess.
- biological requirement for B12 and folate in the human body and the effect of deficiency.
- effects of B12 and folate on haematological parameters.
- biological requirement for the different trace elements in the human body.
- clinical and biochemical features of lead poisoning.
- biological requirement for copper, magnesium and zinc in the human body and the effect of deficiency and excess.
- functions of the major regions of the gastrointestinal tract and associated organs, the principal digestive secretions and their role in respect to nutritional status:
- processes involved in the digestion and absorption of the following nutrient classes:
  Proteins; Carbohydrates; Fats; Nucleic acids; Water and minerals; Trace elements; Vitamins.
- main causes of malabsorption including: gastric surgery with bypass or gastric banding; thyrotoxicosis; pancreatic insufficiency; bile salt insufficiency; mucosal disorders.

- clinical features associated with malabsorption and possible causes of: Diarrhoea, steatorrhoea, borborygmi; weight loss & growth failure; abdominal distension; anaemia; metabolic bone disease; easy bruising.
- physical investigations used to assess nutrition status including Body Mass Index (BMI), skinfold thickness and MUST (Malnutrition Universal Screening Tool).
- metabolism of toxic substances at therapeutic and overdose levels e.g. salicylate and paracetamol.
- national and international guidelines on the timing of collection, type of sample and timing of analysis for use in investigation of the poisoned patient.
- analyses used to monitor chronic substance abuse.
- occupational and environmental toxicology.
- National Poisons Information Service (NPIS) and TOXBASE.
- diagnosis, treatment and support of the poisoned patient, including the estimation of paracetamol, salicylate, ethanol, ethylene glycol and carbon monoxide and other laboratory investigations.
- diagnosis, treatment and support of patients poisoned by heavy metals.
- National Poisons Information Service (NPIS) and TOXBASE.
- diagnosis, treatment and support of the poisoned patient including the estimation and confirmation of the presence of common drugs of abuse (amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine and metabolites, LSD and opiates) and those used in the treatment of chronic abusers including: Buprenorphine and metabolites; Methadone and metabolites.
- legislation relating to the use and abuse of drugs.
- routine toxicology analysis and those only available in specialist centres.
- metabolism of ethanol, acute and chronic abuse of ethanol and other alcohols including methanol and ethylene glycol.
- significance of ethanol, methanol and ethylene glycol levels in acute poisoning, chronic alcohol abuse and legal/forensic cases.
- major categories of inherited metabolic diseases: carbohydrate metabolism (glycogen storage disease); amino acid metabolism (phenylketonuria, maple syrup urine disease, glutaric acidemia type 1); organic acid metabolism (organic acidurias - alcaptonuria);
- fatty acid oxidation and mitochondrial metabolism (medium chain acyl dehydrogenase deficiency, glutaric acidemia type 2);
- porphyrin metabolism (acute intermittent porphyria);
- purine or pyrimidine metabolism (Lesch-Nyhan syndrome);
- steroid metabolism (congenital adrenal hyperplasia);
- mitochondrial function (Kearns-Sayre syndrome);
- peroxisomal function (Zellweger syndrome);
- lysosomal storage disorders (Gaucher's disease).
- metabolic disorders and screening programmes (and their limitations), specialised tests and ongoing monitoring.
- genetic basis of inherited disease.

- metabolic significance and classification of: organic acids; carbohydrate intolerance.
- inborn errors of metabolism presenting with organic aciduria.
- screening tests for organic acidurias and carbohydrates.
- inborn errors of amino acid metabolism.
- underlying metabolic disorder causing cystic fibrosis.
- porphyrin biosynthetic pathway and classification of the porphyrias.
- screening programmes for inherited and congenital disorders.
- Predictive Value, Sensitivity, Specificity, Selectivity, Prevalence, False Negative, False Positive
- Newborn Screening Services: UK Newborn Screening Programme Centre and Blood Spot Forms; Tests offered; Factors that may affect suitability of samples including Blood Transfusion and Prematurity; Patients' rights and ethical issues.
- genetic basis of Down's syndrome.
- screening programmes for inherited and congenital disorders.
- non-laboratory techniques used in the pre-natal screening for Down's syndrome.
- molecular genetics and other analyses should be used.
- mechanism of hormone control and action on target organ to include: Thyroid Stimulating Hormone (TSH); Thyroxine (T4), Free T4 (fT4); Tri-iodothyronine (T3) and/or Free T3 (fT3); anti-Thyroid peroxidase antibodies (TPO).
- synthesis, control and function of hormones in the hypothalamic pituitary-thyroid axis.
- biochemistry and physiology of the thyroid gland.
- measurement of T3, T4 and thyroid stimulating hormone (TSH).
- clinical significance of free hormones compared to total hormone levels, treatment and prognosis.
- synthesis, control and function of the following hormones in health and disease: Growth Hormone; Prolactin; Adrencorticotrophic Hormone (ACTH); TSH, LH and FSH.
- biochemistry and physiology of the hypothalamic pituitary axis.
- mechanism of hormone control and action on target organ of: follicle stimulating hormone (FSH); leutinising hormone (LH); prolactin (PRL); oestradiol (E2); progesterone (PRG); testosterone (TES) and sex hormone binding globulin (SHBG); human chorionic gonadotrophin (HCG) and anti-mullerarin hormone (AMH).
- synthesis, control and function of hypothalamic/pituitary hormones.
- biochemistry and physiology of the female menstrual cycle
- biochemistry and physiology of pregnancy.

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 stand-alone 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;
  - electrochemistry.
  - colourimetry;
  - flame photometry (atomic emission spectrometry);
  - high performance liquid chromatography;
  - gas chromatography;
  - mass spectrometry.
- maintenance and calibration
- range of samples that may be analysed on general chemistry and immunoassay analysers.
- structure of the instrument software/ user interface.
- function and design of the basic instrument and chemistry 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 Specific Protein Markers

- principles, limitations and use of the following techniques:-
  - Gel Electrophoresis;
  - Capillary Electrophoresis;
  - Immunofixation/ Immunotyping;
  - Turbidimetry;
  - Nephelometry;
  - Cold Agglutinins.
- abnormalities on serum protein electrophoresis and major groupings.
- diagnostic patterns most likely to be seen in the following conditions:
  - Acute phase reaction;
  - Chronic Infection;
  - Myeloma / MGUS.
- identification of and monitoring of monoclonal bands.

- investigation of suspected myeloma, diagnostic criteria and prognostic factors.
- Hyperviscosity Syndrome.
- Function and measurement of:
  - Beta2 microglobulin;
  - CRP;
  - Alpha-1-Antitrypsin;
  - Ceruloplasmin;
  - IgE;
  - Complement;
  - Cryoglobulins
  - Carbohydrate Deficient Transferrin.
- measurement of urinary total protein, relationship between serum and urine protein, and diagnostic value in monitoring of renal disease (protein/creatinine ratio);
- identification and typing a monoclonal component in urine;
- measurement and diagnostic value of CSF in multiple sclerosis.
- difference between a fluid that is a Transudate as opposed to an Exudate.

4.3.3 Point of Care Testing (POCT)

- common POCT systems and the role of the laboratory in providing support for them. To include: blood gases and electrolytes, glucose, pregnancy testing, lactic acid, drugs of abuse screening, urine screening, HbA1c, cardiac markers.
- guidelines and policies associated with point of care testing including CPA/ISO standards 22870/15189/RCPath.
- role of POCT in patient focused care (including advantages and disadvantages) and impact on healthcare services delivery.
- pre and post analytical patient preparation, sample collection and analysis.
- principles and limitations of the analytical methods utilized in point of care testing equipment including:
  - Amperometry;
  - Absorbance;
  - Spectroscopic analysis;
  - Reflectance;
  - Fluorescence;
  - Conductimetry;
  - Potentiometry;
  - Multi-wave spectroscopy;
  - Dry-reagent biosensors;
  - Microchip technology;
  - Immunoassay;
  - Non-invasive assays.
- training of clinical staff and competency testing.
- data handling, security and storage.

4.3.4 Therapeutic Drug Monitoring

- purpose of therapeutic drug monitoring (TDM) in terms of clinical diagnosis, treatment and prognosis for different agents including: Lithium, digoxin, phenytoin, carbamazepine (CBZ) and valproate; Gentamicin (or other aminoglycoside antibiotic); Theophylline;
- principles and limitations of pharmacokinetics and pharmacogenomics.
- sampling time, half-life, dosing interval, trough level, minimum effective dose, maximum therapeutic dose.
- sample requirements and monitoring of (for example):
  - Anti-epileptics – lamotrigine;
  - Anti-psychotics – clozapine;
  - Anti-tumour – methotrexate;
  - Cardiac drugs – amiodarone;
  - Anti-retroviral drugs – constituents of HAART;
  - Immunosuppressives – cyclosporin, azathioprine (TMPT phenotyping or genotyping).

4.3.5 Chemical Toxicology

General Toxicology

- measurement and interpretation of other analyses to reflect alcohol use over differing time periods.
- toxic effect posed by carbon monoxide.
- use and availability of hyperbaric treatment.
- use of Point of Care Testing (POCT) as well as laboratory testing.

Drugs of Abuse

- regulations relating to the storage and security of drugs.
- screening and confirmation analysis.
- principles and limitations of pharmacokinetics.
- post mortem samples and drug redistribution.
- sample types used in the detection and estimation of abused drugs, including:
  - Urine;
  - Blood/serum/plasma;
  - Hair;
  - Gastric contents;
  - Saliva/ oral fluid;
  - Tissue samples.
- 'Chain of custody' sample handling and reporting of results.

4.4 Investigation of Specific Disorders

This requires:

• a critical understanding of the application of investigative protocols and diagnostic tests in the assessment of the biochemical status of the patient and biochemical disorders of metabolism;

• a critical understanding of the integration and interpretation of clinical biochemistry parameters with other diagnostic parameters (haematological, imaging, etc.) in the overall clinical assessment of the patient disease processes in clinical medicine;

• and understanding of the effects of pre- and post-analytical variables required for the appropriate interpretation and assessment of diagnostic procedures in clinical biochemistry ;

4.4.1 Fluid and Electrolyte Disorders

- analytical parameters undertaken in the assessment of water and electrolyte metabolism, including sodium and potassium in plasma/serum and urine.
- principles and practice of methods commonly utilised for analysis of sodium and potassium in biological fluids, including the difference between direct and indirect ion selective electrodes and their application with a range of devices (i.e. POCT systems and larger laboratory based systems).
- relationship between osmolality, osmolarity and plasma constituents and calculation of plasma osmolarity.
- principles and practice of the methods available to measure osmolality.
- significance of the water deprivation test.
- causes of electrolyte disturbances and how persistent abnormalities may be investigated further with additional biochemical testing.
- artefactual effects, particularly sample collection.

4.4.2 Acid-Base Disorders

- principles and limitations of pH, pO2, pCO2 and lactate electrodes.
- principles and limitations of the analytical methods employed for bicarbonate.
- sample requirements for blood gas analysis.
- secondary functions of the blood gas analyser (e.g. Hb, measurement of Hb derivatives, other ISE electrodes).
- factors affecting sample integrity and appropriate corrective action.

4.4.3 Kidney Disease

- reference GFR procedures that use exogenous markers, e.g. Chromium EDTA or iohexol clearance.
- methods available to measure urinary protein (including urine test strip methods) and their relative merits.

- monitoring kidney disease with urinary albumen and its specific application for the assessment of diabetic nephropathy.
- analyses in urine that may be used to assess renal tubular function including urine phosphate, glucose, pH and specific proteins.
- effects of renal disease on a range of biochemical analyses other than those specifically listed above, for example plasma potassium, PTH, vitamin D and haematinic investigations.
- categorisation of chronic kidney disease stages based on clinical findings and GFR values.
- calculation and clinical utility of the Acute Kidney Algorithm
- laboratory's role in implementing clinical practice guidelines for the management of AKI and CKD (e.g. NICE, KDIGO)

4.4.4 Liver Function and Associated Disease States

- link between measurement of total protein, albumin and secondary globulin estimation.
- link between bile acid measurement and cholestasis in pregnancy.
- metabolic function of the enzymes listed and the principles and limitations of diagnostic enzymology.
- role and significance of alkaline phosphatase isoenzymes.
- investigations to measure the following core analytes:
  - Total bilirubin;
  - Conjugated (Direct) bilirubin;
  - Total Protein and albumin;
  - Bile Acids;
  - AST, ALT, GGT, ALP, amylase;
- investigations to measure the following associated analytes:
  - Autoantibodies;
  - ALP Isoenzymes;
  - Urine bilirubin and urine urobilinogen;
  - γ-gamma globulins;
  - α-fetoprotein;
  - α1-antitrypsin;
  - Copper and ceruloplasmin.

4.4.5 Diabetes Mellitus and Hypoglycaemia

- WHO diagnostic criteria for diabetes and Impaired Glucose Regulation as endorsed by Diabetes UK.
- investigation of individuals with suspected diabetes and the sample requirements for glucose, HbA1c, insulin, C-Peptide and lipid analyses.
- difference between diabetes, impaired fasting glucose and impaired glucose tolerance.
- self-induced/ maliciously induced hypoglycaemia and its investigation.

- oral glucose tolerance test and interpretation with respect to the WHO criteria.
- methodologies available for the estimation of glucose and the limitations of using glucose levels in the monitoring of diabetes.
- differences found by using different sample types (whole blood, plasma/serum, capillary).
- implications of the NICE guidelines on the monitoring of diabetes and the need for monitoring lipids in diabetes.
- different methodologies for measuring glycated haemoglobin (HbA1c) and the effect of Hb variants on these assays.
- role of measuring glycated protein (fructosamine).
- role of urinary microalbumin and methods available for measurement.
- mechanisms for monitoring and management glucose levels including:
  - diet;
  - different classes of drugs;
  - self-monitoring of blood glucose;
  - effect of slow release drug preparations and fast/slow acting insulin.
- situations that will require closer monitoring than is usual, e.g. pregnancy
- common causes and investigation of fasting hypoglycaemia and reactive hypoglycaemia.
- role of insulin and C-Peptide assays in the investigation of hypoglycaemia.
- metabolic deficiencies that cause hypoglycaemia in neonates/infants and the laboratory investigations used to identify them.
- methods available for urinary sugar analysis and the role of urinary sugar chromatography in neonates.
- reference ranges for all parameters measured by your laboratory when investigating diabetes mellitus and hypoglycaemia and what levels are designated as good control, adequate control and poor control.
- laboratory in the selection, user training and performance monitoring of POCT glucometers within their Trust.
- local protocol for the communication of abnormal glucose results to wards & GPs.
- role of other healthcare services in the management of diabetes (e.g. podiatry, retinal screening, dieticians).
- protocols and laboratory support given in the treatment of diabetic coma.
- synthesis, control and function of aldosterone, cortisol, adrencorticotrophic hormone (ACTH) and catecholamines in health and disease with particular reference to Cushing's Syndrome, Conn's Syndrome and Addison's Disease.
- biochemistry and physiology of the adrenal cortex and medulla.
- biochemistry of Conns and Addison's diseases and their effects on the electrolyte balance.
- role of neurotransmitters in the autonomic nervous system and causes of abnormal secretion.

4.4.6 Lipids, Lipoproteins and Cardiovascular Disease: Core analytes: Cholesterol, Triglyceride, HDL-Cholesterol, Creatine Kinase, Troponin, BNP or NTproBNP. Associated analytes: CK-MB, Myoglobin, hs-CRP

Major Lipids in Atherosclerosis and Cardiovascular Disease

- rationale of treatment of hyperlipidaemia in relationship to cardiovascular disease with reference to the relevant NICE guidelines.
- definition, diagnosis and treatment of patients presenting with Acute Coronary Syndrome (ACS).
- definition, diagnosis, treatment and prognosis of patients presenting with Chronic Heart Failure (CHF).

Diagnosis of Cardiovascular Disease Risk Factors

- laboratory role in the diagnosis, treatment and prognosis of a patient presenting with chest pain, against current national guidelines.
- national and international guidelines in determining risk in association with reference intervals.
- triglyceride measurements in Chronic Heart Disease (CHD) and its association with other disease states particularly pancreatitis.
- principles and limitations of the analytical methods employed and sample requirements for:
  - Cholesterol;
  - Triglyceride;
  - HDL-cholesterol.
- calculation of LDL-cholesterol and its limitations.
- other proposed markers of CHD.

Diagnosis of Acute Coronary Syndrome

- rationale of using multiple analytes in the diagnosis of Acute Coronary Syndrome (ACS).
- use of serial Troponin measurements and different algorithms for rapid assessment of ACS
- impact of laboratory results on treatment of patients presenting with ACS.
- principles and limitations (including clinical sensitivity and specificity) of analytical methods employed for Troponins.
- algorithm for diagnostic use and interpretation of:
  - Troponins;
  - High Sensitive Troponin.
- other markers of ACS and use of POCT.
- use of High Sensitive Troponin in diagnosis of acute coronary injury.

Diagnosis of Chronic Heart Failure

- causes which may result in heart failure as a medical emergency or asymptomatic presentation.
- laboratory role in the diagnosis, treatment and prognosis of a patient presenting with heart failure.
- structural and physiological role and normal reference ranges of BNP or NTproBNP.
- clinical pathway for interpretation of BNP or NTproBNP.
- role that POCT may play in diagnosis of CHF

4.4.7 Disorders of Calcium, Phosphate and Magnesium Homeostasis

- laboratory role in the diagnosis, treatment and prognosis of a patient presenting with:
  - Hypercalcaemia and Hypocalcaemia.
  - Hypermagnesaemia and Hypomagnesaemia.
  - Hypophosphataemia and Hyperphosphataemia.
- biochemical testing for and implications of bone disease, including markers of bone turnover.

4.4.8 Cancer Biochemistry and Tumour Markers (including PSA, AFP, CEA, HCG, FOB and HIAA).

- criteria for the ideal tumour marker use of tumour markers in screening, diagnosis and monitoring malignant disease.
- biochemical consequences of tumour growth such as ectopic hormone production.
- assays for faecal occult blood, PSA, CEA, CA125, CA153, CA19-9, AFP, HCG, HIAA, catecholamines and metadrenalines.
- sample requirements for tumour marker measurement and possible interferences or cross reactions.

4.4.9 Hyperuricaemia and Gout

- analysis of uric acid and diagnostic value in conditions such as gout, renal disease, pregnancy and malignancy.
- relationship between uric acid and other purines in the context of inborn errors of metabolism, for example xanthinuria.

4.4.10 Investigation of Micronutrients

Vitamins

- principles, techniques and limitations of different sample types used in the measurement of vitamins such as:
  - Spectrophotometry;
  - Immunoassay;

- High performance liquid chromatography;
- Gas chromatography.

Trace Elements

- national guidelines for the monitoring of aluminium in patients on renal dialysis.
- monitoring of industrial workers using lead and other heavy metals.
- relationship between magnesium and calcium homeostasis.
- inherited defects affecting the transport and metabolism of copper.
- ceruloplasmin estimation.
- iron measurements and the treatment techniques for patients admitted with an iron overdose.
- principles, techniques and limitations used in the measurement of trace elements including:
  - Spectrophotometry;
  - Flame photometry (atomic emission spectrometry);
  - Atomic absorption spectrophotometry;
  - Mass spectrometry (inductively coupled plasma);
- comparative benefits of using ICP-MS and atomic absorption spectrophotometry for the estimation of trace metals.
- flame photometry and atomic absorption spectrophotometry, and the use of a furnace for estimation of heavy metals.

4.4.11 Gastrointestinal Disorders and Malabsorption

- principles and practice of the analytical investigations used to assess and monitor nutritional status, including:
  - Urea, Albumin Calcium, Phosphate, Alkaline phosphatase, Magnesium, C-reactive protein;
  - Thyroid function tests, Copper, Zinc, Selenium, Iron & Ferritin, Glucose, VitD, Folate;
  - Vit B12.
  - Faecal Elastase
  - Faecal Calprotectin

4. 4.12 Gastrointestinal Inherited Metabolic Disorders and Newborn Screening: Prenatal Screening for Predicting Down's Syndrome

- sweat collection methods and estimation of sodium chloride, osmolality, and electrical conductivity of sweat samples.
- AFP, HCG, inhibin A and Oestriol methods used in the prenatal screening for neural tube defects and Down's syndrome.
- calculation of Down's syndrome risk using the Triple/Quadruple test.
- investigations by specialist units (including IRT and molecular techniques).
- Prenatal Diagnosis including Chorionic Villus Sampling and ethical and medical risks associated

4.4.13 Thyroid Disease

- dynamic function tests requiring estimation of thyroid hormones.
- principles and limitations of total and free hormone assays in general.
- effect of auto-antibodies in the pathogenesis of thyroid disease and evaluation of their use as biomarkers in differential diagnoses.

4.4.14 Abnormal Pituitary Function

- principles and limitations of peptide hormone assays.
- dynamic function tests requiring estimation of pituitary hormones.

4.4.15 Reproductive Endocrinology

- role of dynamic function testing and the assays involved.
- principles and limitations of hormone assays.

4.4.16 Adrenal Disease

- principles and limitations of peptide and steroid hormone assays in general.
- dynamic function tests requiring estimation of adrenal hormones.

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 speciality. 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:

i) Patients or carers in clinics and/or wards where there is direct contact with biomedical and clinical scientists;
ii) Professional groups that have direct patient healthcare role which relies on pathology services including clinical laboratory investigation, advice, treatment evaluation and research;
iii) 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.
- Role of service users with respect to their rights, dignity, values, and autonomy including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing.
- 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:

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

ii) Show a understanding of the importance of financial accountability, budgetary control and resource management.(HCPC SoP 1.2)

iii) 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)

iv) 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)

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

vi) *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)*

vii) *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)*

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

ix) *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.*

x) *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)*

xi) 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)

xii) 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)

xiii) 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)

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

xv) 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)

xvi) 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 speciality 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 speciality. 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:

i) 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)

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

iii) 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 speciality. 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 speciality.
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:

i) 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).

ii) 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)

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

iv) 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)

v) 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)

vi) 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)

vii) 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 speciality.
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 speciality. 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:

i) 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)

ii) 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)

iii) 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)

iv) 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)

v) 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:

i) Patients or carers in clinics and/or wards where there is direct contact with biomedical and clinical scientists;
ii) Professional groups that have direct patient healthcare role which relies on pathology services including clinical laboratory investigation, advice, treatment evaluation and research;
iii) 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

i) 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:

a) 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

b) patients in clinics and wards (e.g. POCT, phlebotomy) where there is direct contact;
c) 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.

ii) 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)

iii) 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 speciality. 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 speciality 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 speciality.

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 speciality.
Patient history and examination and development of clinical investigation and management plans.

Learning outcomes

To be able to:

i) 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)

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

iii) *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).*

iv) *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 speciality through the integration of speciality 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*

v) *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)

vi) *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)*

vii) *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)*

viii) *Demonstrate an experience based understanding of the clinical relevance of the results of speciality 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 speciality. 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 speciality.

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:

i) 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 speciality. (HCPC SoP 15, 15.2, 15.3)

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

iii) 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:

i) Patients or carers in clinics and/or wards where there is direct contact with biomedical and clinical scientists;
ii) Professional groups that have direct patient healthcare role which relies on pathology services including clinical laboratory investigation, advice, treatment evaluation and research;
iii) 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 speciality.

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:

i) 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)

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

iii) 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)

iv) 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)

v) 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)

vi) 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)

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 speciality 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 speciality 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:

i) *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)*

ii) *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)*

iii) *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)*

iv) *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)*

v) *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 speciality. 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

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

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

iii) 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)

iv) 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)

v) 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)

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

vii) 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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