Appendices to Chemical Pathology Transitional Curriculum

Appendix 1:

The scope of chemical pathology is broad, covering the biochemical processes that underlie the whole of human physiology and medicine. Any attempt to list all relevant methods, presentations, conditions and issues would be extensive, but it would inevitably be incomplete and rapidly become out of date.

The table below details the key areas of Chemical Pathology. Each of these areas should be regarded as a context in which trainees should be able to demonstrate Capabilities in Practice (CiPs) and Generic Professional Capabilities (GPCs). Trainees will need to become familiar with the relevant knowledge, skills and values/attitudes related to these areas.

Knowledge	Skills	Values and behaviours
Laboratory		**CiPs: 1, 2, 3, 4, 5, 6, 7, 9**
The curriculum explains the fundamentals of effective laboratory operation. It: • Explains how to arrange sample collection, transport and storage • Describes laboratory automation • Describes internal quality control (IQC) and external quality assurance (EQA) • Describes laboratory computerisation and information technology • Demonstrates the appropriate methods and circumstances for sharing confidential information • Describe and explain health and safety	Trainees will be able to: • Describe and explain effectively sample requirements and collection • Demonstrate fundamental laboratory techniques; e.g. centrifugation, pipetting • Demonstrate interpreting IQC and EQA data • Demonstrate use of computing within the laboratory: databases, spreadsheets and internet, and associated information governance	Trainees will: • Demonstrate a proactive approach to new technology • Demonstrate effective communication with staff both within and outside the laboratory • Demonstrate a critical attitude in assessing and using IQC and EQA data • Demonstrate correct methods of and circumstances for sharing of confidential information • Demonstrate concern for the health and safety of laboratory staff and users
<u>Laboratory methods:</u>		
• Describes common laboratory techniques: e.g. ion-selective electrodes, osmometry, spectroscopy, enzymic assays, immunoassay, chromatography, electrophoresis • Describes specialist laboratory techniques, including: chromatography (thin-layer,	• Demonstrate performance and interpretation of common laboratory techniques • Demonstrate performance and interpretation of some specialist laboratory techniques; e.g. chromatography, mass spectroscopy • Demonstrate ability to recognise and investigate	• Demonstrate a critical approach to the ongoing performance of laboratory methods • Demonstrate understanding of the role of point-of-care testing in patient care and the management and control of associated risks

gas, ion exchange, HPLC), iso-electric focussing, mass spectroscopy and spectrometry, molecular biology (blotting techniques, PCR, sequencing) • Describes the optimisation and evaluation of laboratory methods • Describes mechanisms of common interferences (e.g. haemolysis, jaundice, substrate depletion, heterophilic antibodies, 'hook effect') in assays • Describes the development of reference ranges, and the factors (e.g. age, gender, menstrual cycle) on these • Describes the principles and use of point-of-care methods	problems with assays • Discuss the effect of genetic and environmental influences such as age, sex, nutrition, time of day, stress, posture, hospitalisation and therapeutic agents on biochemical results • Discuss the advantages and disadvantages of point-of-care measurements • Advise on choice, management and safe use of point-of-care equipment	
Method development and validation		
The curriculum: • Discusses how a measurement method is developed, validated and introduced into service use with appropriate reference intervals • Discusses the development of metrological traceability, international reference preparations, calibrants, controls with assigned values, and external quality assurance specimens with unknown values	Trainees will be able to: • Demonstrate an understanding of the principles of method development and validation	Trainees will:
<u>Biological, pre-analytical, and analytical variability:</u>		
• Describes how variability due to biological effects, and pre-analytical and analytical factors, arises • Discusses how this variability affects the results of measurements in the laboratory and what can be done to reduce or allow for it • Discusses uncertainty of measurement	• Interpret variation in results within individuals to determine whether a significant change has occurred	• Demonstrate understanding of the importance of effective liaison with lab users regarding the impact of variability on testing

• Describes how to determine the minimum clinically significant change and how this affects the accuracy and precision required for measurement in the laboratory		
<u>Laboratory management:</u>		
• Describes the organisation of laboratory services • Describes the principles of personnel management • Describes the structure and function of a laboratory • Describes the resourcing and finances of laboratory services • Describes the structure and organisation of a hospital, trust and/or health Board, and a laboratory service's place within this • Describes the principles of assessment and management of risk • Describes the principles of laboratory accreditation The duty biochemist: • Describes the processes of technical and clinical validation	• Demonstrate effective staff management skills • Demonstrate the ability to understand and manage a budget • Demonstrate the ability to develop a business plan • Demonstrate effective interaction with colleagues in other specialties • Demonstrate the ability to develop local guidelines and apply advice from specialist and national bodies (NICE, SIGN) • Demonstrate ability to undertake root cause analysis • Demonstrate understanding of the role of accreditation in ensuring quality of laboratory service and results • Recognise abnormal results due to pre-analytical factors or analytical interference • Recognise abnormal results likely to be due to disease and forms an appropriate differential diagnosis • Interpret biochemical results in the context of other clinical and investigational findings • Demonstrate the ability to use biochemical data to advise on appropriate management	• Demonstrate concern for effective use of resources • Demonstrate effective education and provision of information to laboratory staff and to clinicians • Demonstrate concern to continually improve laboratory service • Demonstrate ability to evaluate issues and possible solutions • Demonstrate concern for patient safety • Demonstrate honesty and candour in managing clinical incidents • Show effective interface between clinicians and the laboratory, as part of a team
Genetics and genomics		**CiPs: 1, 2, 3, 5, 7, 8, 10**

The curriculum:	Trainees will be able to:	Trainees will:
• Describes genome organisation; e.g. chromosome structure, structure of nucleic acids, and the processes of meiosis and mitosis • Describes Mendelian and Non-Mendelian inheritance (e.g. imprinting disorders, mitochondrial inheritance, epigenetic inheritance) • Discusses the impact of genetic variation on complex disease • Summarises protein synthesis, transcription and translation, defects in protein synthesis arising from genetic mutations, and molecular pathology of single gene disorders. Recognises epigenetic defects • Describes methods for targeted and whole-genome sequencing; e.g. PCR, Sanger, DNA arrays whole-genome and whole-exome sequencing • Describes and explains limitations in sequencing platforms • Describes the process of variant classification. Provides awareness of functional in vivo (e.g. biochemical tests on patient samples) and in vitro (e.g. reporter gene assays to assess effect of DNA regulatory variants) techniques used to test variant pathogenicity • Describes the importance of bioinformatics in producing sequence data, the process of variant interpretation, archiving sequence information, and creating information-retrieval tools • Describes the clinical application of genome sequence data to areas such as metabolic disease without known single gene cause, rare disease and cancer • Recognises NHS ethical	• Demonstrate the ability to apply Mendelian genetics and Bayes theorem to calculate pre- and post-test probabilities in genetic counselling • Recognise the principles of genetic/genomic analysis • Demonstrate the ability to use variant classification guidelines and consider the issues surrounding variant reclassification • Demonstrate ability to answer laboratory users queries about classification including the relevance of the term 'variant of unknown significance' • Demonstrate understanding of how sequence variant data is interpreted including quality control steps • Recognise the use and limitations of different specimen types used in genetic testing	• Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information • Recognise issues surrounding consent for genetic testing including the need to explain the possibility of unexpected findings when requesting gene panels, whole-exome or whole-genome sequencing • Demonstrate critical evaluation of current genomic technologies and application to different clinical contexts • Recognise and be able to communicate the limits of certainty surrounding variant classification • Demonstrate respect for patient's requests for information not to be shared, unless this puts the patient, or others, at risk of harm • Demonstrate willingness to seek advice from peers, legal bodies and the General Medical Council (GMC)in the event of ethical dilemmas over disclosure and confidentiality

governance frameworks relating to genomics. Considers optimum storage for data within NHS • Describes the use of cell-free DNA including non-invasive prenatal testing (NIPT); e.g. foetal DNA in maternal blood for Down's syndrome screening and non-invasive prenatal diagnosis (NIPD), which will be increasingly used to test the foetus for known mutations • Recognises the role of genetic data in treatments including gene therapy, pre-implantation genetic testing and pharmacogenomics		
Proteins and proteomics		**CiPs: 3, 5, 7, 8, 10**
The curriculum: • Describes the principles of measurement • Outlines properties and functions of the principal plasma proteins including: albumin, protease inhibitors, transport proteins, caeruloplasmin, clotting factors, complement, immunoglobulins and hormone binding proteins • Discusses the causes, investigation and management of hypoalbuminaemia, paraproteinaemias, cryoglobulinaemia • Discusses inflammatory proteins, the acute phase response, immunoglobulin deficiencies, alpha-1-antitrypsin deficiency, cytokines • Describes the pathophysiology of the acute phase response and explains how this can be assessed in the laboratory • Explains the effect of inflammation on concentrations of plasma proteins	Trainees will be able to: • Demonstrate the ability to assess and appropriately interpret immunofixation and immunosubtraction • Demonstrate the ability to distinguish acute-phase changes from abnormalities due to underlying disease • Interpret laboratory tests in the context of inflammation explaining the correlation with clinical findings • Demonstrate the ability to interpret common laboratory tests for proteinuria • Demonstrate the ability to critically evaluate new biomarkers	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information • Demonstrate a proactive approach to new technology

• Describes the composition of urine proteins in health and disease • Describes the use of CSF protein analysis; e.g. dementia screening • Describes plasmapheresis • Describes and lists potential uses of newer proteomic techniques; e.g. MALDI-TOF MS and LC-ESI-MS/MS		•
Enzymes and metabolomics		**CiPs: 3, 8 ,10**
The curriculum: • Describes the mechanism and kinetics of enzyme action • Discusses stability and induction of enzymes • Describes the tissue specificity/selectivity of common enzymes • Describes the role of cofactors and vitamins in enzyme action • Describes the structural basis, separation, quantitation of isoenzymes • Compares major enzyme assays including: o amylase and lipase o alkaline phosphatase o aminotransferases o angiotensin converting enzyme o creatine kinase o lactate dehydrogenase o gamma-glutamyl transferase o cholinesterase and variants • Recognises techniques used in metabolomics and their clinical application	Trainees will be able to: • Demonstrate the ability to evaluate critically new biomarkers	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate proactive approach to new technology
Endocrinology		**CiPs: 3, 8, 10**
The curriculum: • Describes endocrine physiology, including feedback loops, and the production, control and effects of hormones of the major endocrine glands, including the hypothalamus, pituitary, thyroid,	Trainees will be able to: • Interpret endocrine biochemical investigations, including dynamic function tests • Demonstrate selection of tests for investigation of endocrine disease and appropriate	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues

adrenals (medulla and cortex), and gonads • Describes disorders involving over- and under-activity of endocrine systems • Describes the renin-aldosterone system and endocrine causes of hypertension • Describes inherited endocrine syndromes, including multiple endocrine neoplasia and polyglandular syndrome • Describes biochemical investigations of endocrine systems, including dynamic function tests • Describes non-biochemical investigation, e.g. imaging, in endocrine disease • Explains screening for endocrine disease	interpretation of results	• Demonstrate effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of endocrine disorders
Diabetes mellitus		**See Appendix 2**
Nutrition		**See Appendix 2**
Inborn errors of metabolism		**See Appendix 2**
Haemoglobin and disorders of red cell enzymes		**CiPs: 2, 4, 8, 10**
The curriculum: • Describe haemoglobin metabolism • Discuss anaemia and its investigation, assessment of iron, vitamin B12 and folate status, and detection of abnormal haemoglobins in inherited and acquired disease • Describe red cell enzyme defects	Trainees will be able to: • Describe and explain the pathophysiology of the anaemia based on laboratory results	
Assessment and management of cardiovascular risk		**See Appendix 2**
Cardiac disease		**CiPs: 3, 4, 8, 10**
The curriculum: • Explains the basis for diagnosing acute myocardial damage • Describes the assessment of cardiac dysfunction including natriuretic peptides • Describes and explains the role of biochemical and metabolic	Trainees will be able to: Demonstrate setting cut-offs for acute myocardial limits	Trainees will: • Demonstrate ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of

laboratory investigations in assessing aetiology of cardiac disease		information
Disorders of calcium metabolism		**See Appendix 2**
Water and electrolytes		**CiPs: 3, 4, 8, 10**

The curriculum:
• Discusses distribution of water and electrolytes
• Describes turnover of body fluids
• Outlines regulation of extracellular fluid, osmolality and volume via:
  ○ antidiuretic hormone
  ○ renin-angiotensin-aldosterone
  ○ natriuretic peptides
• Describes the causes, effects and management of:
  ○ water depletion and excess
  ○ hypo- and hypernatraemia
  ○ hypo and hyperkalaemia
  ○ hypophosphataemia
  ○ hypo- and hypermagnesaemia
  ○ metabolic effects of trauma/surgery/stress
• Discusses the principles of intravenous fluid therapy
	Trainees will be able to:
	• Describe and explain management of fluid balance
	• Describe and explain investigation and management of acute and chronic electrolyte disturbances
		Trainees will:
		• Demonstrate ability to relate theoretical knowledge and laboratory results to patient management with appropriate communication with clinical colleagues
		• Demonstrate effective patient education and provision of information
		• Describe and explain the role of laboratory and non-laboratory investigations in electrolyte disorders

Blood gases and acid-base balance		**CiPs: 3, 4, 8, 10**

The curriculum:
• Describes the physiology of:
  ○ normal respiration
  ○ oxygen and carbon dioxide transport
  ○ buffers
• Summarises respiratory and renal mechanisms in acid-base homeostasis
• Discusses ventilation and perfusion defects and their impact on gas exchange
• Describes and explains causes and assessment of acid-base disturbances:
  ○ measurement of H+
  ○ pCO2
	Trainees will be able to:
	• Describe and explain the investigation of acid-base disorders and management
		Trainees will:
		• Show awareness of the role of point-of-care testing in patient management
		• Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues
		• Demonstrate effective patient education and provision of information

○ pO2 ○ saturation • Discusses the concepts of: ○ actual bicarbonate ○ standard bicarbonate ○ base excess • Describes the determinants and assessment of tissue oxygenation • Describes the causes of acidosis, including lactic acidosis • Describes oxygen and free radical toxicity and physiological mechanisms to control these		
Respiratory system		**CiPs: 3, 4, 8, 10**
The curriculum: • Describes respiratory disease biochemical markers and genetic testing involved in their diagnosis, including alpha1 antitrypsin and cystic fibrosis • Describes the role of biochemical investigation of pleural fluid and its interpretation	Trainees will be able to: • Describe and explain laboratory investigation of respiratory disease	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of respiratory disorders
Liver		**CiPs: 3, 4, 8, 10**
The curriculum: • Describes and explains the physiology of the hepatobiliary system • Explains the causes of jaundice in neonates, children and adults • Discusses disease of the hepatobiliary system, including NAFLD, hepatitis, cirrhosis, cholestasis, gallstones and neoplasia, and explains causes and options for treatment • Describes and explains how inherited disorders can cause liver disease • Describes and explains the role of laboratory and non-laboratory investigations in the	Trainees will be able to: • Interpret routine biochemistry tests in the context of liver disease • Demonstrate selection of specialised tests for investigation of liver disease and appropriate interpretation of results	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management with appropriate communication with clinical colleagues • Promote effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of disorders of the liver

investigation of liver disease		
Kidney and urogenital tract		**CiPs: 3, 4, 8, 10**
The curriculum: • Describes the structure, function and disorders of the kidneys and urogenital tract, including the glomerular filtration system; the role and control of the tubular system; the ureters and bladder; the prostate; and the urethra • Describes the endocrine functions of the kidney, including the renin-aldosterone system, vitamin D and erythropoietin • Describes the diseases of the renal tract, including intrinsic and extrinsic disorders, and the effects of drugs and toxins, acute kidney injury and chronic kidney disease • Describes the consequences of renal disease • Describes the biochemical tests for assessing renal function	Trainees will be able to: • Interpret renal function tests, and recognise significant acute and chronic changes • Describe and explain screening for prostate disease	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management with appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of disorders of the kidney and urogenital tract
Gastrointestinal system		**CiPs: 3, 4, 8, 10**
The curriculum: • Describes and explains the physiology of digestion and absorption and explains the role of the gut as an endocrine organ • Discusses disease of the gastrointestinal tract and pancreas including peptic ulceration, malabsorption, inflammatory bowel disease, intestinal and pancreatic failure, neuro-endocrine disorders and neoplasia, and explains causes and options for treatment • Describes and explains the role of laboratory and non-laboratory investigations in the investigation of gastrointestinal disorders	Trainees will be able to: • Interpret routine biochemistry investigations in the context of gastrointestinal disease • Demonstrate selection of tests for investigation of gastrointestinal disease and appropriate interpretation of results	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management with appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of gastrointestinal disorders
Screening		**CiPs: 1, 2, 3, 4, 5, 7, 8, 10**
The curriculum: • Describes the principles underlying screening	Trainees will be able to: • Demonstrate participation in appropriate disease prevention	Trainees will: • Demonstrate the ability to relate theoretical knowledge and

programmes • Describes the principles of primary and secondary prevention and screening • Describes the regulation of screening programmes within the UK • Describes and explains the role of screening in primary and secondary cardiovascular disease prevention • Describes and explains the principles of newborn bloodspot screening programmes in the diagnosis and management of congenital hypothyroidism, inborn errors of metabolism and haemoglobinopathies • Describes and explains antenatal and postnatal screening • Describes and explains the principles of the national bowel cancer screening programme • Discusses screening for macro- and micro-vascular complications of diabetes by means of clinical examination and investigations	or screening programmes • Describe and explain the appropriate use and interpretation of the results of the laboratory investigations in screening for disease or inherited conditions • Advise on the investigation and management of hyperlipidaemia, identification of patients with secondary causes, and screening family members in case of familial dyslipidaemia • Outline biochemical, statistical and ethical issues surrounding newborn bloodspot screening • Outline appropriate specimen collection • Outline biochemical, statistical and ethical issues surrounding antenatal screening • Outline biochemical, statistical and ethical issues surrounding bowel cancer screening	laboratory results to patient management with appropriate communication with clinical colleagues • Promote effective patient education and provision of information • Recognise the need to liaise effectively with specialty services and refer where appropriate
Pregnancy		**CiPs: 2, 3, 4, 8, 10**
The curriculum: • Outlines maternal and foetal physiology • Outlines complications of pregnancy and their detection • Describes the assessment of ectopic pregnancy • Discusses pre-natal investigation of inborn errors • Discusses the effect of pregnancy on co-existing biochemical and metabolic disease • Discusses the effect of biochemical and metabolic disease on the foetus • Describes the assessment and management of hyperglycaemia in pregnancy	Trainees will be able to: • Discuss the effects of pregnancy on routine biochemical tests	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management with appropriate communication with clinical colleagues • Promote effective patient education and provision of information • Demonstrate appropriate and timely liaison with other medical specialty services when required

• Describes and explains the role of laboratory and non-laboratory investigations in the investigation of complications of pregnancy • Describes the assessment and management of pre-eclampsia		
Neonates and childhood		**CiPs: 2, 3, 4, 8, 10**

The curriculum:
• Summarises biochemical problems in the newborn including:
  ○ fluid balance
  ○ jaundice
  ○ liver disease
  ○ hypoglycaemia and hyperglycaemia
  ○ calcium and phosphate homeostasis; metabolic bone disease of prematurity
  ○ hypomagnesaemia
  ○ lactic acidaemia
  ○ hyperammonaemia
  ○ cystic fibrosis
  ○ nutrition
  ○ congenital adrenal hyperplasia (salt-losing, intersex)
  ○ congenital hypothyroidism
• Summarises the physiology, pathology, investigation and management of biochemical disorders seen in childhood, including:
  ○ disorders of growth and development
  ○ calcium and phosphate disturbance
  ○ hypoglycaemia
  ○ hyperammonaemia
  ○ Reye's syndrome
  ○ lactic acidosis
  ○ renal disorders including Fanconi syndrome and tubular defects
  ○ fluid balance
	Trainees will be able to:
	• Discuss factors affecting method selection and biochemical results in paediatric patients
	• Outline appropriate specimen collection
	• Discuss the effects of high haematocrit, haemolysis and severe jaundice as seen in neonates upon common biochemical tests
		Trainees will:
		• Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues
		• Demonstrate effective patient education and provision of information
		• Describe and explain the role of laboratory and non-laboratory investigations in the investigation of paediatric biochemical disorders
		• Demonstrate appropriate and timely liaison with other medical specialty services when required
		• Show awareness of need to manage children in a child-friendly environment
		• Demonstrate practices in accordance with child protection guidelines

Cancer		**CiPs: 2, 3, 4, 8, 10**

The curriculum: • Outlines the nature of malignancy and tumour growth • Outlines the biochemical effects and treatment of cancer, including the use of markers for prostate, lung, breast, ovary, gastro-intestinal, pancreas, thyroid, pituitary, adrenal, neuroblastoma, hepatoblastoma and teratoma	Trainees will be able to: • Describe and explain the use of biochemical markers in diagnosis and monitoring malignancy	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information
Central nervous system (CNS)/neuromuscular		**CiPs: 3, 4, 8, 10**
The curriculum: • Outlines formation and composition of cerebro-spinal fluid (CSF) • Describes and explains the of use of nasal fluid to determine if CSF in origin • Describes and explains CSF tumour markers • Recognises CSF dementia screens • Discusses the biochemistry of psychiatric disease, especially where there are neurological features or atypical responses to antipsychotic therapy • Outlines the biochemistry of muscle disease • Outlines the biochemical causes of chronic neurological presentations including micronutrient deficiencies, toxic metal poisonings, and inborn errors of metabolism	Trainees will be able to: • Interpret CSF findings in common scenarios including possible subarachnoid haemorrhage, infections within the blood-brain barrier, and the effects of tumours and spinal obstruction to CSF flow • Describe and explain the management of rhabdomyolysis • Demonstrate clinical history skills, thus allowing separation of common causes of myopathies and how to investigate • Appreciate exercise testing and its interpretation • Demonstrate willingness to consider other diagnoses and, in discussion with requestors, seek information or direct them to appropriate services	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of CSF and neuromuscular disorders
Toxicology		**CiPs: 2, 3, 4, 7, 8, 10**

The curriculum:
• Summarises the metabolic effects of ethanol
• Discusses the diagnosis and management of overdose; e.g.:
  ○ salicylate, barbiturate, paracetamol, tri-cyclic antidepressants, benzodiazepines
  ○ ethanol and other alcohols
• Discusses the diagnosis and monitoring of drug addiction
	Trainees will be able to:
	• Summarise the effects of post-mortem changes on the results of laboratory investigations
	• Describe and explain the legal procedure surrounding investigation of death
	• Discuss factors affecting method selection in the identification of drugs of abuse, including different body fluids, immunoassay, mass
		Trainees will:
		• Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues
		• Demonstrate effective patient education and provision of information
		• Describe and explain the role of laboratory and non-laboratory investigations in toxicological

including: ○ opiates, amphetamine, MDMA, benzodiazepines, cocaine, ○ alcohol and other psychoactive agents • Discusses the diagnosis and management of poisoning; e.g. ○ lead, mercury, aluminium, carbon monoxide, paraquat ○ iron, ethylene glycol, methanol, organophosphate compounds • Outlines the laboratory investigation of the unconscious and deceased patient • Describes the sources of information about drug toxicity; e.g. pharmacist, National Poisons Information Service	spectrometry (MS) and MS-MS methods and their limitations • Describe and explain investigation and management of common poisonings and how specialist labs are involved in occupational screening for possible poisoning	investigation
Therapeutic drug monitoring		**CiPs: 2, 3, 4, 7, 8, 10**
The curriculum: • Outlines the principles of pharmacokinetics and its effects on half-life, dosage prediction • Describes monitoring of drug therapy; e.g. digoxin, lithium, antiepileptics, theophylline, caffeine, methotrexate, immunosuppressants, and antibiotics • Describes common metabolic effects/side-effects of drugs; e.g. thyroid dysfunction with lithium or amiodarone • Describes the growing role for pharmacogenetics to identify phenotypes more likely to benefit from particular drugs • Describes assessment and monitoring tests; e.g. biochemical assessment of thiopurine therapy (for both initiation and monitoring) • Describes biological drugs and some appreciation of the assay issues around their measurement	Trainees will be able to: • Describe and explain on factors affecting drug action or metabolism • Describe and explain the metabolic effects/side-effects of drugs	Trainees will: • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the initiation and monitoring of therapeutic drugs

Appendix 2

The following sections cover the areas that previously comprised the sub-specialty of metabolic medicine. Trainees should become familiar with all of these areas as regards the laboratory and clinical liaison (CiPs 7–10), **but are only required to gain experience in the direct clinical care (CiP 11) of two of these areas**. The choice of the two areas in which a trainee wishes to develop capabilities in direct clinical care is likely to be guided by the individual's interests and past experience/qualifications, as well as by the opportunities and expertise available within the local training programme.

Disorders of calcium metabolism		**CiPs: 3, 4, 8, 10, (11)**

The curriculum:
• Discuss the physiology and biochemistry and measurement of calcium, magnesium and phosphate, and their hormonal controls
• Describes the bone remodelling cycle
• Describes and explains pathophysiology, causes and therapeutic options in common bone disorders including:
  ○ osteoporosis
  ○ renal osteodystrophy
  ○ Paget's disease
• Demonstrates the biochemistry and pathology of collagen
• Describes biochemical markers of bone disease
• Describes the pathogenesis, investigation and management of renal stone disease
	Trainees will be able to:
	• Demonstrate investigation and management of patients with:
	• hyper and hypocalcaemia
	  ○ calcium sensing receptor abnormalities
	  ○ hypo- and hyper-phosphataemia
	  ○ hypo- and hyper-phosphatasia
	  ○ disorders of magnesium
	  ○ vitamin D deficiency and insufficiency
	  ○ hyperparathyroidism including those who are normocalacemic
	• Demonstrate management of common bone disorders such as osteoporosis and Paget's disease including ability to interpret bone densitometry and radioisotope scans and awareness of the limitations of such scans
	• Demonstrate investigation and management of patients with renal stone disease
		Trainees will:
		• Demonstrate ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues
		• Describe and explain the role of laboratory and non-laboratory investigations in the investigation of disorders of calcium metabolism
		• Demonstrate effective patient education and provision of information
		• Demonstrate involving patients in decision making especially explaining fracture risk and therapeutic benefits and risks in osteoporosis therapy

Assessment and management of cardiovascular risk		**CiPs: 1, 2, 3, 4, 8, 9, 10, (11)**

<u>a. Lipid disorders</u>
The curriculum:
• Describes and explains metabolic basis of lipid metabolism
• Describes pharmacology of lipid-lowering agents
• Discusses the metabolic basis of inherited and acquired hyper- and hypo-lipoproteinaemias
	Trainees will be able to:
	• Demonstrate assessment and management of cardiovascular risk
	• Demonstrate the ability to:
	  ○ investigate and manage hyperlipidaemia
	  ○ identify patients with secondary causes
		Trainees will:
		• Demonstrate involving patients and families in decision making
		• Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues

• Describes the investigation and principles of management of hyperlipidaemia
• Discuss patient classification of:
  ○ familial hypercholesterolaemia
  ○ familial combined dyslipidaemia
  ○ type III dyslipidaemia
  ○ polygenic hypercholesterolemia
  ○ atherogenic lipoprotein phenotypes
  ○ secondary causes
	○ screen family members in case of familial dyslipidaemia
	• Recognise clinical and biochemical features of genetic dyslipidaemias
	• Identify features of micro- and macro-vascular disease
	• Demonstrates diagnosis and management of primary and secondary dyslipidaemias
	• Demonstrate provision of genetic counselling and cascade screening to affected families
		• Show effective patient education and provision of information
		• Show awareness of the need to screen and offer support to other members of the patient's family in the case of severe familial dyslipidaemias

<u>b. Other risk factors</u>
• Explains the physiological basis for atheroma, coronary heart disease and associated risk factors, including chronic kidney disease and metabolic syndrome
• Outline the principles of primary and secondary cardiovascular disease prevention and summarise lipid treatment and pharmacology including:
  ○ Lipid lowering therapies
  ○ Appropriate adjunctive therapy
• Describes and explains the role of laboratory and non-laboratory investigations in the investigation of cardiovascular disorders
• Describes the secondary causes of hypertension
• Describes pharmacology of antihypertensive medications
• Compare current methods of calculating cardiovascular risk and critically evaluate
	• Summarise an estimation of cardiovascular risk
	• Demonstrate management of factors contributing to atherosclerosis, including diabetes, obesity, renal disease and hypertension
	• Shows provision of appropriate dietetic advice
	• Recognise when to refer patients for specialised investigations and management; e.g. cardiology, vascular surgery
	• Demonstrate investigation and management of patients with hypertension
		• Demonstrate involving patients and families in decision making
		• Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management with appropriate communication with clinical colleagues
		• Demonstrate effective patient education and provision of information

Diabetes mellitus		**CiPs: 1, 2, 3, 8, 10, (11)**
The curriculum: • Describes the different types of diabetes mellitus, their pathogenesis and presentations • Explains the criteria for the diagnosis of diabetes, including in pregnancy • Explains the available therapies	Trainees will be able to: • Demonstrate assessment of glucose control • Demonstrate clinical care of patients with diabetes, including screening for long-term complications • Demonstrate the ability to	Trainees will: • Demonstrate and show the ability to work as part of a multidisciplinary team for the acute and long-term care of patients with diabetes • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient

for glucose control and their applicability in different clinical situations • Describes the process of haemoglobin non-enzymatic glycation and the influence of haemoglobin variants on analysis • Explains the metabolic and biochemical complications of diabetes, including diabetic ketoacidosis and hyperosmolar hyperglycaemic state • Discusses the long-term vascular, ocular, neurological and other complications of diabetes, and the role of screening	initiate appropriate therapy for diabetes in the acute situation, and to adjust therapy to changing circumstances • Demonstrate the ability to advise on appropriate methodology for assessing glycaemic control • Demonstrate awareness of the importance of screening for long-term complications	management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of diabetes
Inborn errors of metabolism		**CiPs: 1, 2, 3, 4, 5, 8, 9, 10, (11)**
The curriculum: • Describes the biochemical basis of inborn errors of metabolism • Describes and explains the use of specialised dietary and drug treatments in patients with inherited metabolic disease • Demonstrates awareness of the range of treatment options available for inherited metabolic disease (e.g. enzyme replacement therapy) and their potential problems • Describes the presentation and course of common IEMs, including phenylketonuria, galactosaemia, homocystinuria, branch-chain amino acid disorders, fatty acid oxidation disorders, lysosomal, metals, mitochondrial, glycogen storage disorders, mucopolysaccharide, organic acid, peroxisomal, purine disorders, acute and cutaneous porphyrias • Describes pre-natal investigation of the foetus • Discusses analysis of amino acids, organic acids, carnitine and acylcarnitines, enzyme activity, mucopolysaccharides, tissue culture and DNA	Trainees will be able to: • Demonstrate emergency management of common and important metabolic presentations, including metabolic acidosis, hypoglycaemia, hyperammonaemia, acute porphyrias • Show choice and interpretation of appropriate investigations • Demonstrate development of management plans with patients (and carers) for routine and emergency management • Demonstrate working effectively as part of a multidisciplinary team • Demonstrate counselling affected families and offer advice on prevention and treatment of exacerbations of the disease in question • Demonstrate liaison with specialist centres about the management of adults with inherited metabolic diseases and the organisation of specific treatments where appropriate	Trainees will: • Demonstrate ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Administer treatment to acutely ill patients and their families in a sympathetic way • Demonstrate involvement of patients and relatives in decision-making • Promote effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of metabolic disorders • Demonstrate counselling techniques and advise affected families on prevention and treatment of disease exacerbations

• Discusses the metabolic basis, investigation, diagnosis and monitoring of porphyria	• Recognise and sustain supportive relationships with patients with whom care will be prolonged and potentially life long • Demonstrate relevant evidenced-based information and, where appropriate, effective patient education with support of the multidisciplinary team • Demonstrate promoting and encouraging involvement of patients in appropriate support networks, both to receive support and to give support to others • Demonstrate setting long-term realistic goals	• Show support to patients in transition from paediatric to adult care • Demonstrate appreciation for the skills of other clinicians involved in delivering care
<u>Nutrition</u>		**CiPs: 1, 2, 3, 4, 8, 9, 10, (11)**
<u>a. Obesity</u>		
The curriculum: • Describes and explains the prevalence and causes of obesity • Describes and explains the genetic causes of obesity • Describes and explains risks and co-morbidities • Describes and explains dietary, pharmaceutical and surgical management	Trainees will be able to: • Demonstrate assessment of obesity • Demonstrate dietary and medical management of severe and complex obesity • Demonstrate assessment and management of metabolic complications of obesity; e.g. insulin resistance syndrome, non-alcoholic fatty liver disease (NAFLD) • Demonstrate management of patients prior to and following bariatric surgery including how patients are selected and complications managed • Demonstrate working effectively as part of a multidisciplinary team	Trainees will: • Recognise obesity to be an illness and treats patients in a sympathetic manner • Recognise the psychological aspects of obesity • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Demonstrate effective patient education and provision of information

b. Malnutrition – nutritional assessment and nutritional support		
• Describes and explains body composition, energy homeostasis, and the consequences of deficiency of dietary components • Explains the options for clinical and biochemical nutritional assessment • Explains the options for nutritional support • Explains the use of parenteral nutrition, including its complications and monitoring • Describes the assessment of capacity and the care of the vulnerable patient • Describes the effects and investigation of vitamin deficiency or excess • Describes the effects of systemic disease on nutritional status • Describes the effect of severe acute illness on nutritional requirements • Describes the effects of micronutrient deficiency and excess in terms of specific clinical features, pathophysiology and biochemical abnormalities	• Demonstrate assessment of nutritional status • Demonstrate selection of appropriate route for nutritional support • Demonstrate working effectively as part of a multidisciplinary team • Shows appropriate prescription of enteral and parenteral feeding regimes • Demonstrate management of feeding lines • Demonstrate management of patients with high losses of fluid or electrolytes • Demonstrate management of short bowel syndrome • Demonstrate management of refeeding syndrome and other complications of nutritional support • Demonstrate taking account of fluid balance, fluid prescription, nutrient intake and drug prescriptions when providing nutritional support	• Demonstrate appreciation for the skills of other clinicians involved in delivering care • Demonstrate the ability to relate theoretical knowledge and laboratory results to patient management by appropriate communication with clinical colleagues • Promote effective patient education and provision of information • Describe and explain the role of laboratory and non-laboratory investigations in the investigation of nutritional disorders • Show a willingness to assess different options for nutritional support and discuss them with the patient, carers and other clinicians • Demonstrate awareness of psychological causes and effects of malnutrition

Appendix B

This appendix contains lists of workplace-based assessments (WPBAs). The requirements for each WPBA area per Whole Time Equivalent (WTE) year of training are included. The aim of the programme of WPBAs is that curriculum delivery on chemical pathology training programmes can become standardised. This will ensure that the trainee experience is improved. WPBAs will include a mini clinical evaluation exercise (mini-CEX), case-based discussion (CbD), and multi-source feedback (MSF) in all years. However, in years 1 and 2, direct observation of practical skills (DOPS) will be assessed and this will change to evaluation of clinical events (ECE) assessment in subsequent years.

The WPBAs listed in this appendix are not an exhaustive means of evidencing attainment; additional evidence, not included in this appendix, may be used to help make a judgement on a trainee's capability.

Direct observation of practical skills (DOPS) (12 mandated in Year 1 and 11 mandated in Year 2)

12 DOPS will be required in year 1 and 11 DOPS in year 2. These are specified in the lists below. Trainees will need to select the pertinent assessment from the options on the DOPs form found via the Learning Environment for Pathology Trainees (LEPT) system.

Year 1

1. Experience with specimen reception procedures
2. Understanding and awareness of IQA and EQA
3. Carry out and present a clinical or laboratory audit
4. Participate in a journal club, demonstrating ability to critically appraise
5. Carry out a teaching activity
6. Demonstrate competence in duty biochemist activity
7. Operation of a centrifuge
8. Assessment of pipette technique
9. Assessment of preparation of solutions including appropriate calculations
10. Carrying out a calibration curve experiment including standardisation
11. Experience with operation of an automated analyser
12. Demonstrate of common POCT devices
    a. Glucometer
    b. Blood gas analyser
    c. Urinalysis (procedure only in case trainee is colour blind)
    d. Pregnancy testing

Year 2

1. Awareness of EQA and demonstration of ability to investigate and address issues in this area
2. Carry out and present a clinical or laboratory audit
3. Participate in a journal club, demonstrating ability to critically appraise
4. Carry out teaching activity
5. Demonstrate competence in duty biochemist activity
6. Demonstrate providing advice to a colleague in writing and/or verbally
7. Operation of a spectrophotometer
8. Operation of an osmometer
9. Carry out an HPLC/mass spectrometry experiment
10. Carry out electrophoresis
11. Operation of common POCT devices (all required to satisfy this DOP criterion)

a. Glucometer
b. Blood gas analyser
c. Urinalysis (procedure only in case trainee is colour blind)
d. Pregnancy testing

12. Plan and perform the following key validation/verification experiments either separately or as for a whole method (all required to satisfy this DOP criterion)
    - Accuracy
    - Imprecision
    - Limit of detection and quantitation
    - Recovery
    - Interference

Evaluation of clinical events (ECE) (seven mandated in year 3, six mandated in year 4, six free choices in year 5)

Seven ECEs will be required in year 3 and six ECEs in years 4 and 5. For years 3 and 4 these are specified in the below lists. For year 5, there will be a minimum of six free-choice ECEs agreed as part of the personal development plan (PDP). Trainees will need to select the pertinent assessment from the options on the ECE form found via the LEPT system.

Year 3

1. Experience with health and safety oversight and demonstration of involvement with addressing an issue in this area
2. Carry out and present a clinical or laboratory audit
3. Participate in a journal club, demonstrating ability to critically appraise
4. Carry out teaching activity
5. Demonstrate competence in duty biochemist activity
6. Demonstrate providing advice to a colleague in writing and/or verbally
7. Plan and perform a method validation/verification

Year 4

1. Carry out and present a clinical or laboratory audit
2. Participate in a journal club, demonstrating ability to critically appraise
3. Carry out a teaching activity
4. Demonstrate competence in duty biochemist activity
5. Demonstrate providing advice to a colleague in writing and/or verbally
6. Carry out a small management project

Year 5

Six free-choice ECEs to be agreed as part of a PDP.

Case-based discussion (CbD)

This section details the requirements for CbD.

Minimum of six per year in years 1 to 5 (four CbDs as mandated and two free choice)

In the first two years of training will be a series of simulated CbDs, which are defined by the college to include learning objectives around clinical, basic and analytical science. These are to be delivered then signed off via the LEPT system by the educational supervisor. A minimum of four of six are mandated per year, with another two from cases selected from the day-to-day work of the trainee. Each CbD would be allocated up to six weeks for personal research before discussing findings with the educational supervisor. The aim is to achieve curriculum delivery and assessment integration and ensure that trainees in the early years all receive the same high-quality experience.

We have included the simulated CbDs in the LEPT system. Each of the CbDs can cover, for example, a mix of the following subject areas so that curriculum delivery is integrated:

- Core clinical, basic and analytical science relevant to the specialty as to be defined by the GPC curriculum group
- NHS and laboratory structure
- Laboratory management
- Understanding of theory behind analytical science:
    - ISEs
    - osmometry
    - immunoassays
    - enzyme-based assays
    - electrophoresis
    - chromatography
    - mass spectrometry
    - reference ranges
    - assay interference

The mandated cases are as follows:

1. Sodium and electrolytes case
2. Renal case
3. Acid-base case
4. Calcium case
5. Thyroid case
6. Adrenal case
7. Gastro-intestinal tract case
8. Pituitary case

Years 3–5 (six free-choice CbDs)

Six CbDs will be required each WTE year to include a free choice of a broad topic selection covering the extent of the curriculum.

Mini clinical evaluation exercise (Mini-CEX) (six free choice mini-CEX per WTE year)

A minimum of six per year of training in a broad selection of topics covering the curriculum.

Multi-source feedback (MSF)

A minimum of three during training; typically, in ST3, ST5 and ST7.

All trainees are required to undertake three MSF assessments throughout their training at year 1, 3 and 5 (i.e., ST1/3, ST3/5 and ST5/7) prior to the award of a Certificate of Completion of Training.