Pearson BTEC Level 4 Diploma in Healthcare Science

Specification

New Apprenticeship Standards –
Competence-based qualification (England only)

First registration September 2017

Edexcel, BTEC and LCCI qualifications

Edexcel, BTEC and LCCI qualifications are awarded by Pearson, the UK's largest awarding body offering academic and vocational qualifications that are globally recognised and benchmarked. For further information, please visit our qualifications website at qualifications.pearson.com. Alternatively, you can get in touch with us using the details on our contact us page at qualifications.pearson.com/contactus

About Pearson

Pearson is the world's leading learning company, with 35,000 employees in more than 70 countries working to help people of all ages to make measurable progress in their lives through learning. We put the learner at the centre of everything we do, because wherever learning flourishes, so do people. Find out more about how we can help you and your learners at qualifications.pearson.com

Pearson would like to acknowledge the support of the School of Healthcare Science, healthcare science professional bodies and organisations, and the significant number of scientists in the healthcare science workforce who contributed to the development of this qualification.

ISBN 978 1 446 95035 7

Contents

1 Introducing BTEC Competence-based qualifications for the New Apprenticeship Standards

Overview

In October 2013, the government began the implementation of the plan to reform apprenticeships in England. The reform includes changes that move the design of apprenticeships into the hands of employers with the aim of making them more rigorous and responsive to employers' needs. Employer groups, referred to as Trailblazers, now lead on the development of apprenticeships for occupations where they identify the need for apprentices.

Pearson has been working closely with Trailblazer employer groups in the development of different types of assessment programmes and qualifications to support the delivery of these new apprenticeships. Employers are continuing to value competence-based qualifications as a part of these new apprenticeships.

Within the new apprenticeships, competence-based qualifications give learners the opportunity to develop and demonstrate their competence, in line with the Apprenticeship Standards developed by Trailblazer employer groups. These new Apprenticeship Standards describe the knowledge, skills and behaviours (KSBs) required to undertake a specific occupation well, and to operate confidently within a sector. They focus on how an apprentice should demonstrate mastery of an occupation and, where they exist, meet sector professional registration requirements.

Competence-based qualifications are outcome based with no fixed learning programme, therefore allowing flexible delivery to meet the individual needs of learners and their employers. Learners will work towards their qualifications primarily in the workplace or in settings that replicate the working environment as specified in the assessment requirements from the Trailblazer employer groups.

Employers, or colleges and training centres, working in partnership with employers, can offer these qualifications as long as they have access to appropriate physical and human resources and that the necessary quality-assurance systems are in place.

Sizes of Competence-based qualifications

For all regulated qualifications, we specify a total number of hours that learners are expected to undertake in order to complete and show achievement for the qualification – this is the Total Qualification Time (TQT). The TQT value indicates the size of a qualification.

Within the TQT, we identify the number of Guided Learning Hours (GLH) that a centre delivering the qualification needs to provide. Guided learning means activities that directly or immediately involve tutors and assessors in teaching, supervising, and invigilating learners, for example lectures, tutorials, online instruction and supervised study.

As well as guided learning, there may be other required learning that is directed by tutors or assessors. This may include, for example, private study, preparation for assessment and undertaking assessment when not under supervision, such as preparatory reading, revision and independent research.

As well as TQT and GLH, qualifications can also have a credit value – equal to one tenth of TQT, rounded to the nearest whole number.

TQT and credit values are assigned after consultation with employers and training providers delivering the qualifications.

Competence-based qualifications for the New Apprenticeship Standards are generally available in the following sizes:

- Award – a qualification with a TQT value of 120 or less (equivalent to a range of 1–12 credits)
- Certificate – a qualification with a TQT value in the range of 121–369 (equivalent to a range of 13–36 credits)
- Diploma – a qualification with a TQT value of 370 or more (equivalent to 37 credits and above).

Other size references, such as the Extended Diploma, can be used in a suite of qualifications depending on the specific needs of different sectors and Trailblazer employer groups.

2 Qualification summary and key information

Qualification title	Pearson BTEC Level 4 Diploma in Healthcare Science
Qualification Number (QN)	603/2313/9
Regulation start date	01/09/2017
Operational start date	01/09/2017
Approved age ranges	18+ Please note that sector-specific requirements or regulations may prevent learners of a particular age from embarking on this qualification. Please refer to the assessment requirements in *Section 8 Assessment*.
Total Qualification Time (TQT)	1000
Guided Learning Hours (GLH)	686
Credit value	100
Assessment	Portfolio of evidence (internal assessment).
Grading information	The qualification and units are graded pass/fail.

Qualification title	Pearson BTEC Level 4 Diploma in Healthcare Science
Entry requirements	No prior knowledge, understanding, skills or qualifications are required before learners register for this qualification. However, apprentices without Level 2 English and maths will need to achieve this prior to taking the end-point assessment. Centres must also follow the *Pearson Access and Recruitment policy* (see *Section 7 Access and recruitment*).
Funding	The Trailblazer Apprenticeship funding rules can be found on the Skills Funding Agency's website at www.gov.uk/government/collections/sfa-funding-rules

Centres will need to use the Qualification Number (QN) when they seek public funding for their learners. The qualification title, unit titles and QN will appear on each learner's final certificate. Centres should tell learners this when recruiting them and registering them with Pearson. There is more information about certification in our *UK Information Manual*, available on our website, qualifications.pearson.com

3 Qualification purpose

Qualification objectives

The Pearson BTEC Level 4 Diploma in Healthcare Science is for learners who are employed as apprentices in the role of healthcare science associate and working towards gaining their apprenticeship.

However, it is not just those working towards an apprenticeship who can undertake this qualification, those currently employed as healthcare science associates can complete the qualification to confirm their knowledge, skills and behaviours of the job role.

The healthcare science (HCS) associate workforce supports the work of healthcare science Practitioners and Clinical Scientists in performing high-quality, safe diagnostic, therapeutic and monitoring technical and scientific procedures from conception to end of life in job roles within hospitals, general practice and other settings in the healthcare sector and across all areas of healthcare science. They perform a wide range of routine technical and scientific procedures, with minimal supervision, within one of the divisions in HCS, following specific protocols and in accordance with health, safety, governance and ethical requirements.

Activities carried out by healthcare science associates in the specific area/environment in which they work include: supporting the development and maintenance of standards/protocols as required; contributing to the safe, effective and efficient functioning of diagnostic/therapeutic services; supporting junior staff in learning required skills and behaviours; quality controlling the technical processing of biological samples and physiological and other diagnostic tests; managing technical data and writing technical reports.

The qualification gives learners the opportunity to develop:

- wider sector-related knowledge to underpin occupational competence in the role of a healthcare science associate. This includes knowledge and understanding of the requirements of the NHS constitution and good scientific practice for person-centred care and support, involving patients and the public in HCS and in making choices about their care, good mentoring practice, legislation and policies in HCS and quality management
- technical sector-related knowledge to underpin occupational competence in their own role and those of others within a healthcare science team. Learners will be able to gain the underpinning knowledge from the following themes: pathology investigations of disease and disorders, clinical investigations of human functions and systems, imaging investigations and medical physics, and clinical engineering and the benefits of research
- a range of technical skills and abilities to support competence in the job role' this includes skills in performing equipment management skills, recognising problems, undertaking appropriate audit/research/innovation activities that support quality improvement, plan/assess the work of the team and promote mental health and wellbeing
- a positive attitude to following Standard Operating Procedures (SOPs) and codes of practice, and professional behaviours such as developing practice and performance, working within the limits of own role, respecting the rights of others and working collaboratively and safely, mentoring and the delivery of high-quality service outcomes and continuous improvements.

Learners will benefit by achieving a nationally recognised qualification specifically for healthcare scientists at Level 4, and this will enable them to register as a healthcare science associate with the Academy for Healthcare Science.

Relationship with previous qualifications

This qualification does not replace any other Pearson BTEC qualifications.

Apprenticeships

The Pearson BTEC Level 4 Diploma in Healthcare Science fully satisfies the on-programme requirement within the Healthcare Science Associate Apprenticeship Standard. Learners must complete this requirement before progressing to the end-point assessment (EPA).

The published Healthcare Science Associate Apprenticeship Standard and Assessment Plan can be found at:
www.gov.uk/government/publications/apprenticeship-standard-healthcare-science-associate

Progression opportunities

Learners who achieve the Pearson BTEC Level 4 Diploma in Healthcare Science and all other apprenticeship requirements can progress to achieving the full Apprenticeship certification that confirms competency in the job role stated on the previous page. In the longer term, learners can progress to more senior or complex job roles such as Healthcare Science Practitioner.

Achievement of the Pearson BTEC Level 4 Diploma in Healthcare Science is part of the assessment gateway requirement to show that learners are ready to undertake the end-point assessment (EPA) for the Healthcare Science Trailblazer Apprenticeship. On successful completion of the EPA and achievement of the Apprenticeship, learners will be able to register on the Academy for Healthcare Science (AHCS) professional register.

Non-apprentice learners who complete the qualification can also then register on the AHCS professional register.

The content of the qualification will provide learners with a solid basis of knowledge, skills and appropriate behaviours to enable them to progress within the NHS Modernising Scientific Careers Framework and enable them to progress to become healthcare science associates. The content of the qualification will allow learners to progress to healthcare science degrees and allow them to become Healthcare Science Practitioners.

Learners who complete the Level 4 Diploma can use their learning to apply for opportunities to progress to a Level 6 Apprenticeship.

In addition, the emphasis on self-development, reflective practice and working with others will help learners to enhance their general career progression in the workplace.

Industry support and recognition

The Pearson BTEC Level 4 Diploma in Healthcare Science was developed through close collaboration with the Healthcare Science Associate Trailblazer employer group, professional bodies and further and higher education representatives.

This qualification is supported by:

- employers: Newcastle upon Tyne Hospitals NHS Trust, Sheffield Teaching Hospitals NHS Foundation Trust, NHS Blood and Transplant, Newcastle Centre, Gloucestershire Hospitals NHS Foundation Trust, The Royal Marsden NHS Foundation Trust, Western Sussex Hospitals NHS Foundation Trust, Public Health Laboratory (Bristol), Sherwood Forest Hospitals NHS Foundation Trust, West Hertfordshire Hospitals NHS Trust, Cardiff and Vale University Health Board, University Hospital of Wales, Doncaster and Bassetlaw Hospitals NHS Foundation Trust, Royal Cornwall Hospitals Trust, East Kent Hospitals University NHS Foundation Trust, Viapath (Serco, Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust)
- professional organisations: Healthcare Science Professional Body Group, Health Education England, Public Health England, Institute of Decontamination Sciences, Academy for Healthcare Science, Association of Health Professions in Ophthalmology
- Sector Skills Council: Skills for Health, Cogent.

4 Qualification structure

Pearson BTEC Level 4 Diploma in Healthcare Science

Learners will need to meet the requirements outlined in the table below before the qualification can be awarded.

Minimum number of credits that must be achieved	100
Minimum number of credits that must be achieved at Level 4 or above	51
Number of mandatory credits that must be achieved	37
Number of optional credits that must be achieved	63

Please note that there are some required unit combinations in the structure. Please check the table below and individual units for details.

Unit number	Mandatory units – Group A	Level	Credit	Guided learning hours
1	Skills for Lifelong Learning	4	2	16
2	Professional Practice and Person-centred Care	4	5	40
3	Legal and Ethical Context of Practice	4	3	24
4	Health, Safety and Security in the Healthcare Science Environment	4	3	25
5	Technical Scientific Services	4	5	40
6	Effective Communication in Healthcare	4	4	35
7	Audit, Research, Development and Innovation	4	5	20
8	Leadership and Teamwork	4	3	24
9	Teaching, Learning and Assessing Practical Skills	4	4	32
10	Continuing Personal and Professional Development	4	3	20

Unit number	Optional units – Group B	Level	Credit	Guided learning hours
11	Scientific Basis of Healthcare Science: Clinical Science	4	25	200
12	Scientific Basis of Healthcare Science: Genetics and Genomics and Clinical Bioinformatics	4	10	80
13	Scientific Basis of Healthcare Science: Pharmacology and Therapeutics	4	5	40
14	Scientific Basis of Healthcare Science: Epidemiology and Public Health	4	10	80
15	Scientific Basis of Healthcare Science: Mathematics, Statistics and Physical Sciences	4	10	80
16	Point of Care Testing	4	5	40
17	The Building Blocks of Life	4	20	160
18	The Science Behind the Cure	4	20	160
19	General Laboratory Practice	4	11	88
20	Procedures for Witnessing in the HFEA-licensed Fertility Clinic	3	2	15
21	Check documentation of Consent in the HFEA-licensed Fertility Clinic	3	3	17
22	Identify and Instruct Individuals Providing Semen Samples in the HFEA-licensed Fertility Clinic	3	3	17
23	Laboratory Practice in the HFEA-licensed Reproductive Science Laboratory	4	3	25
24	Principles and Organisation of Services in the HFEA-licensed Fertility Clinic	4	3	25
25	Reproductive Sciences: Human Body Systems – Biological Basis of Reproductive Systems	4	4	30
26	Prepare Culture Systems for Gametes and Embryos in the HFEA-licensed Reproductive Science Laboratory	4	5	40
27	Prepare Documents for the Transport of Gametes and Embryos to and from Other Fertility Clinics	4	5	40
28	Semen Assessment	4	5	40
29	Clinical Biochemistry in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240

Unit number	Optional units – Group B	Level	Credit	Guided learning hours
30	Haematology in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
31	Clinical Immunology in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
32	Histocompatibility and Immunogenetics in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
33	Transfusion Science – Blood Transfusion in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
34	Transfusion Science – Stem Cell and Tissue Transplantation *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
35	Histology in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
36	Cytology in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
37	Microbiology in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
38	Virology in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
39	Principles and Practice of Decontamination Science	4	5	26
40	Preparation of Medical Devices for the Cleaning and Disinfection Process	4	5	26
41	Cleaning and Disinfection of Medical Devices: Manual Processes	4	5	30
42	Cleaning and Disinfection of Medical Devices: Automated Processes	4	5	40

Unit number	Optional units – Group B	Level	Credit	Guided learning hours
43	Inspection, Assembly, Packaging of Medical Devices in a Controlled Environment	4	10	76
44	Terminal Processing including Sterilisation and High Level Disinfection	4	5	36
45	Testing, Maintenance and Breakdown Management of Decontamination Equipment	4	5	40
46	Principles and Practice of Flexible Endoscope Decontamination	4	6	50
47	The Role of the Genetic Counsellor	4	5	41
48	Genetics and Genomics in Practice *Learners taking this unit must also take Unit 19: General Laboratory Practice*	4	30	240
49	Scientific Basis of Cardiovascular, Respiratory and Sleep Science: Cardiac Embryology, Anatomy and Physiology	4	15	120
50	Scientific Basis of Cardiovascular, Respiratory and Sleep Science: Anatomy, Histology and Physiology of the Respiratory System	4	15	120
51	Scientific Basis of Cardiovascular, Respiratory and Sleep Science: Scientific Basis of Respiratory Disorders of Sleep	4	10	80
52	Principles of Ultrasound	4	3	24
53	Recognising ECG Abnormalities in Adults	4	10	80
54	Ambulatory ECG Monitoring	4	20	160
55	Ambulatory Blood Pressure Monitoring	4	15	120
56	Assist in Cardiac Stress Testing *Learners taking this unit must also complete Unit 53: Recognising ECG Abnormalities in Adults*	4	6	48
57	Introduction to Congenital Heart Disease	4	4	25
58	Recognising ECG Abnormalities in Children	4	10	80
59	Spirometry, Static Lung Volumes and Bronchodilator Response in Adults	4	15	120
60	Measurement of Single Breath Gas Transfer	4	15	120
61	Performing Overnight Oximetry	4	10	80
62	Spirometry, Static Lung Volumes and Bronchodilator Response in Children	4	15	120

Unit number	Optional units – Group B	Level	Credit	Guided learning hours
63	Scientific Basis of Neurosensory Sciences: Applied Physics and Measurement	4	15	120
64	Scientific Basis of Neurosensory Sciences: Applied Anatomy, Physiology and Pathophysiology: The Nervous System	4	10	80
65	Scientific Basis of Neurosensory Sciences: Applied Anatomy, Physiology and Pathophysiology: The Ear	4	5	40
66	Adult hearing Screening and Assessment	4	25	200
67	Hearing Aid repair and Maintenance	4	15	120
68	Assisting with Electroencephalography	4	15	120
69	Performing Machine Function Tests	4	7	58
70	Assist in the Recording of Visual Evoked Potentials	4	6	52
71	Assist in the Recording of Visual Electrophysiological Investigations	4	6	52
72	Assist during Nerve Conduction Studies and Electromyography	4	6	52
73	Ophthalmic and Vision Science: Applied Microbiology	4	6	52
74	Ophthalmic Pharmacology	4	6	48
75	Instill Eye Medication for Purpose of Investigation or Treatment	4	5	40
76	Anatomy, Physiology and Pathophysiology of the Visual System	4	6	48
77	Imaging the Eye with Fundus Camera and Optical Coherence Tomography	4	6	48
78	Measure Visual Acuity	3	3	17
79	Visual Field Assessment	3	5	40
80	Measure Optical Prescriptions and Refractive Error	3	5	42
81	Introduction to Gastrointestinal Physiology	4	5	42
82	Performing a Breath Test for Carbohydrate Malabsorption *Learners taking this unit must also take Unit 81: Introduction to Gastrointestinal Physiology*	4	8	64

Unit number	Optional units – Group B	Level	Credit	Guided learning hours
83	Performing Percutaneous Tibial Nerve Stimulation (PTNS) in Patients with Faecal and Urinary Incontinence Over Active Bladder (OAB) *Learners taking this unit must also take Unit 81: Introduction to Gastrointestinal Physiology*	4	12	96
84	24 hour Upper Gastrointestinal Physiology Studies: Post-Recording Management Studies *Learners taking this unit must also take Unit 81: Introduction to Gastrointestinal Physiology*	4	10	80
85	Assist in Post Sacral Nerve Stimulation Implantation Follow-up Clinics *Learners taking this unit must also take Unit 81: Introduction to Gastrointestinal Physiology*	4	6	52
86	Preparing Equipment for Ambulatory 24 Hour Monitoring, including pH and Combined pH/Impedance Studies *Learners taking this unit must also take Unit 81: Introduction to Gastrointestinal Physiology*	4	6	52
87	Preparing Lower GI equipment: High Resolution Anorectal Manometry *Learners taking this unit must also take Unit 81: Introduction to Gastrointestinal Physiology*	4	6	46
88	Preparing Lower GI equipment: Endoanal Ultrasound *Learners taking this unit must also take Unit 81: Introduction to Gastrointestinal Physiology*	4	6	46
89	The Urinary System	4	6	48
90	Performing Urine Dip Stick Analysis	4	3	20
91	Ultrasound Measurement of Post-Void Residual Urine	4	12	96
92	Assisting with Standard Urodynamic Studies	4	10	80
93	Assisting with Flowmetry Studies	4	10	80

Unit number	Optional units – Group B	Level	Credit	Guided learning hours
94	Introduction to Autonomic Science	4	8	64
95	Assist in Performing Tilt Testing	4	6	48
96	Withdrawal of Blood from an Indwelling Peripheral Cannula	4	3	15
97	Assist with the Assessment of Plasma Catecholamine and Biochemical Levels	4	7	56
98	Assist in Performing Situational Provocation Testing	4	7	56
99	Peripheral Intravenous Cannulation as Part of Autonomic Testing	5	5	40
100	Introduction to Vascular Science	4	3	20
101	Measuring Ankle Brachial Pressure Index	3	2	14
102	Measurement of Post-Exercise Ankle Brachial Pressure Index	4	6	48
103	Scientific Basis of Physical Sciences: Mathematics, Statistics and Informatics	4	10	80
104	Scientific Basis of Engineering: Electrical and Basic Electronics	4	15	120
105	Scientific Basis of Engineering: Basic Mechanics	4	15	120
106	Scientific Basis of Physical Sciences Scientific Basis of Medical Physics	4	30	240
107	Clinical Engineering Workshop Skills	4	4	32
108	The Medical Equipment Lifecycle	4	6	48
109	Acceptance Testing of New Medical Equipment	4	6	48
110	Planned Preventive Maintenance	4	4	32
111	Diagnosing and Rectifying Equipment Faults	4	4	32
112	Decommissioning and Disposal of Medical Equipment	4	6	48
113	Medical Engineering in Practice	4	15	120
114	Rehabilitation Engineering in Practice	4	15	120
115	Renal Technology in Practice	4	15	120
116	Ionising Radiation Engineering in Practice	4	15	120
117	Working Practices in Physical Sciences	4	5	40
118	Radiotherapy Physics in Practice	4	20	160

Unit number	Optional units – Group B	Level	Credit	Guided learning hours
119	Nuclear Medicine in Practice	4	20	160
120	Radiation Physics in Practice	4	20	160
121	Introduction to Data Science and Data Management in Clinical Bioinformatics	4	10	80
122	Introduction to Clinical Bioinformatics (Genomics)	4	10	80
123	Introduction to UNIX	4	7	22
124	Safe Use of Information Communication Technology within the Clinical Environment	4	10	80
125	Informatics for Physical Sciences	4	9	76
126	Technical Support for Computerised Medical Devices	4	10	80
127	Project Management	4	5	40
128	Clinical Bioinformatics in Practice (Cancer Genomics)	4	20	160
129	Clinical Bioinformatics in Practice (Infectious Diseases)	4	20	160
130	Clinical Bioinformatics in Practice (Rare Diseases)	4	20	160
131	Measurement of Toe Pressure by Photoplethysmography (PPG) *Learners taking this unit must also take Unit 102: Measurement of Post-Exercise Ankle Brachial Pressure Index*	4	10	80
132	Measurement of Transcutaneous Oxygen (TCPO2) *Learners taking this unit must also complete Unit 102: Measurement of Post-Exercise Ankle Brachial Pressure Index and Unit 131: Measurement of Toe Pressure by Photoplethysmography (PPG)*	4	10	80

5 Programme delivery

Centres are free to offer these qualifications using any mode of delivery that meets learners' and employers' needs.

A learner must be employed as an apprentice in the job role specified in the Apprenticeship Standard and have an apprenticeship agreement in place at the start of the apprenticeship programme. Centres must make sure that learners have access to specified resources and to the sector specialists delivering and assessing the units. Centres must adhere to the Pearson policies that apply to the different models of delivery. Our policy *Collaborative and consortium arrangements for the delivery of vocational qualifications policy* can be found on our website.

There are various approaches to delivering a successful, competence-based qualification; the section below outlines elements of good practice that centres can adopt, as appropriate to the requirements of the apprenticeship programme.

Elements of good practice

- Carrying out a thorough induction for learners to ensure that they completely understand the apprenticeship programme and what is expected of them. The induction could include, for example, the requirements of the apprenticeship programme, an initial assessment of current competency levels, assessment of individual learning styles, identification of training needs, an individual learning plan, details of training delivery and the assessment process.
- Having regular progress meetings with the learner to keep them engaged and motivated, and ensuring that there are open lines of communication among all those involved in delivering the training and assessment.
- Using flexible delivery and assessment approaches to meet the needs of the learner and the organisational context and requirements, through the use of a range of approaches, for example virtual learning environments (VLEs), online lectures, video, printable online resources, virtual visits, webcams for distance training, eportfolios.
- Balancing on-the-job and off-the-job training to meet the requirements of the apprenticeship. It is a mandatory requirement in the new apprenticeships that learners have a minimum of 20 per cent or equivalent off-the-job training. Trainers need to use a range of teaching and learning methods to deliver this training effectively while still meeting varying learner needs. Examples of teaching and learning methods for off-the-job training could include: enquiry-based learning, real-world problem solving, reflective practice, questioning and discussions, demonstration, practising ('trial and error'), simulation and role play, peer learning and virtual environments. Trainers also need to plan opportunities for the development and practising of skills on the job. The on-the-job element of the programme offers opportunities for assessment and plays an important role in developing the learners' routine expertise, resourcefulness and business-like attitude. It is important that there is intentional structuring of practice and guidance to supplement the learning and development provided through engagement in everyday work activities. Teaching and learning methods, such as coaching, mentoring, shadowing, observation, collaboration and consultation, could be used in this structured on-the-job learning.

- Developing a holistic approach to assessment by matching evidence to the required competencies as appropriate and, wherever possible, to reduce the assessment burden on learners and assessors. It is good practice to draw up an assessment plan that aligns the competencies to be achieved with the learning process and that indicates how and when assessment will take place.
- Discussing and agreeing with the learner and their line manager suitable times, dates and work areas where assessment will take place. Learners and managers should be given regular and relevant feedback on performance and progress.
- Ensuring that learners are allocated a mentor in the workplace to assist them in the day-to-day working environment and to act as a contact for the assessor/trainer.
- Ensuring that sufficient and relevant work is given to learners in order to allow them to gain wider employment experience and enable them to develop the competencies and the related knowledge, skills and behaviours stated in the Apprenticeship Standard within their contracted working hours.

For further information on the delivery and assessment of the New Apprenticeship Standards please refer to *The Trailblazer Apprenticeship Funding Rules* at: www.gov.uk/guidance/sfa-funding-rules

6 Centre resource requirements

As part of the approval process, centres must make sure that the resource requirements below are in place before offering the qualification.

- Centres must have the appropriate physical resources to support delivery and assessment of the qualification. For example, a workplace in line with industry standards, or a Realistic Working Environment (RWE) where permitted, as specified in the assessment strategy for the sector, equipment, IT, learning materials, teaching rooms.
- Where RWE is permitted, it must offer the same conditions as the normal, day-to-day working environment, with a similar range of demands, pressures and requirements for cost-effective working.
- Centres must meet any specific human and physical resource requirements outlined in the assessment strategy in *Annexe A* and the additional information sections of each unit. Staff assessing learners must meet the occupational competence requirements in the assessment strategy.
- There must be systems in place to ensure continuing professional development for staff delivering the qualification.
- Centres must have appropriate health and safety policies, procedures and practices in place for the delivery and assessment of the qualification.
- Centres must have in place robust internal verification systems and procedures to ensure the quality and authenticity of learners' work as well as the accuracy and consistency of assessment decisions between assessors operating at the centre. For information on the requirements for implementing assessment processes in centres, please refer to the *NVQ Quality Assurance Handbook* and the *Pearson Edexcel NVQs, SVQs and competence-based qualifications – Delivery Requirements and Quality Assurance Guidance* on our website.
- Centres must deliver the qualification in accordance with current equality legislation. For further details on Pearson's commitment to the Equality Act 2010, please see *Section 7 Access and recruitment*. For full details on the Equality Act 2010, visit www.legislation.gov.uk

7 Access and recruitment

Our policy on access to our qualifications is that:

- they should be available to everyone who is capable of reaching the required standards
- they should be free from barriers that restrict access and progression
- there should be equal opportunities for all wishing to access the qualifications.

Centres must ensure that their learner recruitment process is conducted with integrity. This includes ensuring that applicants have appropriate information and advice about the qualification to ensure that it will meet their needs.

All learners undertaking an Apprenticeship Standard must be employed as an apprentice in the job role specified in the Apprenticeship Standard and have a contract of employment at the start of the first day of their apprenticeship.

Centres should review applicants' prior qualifications and/or experience, considering whether this profile shows that they have the potential to achieve the qualification.

Prior knowledge, skills and understanding

There are no entry requirements or prior learning/experience requirements for these qualifications, though learners may have taken the Level 2 qualification.

Access to qualifications for learners with disabilities or specific needs

Equality and fairness are central to our work. Pearson's *Equality Policy* requires all learners to have equal opportunity to access our qualifications and assessments and that our qualifications are awarded in a way that is fair to every learner.

We are committed to making sure that:

- learners with a protected characteristic (as defined by the Equality Act 2010) are not, when they are undertaking one of our qualifications, disadvantaged in comparison to learners who do not share that characteristic
- all learners achieve the recognition they deserve from undertaking a qualification and that this achievement can be compared fairly to the achievement of their peers.

For learners with disabilities and specific needs, the assessment of their potential to achieve the qualification must identify, where appropriate, the support that will be made available to them during delivery and assessment of the qualification. Please see the information regarding reasonable adjustments and special consideration in *Section 8 Assessment*.

8 Assessment

To achieve a pass for this qualification, the learner must achieve all the units required in the stated qualification structure.

Language of assessment

Assessments for the units in this qualification are in English only.

A learner taking the qualification may be assessed in British or Irish Sign Language where it is permitted for the purpose of reasonable adjustment.

Further information on access arrangements can be found in the Joint Council for Qualifications (JCQ) document *Adjustments for candidates with disabilities and learning difficulties, Access Arrangements and Reasonable Adjustments*. The document is available on our website.

Internal assessment

The units in this qualification are assessed through an internally and externally quality-assured portfolio of evidence made up of evidence gathered during the course of the learner's work.

Each unit has specified learning outcomes and assessment criteria. To pass each unit the learner must:

- achieve **all** the specified learning outcomes
- satisfy **all** the assessment criteria by providing sufficient and valid evidence for each criterion
- prove that the evidence is their own.

The learner must have an assessment record that identifies the assessment criteria that have been met. The assessment record should be cross-referenced to the evidence provided. The assessment record should include details of the type of evidence and the date of assessment. Suitable centre documentation should be used to form an assessment record.

It is important that the evidence provided to meet the assessment criteria for the unit and learning outcomes is:

Valid	relevant to the standards for which competence is claimed
Authentic	produced by the learner
Current	sufficiently recent to create confidence that the same skill, understanding or knowledge persist at the time of the claim
Reliable	indicates that the learner can consistently perform at this level
Sufficient	fully meets the requirements of the standards.

Recognition of Prior Learning (RPL) – where a learner can demonstrate that they can meet a unit's requirements through knowledge, understanding or skills they already possess without undertaking a course of development. They must submit sufficient, reliable, authentic and valid evidence for assessment. Evidence submitted that is based on RPL should give the centre confidence that the same level of skill, understanding and knowledge exists at the time of the claim as existed at the time the evidence was produced. RPL is acceptable for accrediting a unit, several units, or a whole qualification.

Further guidance is available in our policy document *Recognition of prior learning policy and process*, available on our website.

Assessment Strategy

The assessment strategy for this qualification is included in *Annexe A*. It sets out the overarching assessment requirements and the framework for assessing the units to ensure that the qualification remains valid and reliable. It has been developed by the Healthcare Science Trailblazer employer group.

Types of evidence

To achieve a unit, learners must gather evidence that shows that they have met the required standard specified in the assessment criteria, Pearson's quality-assurance arrangements (please see *Section 10 Quality assurance*) and the requirements of the assessment strategy given in *Annexe A*. In line with the assessment strategy, evidence for internally-assessed units can take a variety of forms as indicated below:

- direct observation of the learner's performance by their assessor (O)
- outcomes from oral or written questioning (Q&A)
- products of the learner's work (P)
- personal statements and/or reflective accounts (RA)
- outcomes from simulation (S)
- professional discussion (PD)
- authentic statements/witness testimony (WT)
- expert witness testimony (EWT)
- evidence of Recognition of Prior Learning (RPL).

Learners can use the abbreviations in their portfolios for cross-referencing purposes.

Learners can also use one piece of evidence to prove their knowledge, skills and understanding across different assessment criteria and/or across different units. It is not necessary for learners to have each assessment criterion assessed separately. They should be encouraged to reference evidence to the relevant assessment criteria. However, the evidence provided for each unit must clearly reference the unit being assessed. Evidence must be available to the assessor, the internal verifier and the Pearson Standards Verifier.

Any specific evidence requirements for a unit are given in the *Assessment* section of the unit.

Further guidance on the requirements for centre quality-assurance and internal verification processes is available on our website. Please see *Section 12 Further information and useful publications* for details.

Assessment of knowledge and understanding

Knowledge and understanding are key components of competent performance, but it is unlikely that performance evidence alone will provide sufficient evidence for knowledge-based learning outcomes and assessment criteria. Where the learner's knowledge and understanding is not apparent from performance evidence, it must be assessed through other valid methods and be supported by suitable evidence. The evidence provided to meet these learning outcomes and assessment criteria must be in line with the assessment strategy. Any specific assessment requirements are stated in the *Unit assessment requirements* section of each unit in *Section 11 Unit format*.

Appeals

Centres must have a policy for dealing with appeals from learners. Appeals may relate to incorrect assessment decisions or unfairly conducted assessment. The first step in such a policy is a consideration of the evidence by a lead internal verifier or other member of the programme team. The assessment plan should allow time for potential appeals after learners have been given assessment decisions.

Centres must document all learners' appeals and their resolutions. Further information on the appeals process can be found in our *Enquiries and appeals about Pearson vocational qualifications policy*, available on our website.

Dealing with malpractice

Malpractice means acts that undermine the integrity and validity of assessment, the certification of qualifications and/or may damage the authority of those responsible for delivering the assessment and certification.

Pearson does not tolerate actions (or attempted actions) of malpractice by learners, centre staff or centres in connection with Pearson qualifications. Pearson may impose penalties and/or sanctions on learners, centre staff or centres where incidents (or attempted incidents) of malpractice have been proven.

Malpractice may arise or be suspected in relation to any unit or type of assessment within the qualification. For further details on malpractice and advice on preventing malpractice by learners please see the *Centre Guidance: Dealing with Malpractice* document, available on our website.

Internal assessment

Centres are required to take steps to prevent malpractice and to investigate instances of suspected malpractice. Learners must be given information that explains what malpractice is for internal assessment and how suspected incidents will be dealt with by the centre. The *Centre Guidance: Dealing with Malpractice* document gives full information on the actions we expect you to take.

Pearson may conduct investigations if we believe that a centre is failing to conduct internal assessment according to our policies. The above document gives more information and examples, and details the penalties and sanctions that may be imposed.

In the interests of learners and centre staff, centres need to respond effectively and openly to all requests relating to an investigation into an incident of suspected malpractice.

Learner malpractice

The head of centre is required to report incidents of suspected learner malpractice that occur during Pearson examinations. We ask centres to complete a *JCQ Form M1* (available at www.jcq.org.uk/exams-office/malpractice) and email it with any accompanying documents (signed statements from the learner, invigilator, copies of evidence, etc.) to the Investigations Team at pqsmalpractice@pearson.com. The responsibility for determining appropriate sanctions or penalties to be imposed on learners lies with Pearson.

Learners must be informed at the earliest opportunity of the specific allegation and the centre's malpractice policy, including the right of appeal. Learners found guilty of malpractice may be disqualified from the qualification for which they have been entered with Pearson.

Teacher/centre malpractice

The head of centre is required to inform Pearson's Investigations Team of any incident of suspected malpractice by centre staff, before any investigation is undertaken. The head of centre is requested to inform the Investigations Team by submitting a *JCQ Form M2(a)* (available at www.jcq.org.uk/malpractice) with supporting documentation to pqsmalpractice@pearson.com. Where Pearson receives allegations of malpractice from other sources (for example Pearson staff, anonymous informants), the Investigations Team will conduct the investigation directly or may ask the head of centre to assist.

Incidents of maladministration (accidental errors in the delivery of Pearson qualifications that may affect the assessment of learners) should also be reported to the Investigations Team using the same method.

Heads of centres/principals/chief executive officers or their nominees are required to inform learners and centre staff suspected of malpractice of their responsibilities and rights, please see section *6.15* of the *JCQ Suspected Malpractice in Examinations and Assessments Policies and Procedures* document.

Pearson reserves the right in cases of suspected malpractice to withhold the issuing of results/certificates while an investigation is in progress. Depending on the outcome of the investigation, results and/or certificates may not be released or they may be withheld.

We reserve the right to withhold certification when undertaking investigations, audits and quality-assurance processes. You will be notified within a reasonable period of time if this occurs.

Sanctions and appeals

Where malpractice is proven, we may impose sanctions or penalties.

Where learner malpractice is evidenced, penalties may be imposed such as:

- mark reduction for affected external assessments
- disqualification from the qualification
- debarment from registration for Pearson qualifications for a period of time.

If we are concerned about your centre's quality procedures, we may impose sanctions such as:

- working with you to create an improvement action plan
- requiring staff members to receive further training
- placing temporary blocks on your certificates
- placing temporary blocks on registration of learners
- debarring staff members or the centre from delivering Pearson qualifications
- suspending or withdrawing centre approval status.

The centre will be notified if any of these apply.

Pearson has established procedures for centres that are considering appeals against penalties and sanctions arising from malpractice. Appeals against a decision made by Pearson will normally be accepted only from the head of centre (on behalf of learners and/or members or staff) and from individual members (in respect of a decision taken against them personally). Further information on appeals can be found in our *Enquiries and appeals about Pearson vocational qualifications policy*, available on our website. In the initial stage of any aspect of malpractice, please notify the Investigations Team (via pqsmalpractice@pearson.com) who will inform you of the next steps.

Reasonable adjustments to assessment

Centres are able to make adjustments to assessments to take account of the needs of individual learners in line with the guidance given in the document *Supplementary guidance for reasonable adjustments and special consideration in vocational internally assessed units*. In most instances, adjustments can be achieved by following the guidance, for example allowing the use of assistive technology or adjusting the format of the evidence. We can advise you if you are uncertain as to whether an adjustment is fair and reasonable. Any reasonable adjustment must reflect the normal learning or working practice of learners in a centre or working within the occupational area.

Further information on access arrangements can be found in the Joint Council for Qualifications (JCQ) document *Adjustments for candidates with disabilities and learning difficulties, Access Arrangements and Reasonable Adjustments*.

Both documents are on our website.

Special consideration

Centres must operate special consideration in line with the guidance given in the document *Supplementary guidance for reasonable adjustments and special consideration in vocational internally assessed units*. Special consideration may not be applicable in instances where:

- assessment requires the demonstration of practical competence
- criteria have to be met fully
- units/qualifications confer a license to practice.

Centres cannot apply their own special consideration; applications for special consideration must be made to Pearson and can be made only on a case-by-case basis. A separate application must be made for each learner and certification claims must not be made until the outcome of the application has been received.

Further information on special consideration can be found in the Joint Council for Qualifications (JCQ) document *Adjustments for candidates with disabilities and learning difficulties, Access Arrangements and Reasonable Adjustments*.

Both of the documents mentioned above are on our website.

9 Centre recognition and approval

Centre recognition

Centres offering mandatory qualifications for the New Apprenticeship Standards must be listed on the Skills Funding Agency's Register of Training Organisations and have a contract to deliver the New Apprenticeship Standards.

Centres that have not previously offered BTEC competence-based qualifications need to apply for and be granted centre recognition and approval to offer individual qualifications.

Existing Pearson centres seeking approval to offer BTEC Competence-based qualifications for the New Apprenticeship Standards, will be required to submit supplementary evidence for approval, aligned with the associated new standards and assessment requirements.

Guidance on seeking approval to deliver Pearson vocational qualifications is available at qualifications.pearson.com/en/support/support-for-you/work-based-learning.html

Approvals agreement

All centres are required to enter into an approval agreement, which is a formal commitment by the head or principal of a centre, to meet all the requirements of the specification and any associated codes, conditions or regulations. Pearson will act to protect the integrity of the awarding of qualifications. If centres do not comply with the agreement, this could result in the suspension of certification or withdrawal of approval.

10 Quality assurance

Quality assurance is at the heart of vocational qualifications and Apprenticeships.

Centres are required to declare their commitment to ensuring quality and to giving learners appropriate opportunities that lead to valid and accurate assessment outcomes.

Pearson uses external quality-assurance processes to verify that assessment, internal quality assurance and evidence of achievement meet nationally defined standards. Our processes enable us to recognise good practice, manage risk effectively and to support centres to safeguard certification and quality standards.

Our Standards Verifiers provide advice and guidance to enable centres to hold accurate assessment records and assess learners appropriately, consistently and fairly. Centres offering competence-based qualifications as part of the New Apprenticeship Standards will receive at least one visit from our Standards Verifier, followed by ongoing support and development. This may result in more visits or remote support, as required to complete standards verification. The exact frequency and duration of Standards Verifier visits/remote sampling will reflect the level of risk associated with a programme, taking account of the:

- number of assessment sites
- number and throughput of learners
- number and turnover of assessors
- number and turnover of internal verifiers
- amount of previous experience of delivery.

If a centre is offering a competence-based qualification alongside other qualifications related to the same Apprenticeship Standard, wherever possible, we will allocate the same Standards Verifier for both qualifications.

Following registration, centres will be given further quality assurance and sampling guidance.

11 Unit format

Each unit has the following sections.

Unit number

The number is in a sequence in the specification. Where a specification has more than one qualification, numbers may not be sequential for an individual qualification.

Unit title

This is the formal title of the unit that will appear on the learner's certificate.

Level

All units and qualifications have a level assigned to them. The level assigned is informed by the level descriptors defined by Ofqual, the qualifications regulator.

Unit type

This says if the unit is mandatory or optional for the qualification. See information in *Section 4 Qualification structure* for full details.

Credit value

All units in this qualification have a credit value. The minimum credit value is 1 and credits can be awarded in whole numbers only.

Guided Learning Hours (GLH)

Guided Learning Hours (GLH) is the number of hours that a centre delivering the qualification needs to provide. Guided learning means activities that directly or immediately involve tutors and assessors in teaching, supervising, and invigilating learners, for example lectures, tutorials, online instruction and supervised study.

Pearson has consulted with users of the qualification and has assigned a number of hours to this activity for each unit.

Unit summary

This summarises the purpose of the unit and the learning the unit offers.

Additional information

This provides additional clarification where appropriate on the range of requirements for the assessment of the unit. Learners must provide evidence according to each of the requirements stated in this section.

Standard Operating Procedures

Learners should be able to analyse data and use equipment, methods and other technology in accordance with Standard Operating Procedures (SOPs). Learners should therefore understand and follow the SOP related to their own practice, consulting and taking advice from colleagues where appropriate.

Learning outcomes

The learning outcomes set out what a learner will know, understand or be able to do as the result of a process of learning.

Assessment criteria

The assessment criteria specify the standard the learner is required to meet to achieve a learning outcome.

Unit 1: Skills for Life-long Learning

Level: 4

Unit type: Mandatory

Credit value: 2

Guided learning hours: 16

Unit summary

In this unit, you will develop the study skills that are needed for successful study and to support lifelong learning. The unit will support you to identify and analyse your learning abilities and requirements and develop your study plan.

Additional information

AC1.1 includes:

- self-motivation
- self-direction
- self-discipline
- critical thinking
- accountability
- problem solving
- taking responsibility for their own learning
- managing own time
- setting own goals.

AC1.2 includes:

- online databases
- scientific papers.

AC1.3 includes:

- essays
- reports
- presentations in meetings and to groups
- taking effective notes.

AC1.4 includes:

- presenting information using numbers and charts.

AC2.2 includes:

- quoting the work or ideas of others without acknowledgement
- inadequate referencing, including inaccurate formatting
- taking information from electronic or other sources without acknowledgement
- paraphrasing, i.e. altering some words or order with acknowledgement
- collusion, i.e. collaborating with others without acknowledging own contribution
- failure to acknowledge assistance
- use of material written by professional agencies or other persons
- self-plagiarism, i.e. submitting own work previously used for a qualification or not citing own earlier work
- false citation, i.e. cite sources not directly consulted.

Sources

www.ox.ac.uk/students/academic/guidance/skills/plagiarism?wssl=1

www.princeton.edu/pr/pub/integrity/pages/misreprestation/

AC3.1 includes:

- footnote style
- numbered style
- author-date style.

AC4.5 includes:

- colleagues and trusted individuals
- networks
- agencies that support learners, e.g. within an academic institution or own workplace.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to demonstrate the qualities and abilities required of an independent learner	1.1	Discuss the qualities required of an independent learner			
		1.2	Evaluate information from a variety of sources			
		1.3	Incorporate information into study and working practice			
		1.4	Present work in a range of formats			
		1.5	Interpret information using numbers and charts			
		1.6	Use information and communication technology (ICT) effectively in study and working practice			
		1.7	Explain own approach to solving problems			
		1.8	Explain the importance of critical reflection to support personal development			
		1.9	Explain the need and requirements for Continuing Professional Development			
2	Understand plagiarism and the importance and consequences of plagiarism	2.1	Explain the term plagiarism and the different forms plagiarism can take			
		2.2	Explain the consequences of plagiarism in the context of academic work, work-based assessment and Good Scientific Practice			
		2.3	Discuss the use and abuse of plagiarism software			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to correctly reference information sources	3.1	Explain the different methods for referencing information sources			
		3.2	Demonstrate the ability to reference information sources			
4	Be able to maintain own health and well-being	4.1	Explain the importance of maintaining own health and well-being			
		4.2	Explain measures taken to maintain own health			
		4.3	Discuss obstacles to own development as an effective learner and practitioner			
		4.4	Undertake measures to overcome potential obstacles			
		4.5	Explain the support mechanisms that are available to learners			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 2: Professional Practice and Person-centred Care

Level: 4

Unit type: Mandatory

Credit value: 5

Guided learning hours: 40

Unit summary

All patients and service users are entitled to a good standard of professional practice and probity from the healthcare science workforce, including the observance of professional codes of conduct and ethics. In this unit, you will develop an understanding of and consistently apply the principles of good scientific practice[1] (which sets out the principles, values and the standards of behaviour and practice for this workforce). You should also be clear about how these principles apply to the role of a Healthcare science associate. The unit consolidates and builds on learning from the Pearson BTEC Level 2 Diploma in Healthcare Science.

Additional information

AC1.1 includes:

- the Health Education England five key workforce characteristics
- the NHS Constitution
- NHS values, including compassion, transparency, candour, openness and leadership.

AC2.1 includes:

- structure of healthcare science into four divisions
- specialisms within each division
- the healthcare science career framework and requirements for progression
- education and training programmes
- leadership of the healthcare science profession (e.g. the role of the chief scientific officer)
- the role of the National School of Healthcare Science
- the Modernising Scientific Careers programme
- contribution of the healthcare science workforce to health and healthcare services.

[1] The Academy for Healthcare Science: Good Scientific Practice: www.ahcs.ac.uk/wordpress/wp-content/uploads/2013/09/AHCS-Good-Scientific-Practice.pdf

AC3.3 includes:

- how healthcare science services can work in partnership with patients and service users to ensure the views of patients are central to delivering, developing and maintaining high-quality, safe services
- the importance of supporting patients and the public to promote and manage their own health.

AC3.4 includes:

- how patients can and do contribute to healthcare science education in the academic and work-based setting.

AC3.8:

- should be assessed as informed consent applies to clinical care, research, audit and teaching
- should include limits of consent.

AC4.1 includes:

- providing all relevant information related to tests, investigations and treatment
- limits of confidentiality
- the importance of introducing self and explaining own role to every patient
- treating every person with compassion, dignity and respect, and maintain the confidentiality of the patient and patient information
- upholding the rights and autonomy of every patient
- explaining how to support patients to manage their own care as appropriate
- developing partnerships with patients/carers/families
- explaining the rights of patients with regard to giving informed consent for treatment when required.

AC5.1 includes:

- role of the Academy for Healthcare Science
- role of the Health and Care Professions Council.

AC5.2 includes:

- procedures to follow if cautioned, charged with a criminal offence, suspended, or have restrictions placed on personal scientific, clinical or professional practice anywhere in the world
- the need to work within own agreed scope of practice and the limits of own personal competence
- own role in the diagnostic and therapeutic process and in maintaining health and well-being
- seeking advice or refer to another professional appropriately
- exercising own professional duty of care
- exercising professional judgement and practising within the legal and ethical boundaries of the role of a healthcare science associate
- the need, where appropriate, to hold indemnity insurance
- the importance of probity and honesty in all aspects of own professional practice

- the importance of personal health and well-being to ensure personal performance and judgement is not affected by their own health.

Learning outcome 7 includes:

- how mental health conditions may influence a person's needs in relation to the care that they may require
- how positive attitudes towards those with mental health conditions, dementia or learning disabilities will improve the care and support they receive
- adaptations to own practice to support people with mental health conditions, including learning disabilities
- the meaning of mental capacity in relation to how care is provided.

AC7.7 includes:

- emotional literacy
- resilience.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the current structure and function of health and social care services in the UK	1.1	Describe the current structure and function of health and social care services in the UK			
		1.2	Discuss current national NHS policies and practice			
		1.3	Explain how own department implements a national policy			
		1.4	Assess the purpose of the NHS Constitution			
		1.5	Explain how the principles and core values of the NHS Constitution are embedded within own department			
2	Understand the structure of the healthcare science workforce and the role of the healthcare science associate	2.1	Explain the structure of the healthcare science workforce			
		2.2	Explain the role of the healthcare science associate, including their role within the multi-disciplinary team			
		2.3	Explain how the healthcare science associate contributes to the delivery of safe, quality assured high-quality healthcare			
		2.4	Explain how own role contributes to the delivery of safe, quality-assured healthcare			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the importance of patient-centred healthcare	3.1	Explain the importance of placing the patient at the centre of care			
		3.2	Explain the partnership between the patient and healthcare professional and the boundaries of that partnership			
		3.3	Discuss how patient-centred care translates into: • own organisation • own area of work • own practice.			
		3.4	Explain how the voice of patients and the public is embedded in all aspects of healthcare and healthcare science			
		3.5	Discuss the role of patient support groups in healthcare and healthcare science			
		3.6	Discuss the role of services/bodies supporting patients, e.g. Patient Advice and Liaison Service (e.g. PALS, Healthwatch)			
		3.7	Explain the need for openness and transparency in the management and delivery of healthcare			
		3.8	Explain how the legal framework for informed consent applies to clinical care, research, audit and teaching			
		3.9	Obtain and document appropriate consent in line with protocols			
4	Be able to place the patient at the centre of care at all times	4.1	Demonstrate patient-centred care in own working practice			
		4.2	Explain the key factors influencing the dignity, rights, privacy and confidentiality of patients/colleagues			
		4.3	Evaluate how critical reflection helps maintain and support the quality and safety of patient care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Understand the requirements for safe practice as a healthcare science associate	5.1	Explain the regulatory framework for the healthcare science workforce			
		5.2	Explain how the principles and values set out in Good Scientific Practice apply to own practice			
		5.3	Discuss how the standards of proficiency for a healthcare science associate apply to own role			
		5.4	Discuss why high levels of probity are required for healthcare science associates			
		5.5	Explain what support is available when professionalism or ethics are compromised			
6	Be able to practice as a healthcare science associate safely and effectively within own scope of practice	6.1	Work within the agreed scope of practice for own role lawfully, safely and effectively			
		6.2	Engage in evidence-based practice			
		6.3	Make professional judgements drawing on appropriate skills and knowledge			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Be able to promote mental health and well-being	7.1	Explain the principles underpinning the promotion of mental health and well-being			
		7.2	Define the terms 'mental well-being', 'mental health' and 'mental ill health'			
		7.3	Know the prevalence of individuals who may experience mental health problems in the UK			
		7.4	Discuss the importance of promoting positive mental health			
		7.5	Discuss the factors that promote and protect mental health and well-being			
		7.6	Explain the needs and experiences of people with mental health conditions, dementia or learning disabilities in own area of work			
		7.7	Describe the key factors in protecting and supporting good mental health			
		7.8	Demonstrate the promotion of mental health and well-being in own setting			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 3: Legal and Ethical Context of Practice

Level: 4

Unit type: Mandatory

Credit value: 3

Guided learning hours: 24

Unit summary

The healthcare science workforce is committed to promoting the welfare and well-being of the patient over and above any personal considerations. In this unit, you will develop an understanding of the legal and ethical boundaries of your practice and when and how to seek advice. This unit includes some of the core knowledge and skills required to meet the Level 4 Apprenticeship Standard.

Additional information

AC1.3 includes:

The principles, guidance and law with respect to:

- medical ethics
- people's right to privacy and confidentiality, including after they have died
- informed consent and how to gain informed consent
- the limits of informed consent
- equality and diversity
- safeguarding
- the use of chaperones.

AC2.1 includes:

- the need to maintain a complete record.

AC2.4 includes:

- safeguarding, if involved in direct patient care.

AC3.2 includes:

- the need to take account of individual physical, psychological, religious and cultural needs when delivering healthcare.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the ethical, legal and governance requirements arising from working at the level of a healthcare science associate	1.1	Explain how Good Scientific Practice sets the principles and values for the healthcare science workforce			
		1.2	Discuss the ethical, legal and governance requirements arising from working at the level of healthcare science associate			
		1.3	Explain own role and career within healthcare science			
2	Be able to work in accordance with the information governance legal framework	2.1	Explain the principles, guidance and law with respect to information governance			
		2.2	Discuss the safe and effective use of health and social care information			
		2.3	Explain when, and how, to share information and advice between peers in accordance with current legislation and policy			
		2.4	Demonstrate the ability to take responsibility for the care you provide and its impact on patients			
		2.5	Maintain accurate records in accordance with applicable legislation, protocols and guidelines			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand equality and diversity legislation	3.1	Explain current equality and diversity legislation and policies and local ways of working			
		3.2	Explain the impact of culture, equality and diversity on practice and what this means for own role			
		3.3	Describe the social model of disability and how it underpins positive attitudes towards disability and involving people in their own care			
		3.4	Analyse how stereotyping can increase stigma and negative attitudes towards people with disabilities and those experiencing mental health problems			
4	Understand how to practice in a non-discriminatory manner in accordance with the Equality Act 2010	4.1	Explain the consequences of not meeting the requirements of the Equality Act 2010			
		4.2	Explain the need to take account of individual physical, psychological, religious and cultural needs when delivering healthcare			
		4.3	Explain how you address a patient, carer or service user's needs in own practice			
		4.4	Explain the need to respect and uphold the rights, dignity, values and autonomy of patients			
		4.5	Explain the need to address issues of inequality of service provision for all communities			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 4: Health, Safety and Security in the Healthcare Science Environment

Level: 4

Unit type: Mandatory

Credit value: 3

Guided learning hours: 25

Unit summary

In this unit, you will develop the knowledge and skills to be able to establish and consistently maintain a safe and secure healthcare science environment, drawing on the knowledge, skills, attitudes and behaviours required for safe and effective practice. This unit includes some of the core knowledge and skills required to meet the Level 4 apprenticeship standard.

Additional information

AC1.1. includes:

- the role of national organisations, e.g. NHS England
- how effective communication underpins high-quality and safe patient services/patient care, including shared decision making
- how current health and safety legislation and regulations impact on the healthcare science work environment
- how duty of care contributes to safe practice
- why it is important that the healthcare science workforce takes reasonable care of health and safety at work for themselves, members of their team and others.

AC1.3 includes:

- health and safety legislation
- departmental guidelines
- organisational regulations.

AC1.5 includes:

- requirements of the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013.

AC4.1 includes:

- the individual
- healthcare staff
- patients
- the public.

AC4.2 includes:

- categorisation of near misses and clinical incidents
- analysis of near misses and clinical incidents
- definition of terms 'never events' and serious untoward incidents
- strategies to reduce 'never events' and serious untoward incidents in own organisation.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to maintain a safe, secure and healthy working environment, working within regulations, legislation and codes of practice	1.1	Discuss the wider context of safety in the NHS, including how the culture of an organisation influences safety			
		1.2	Apply current regulations with respect to service user safety and safe systems within own area of work			
		1.3	Know the role of the Health and Safety Executive in patient and service user incident investigation			
2	Be able to use equipment safely in the healthcare science work environment	2.1	Explain the regulations and current procedures governing the use of equipment found in own work setting			
		2.2	Assess the risks and implications of using defective equipment in own area of practice			
		2.3	Demonstrate use of relevant equipment within manufacturers' guidelines and relevant protocols and procedures			
		2.4	Take remedial action for common equipment faults in line with own organisation's policy			
		2.5	Select appropriate personal protective equipment and use it correctly			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to control infection risks in accordance with departmental protocols	3.1	Explain organisational guidelines and protocols for hygiene and infection control			
		3.2	Apply own organisation's protocols for hygiene and infection control in own area of practice			
4	Understand the need to maintain a safe, secure and healthy working environment	4.1	Explain the importance of health, safety and security in own area of work			
		4.2	Explain the actions that may be taken to manage risks and improve patient safety in healthcare settings			
		4.3	Explain the critical incident reporting process in own area of practice			
		4.4	Discuss the importance of promoting a no-blame culture			
		4.5	Explain approaches to procedures for identifying and reporting critical incidents in own organisation			
		4.6	Explain procedure for receiving and responding to complaints in own organisation			
		4.7	Identify two recent critical incidents and analyse the incident, including cause and agreed actions			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 5: Technical Scientific Services

Level: 4

Unit type: Mandatory

Credit value: 5

Guided learning hours: 40

Unit summary

In this unit, you will develop the knowledge and skills to be able to undertake key technical and scientific tasks aligned to the Level 4 apprenticeship standard, including quality.

Additional information

AC2.5 includes:

- Standard Operating Procedures
- advice from senior colleagues.

Learning outcome 4 includes:

- preventative maintenance
- fault finding
- calibration.

AC4.1 includes:

- specification
- procurement
- commissioning
- preventative maintenance
- fault finding and repair
- calibration
- safety testing and decommissioning.

AC4.3 includes:

- adherence to appropriate infection prevention control techniques.

AC4.4 includes:

- preparation
- performance
- equipment management skills, which could include:
  - preventative maintenance or
  - fault finding or
  - calibration
- record keeping
- reporting procedures
- problem solving.

AC5.3 includes:

- Department of Health, Central Alerting System, Medical Device Alerts.

AC7.3 includes:

- seeking advice when required
- recording and reporting the outcome of risk assessments.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the range of technical scientific services provided within own working context	1.1	Explain how the technical scientific services contribute to individual patient care and patient care pathways			
		1.2	Explain the links to services available in other healthcare science specialisms that may be involved in ongoing patient care			
		1.3	Identify the appropriate technical investigations for relevant clinical conditions			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to work within protocols and procedures in patient investigation, treatment or management	2.1	Explain the development of protocols and procedures in own job role			
		2.2	Assess the importance of protocols and procedures for the services provided within own working context			
		2.3	Apply own organisation's protocols and procedures within own work area			
		2.4	Undertake a range of activities with respect to healthcare science technical data, including: • analysis • interpretation • recording • presenting			
		2.5	Demonstrate the ability to make reasoned decisions to initiate/continue/modify or cease using techniques/procedures			
		2.6	Identify and explain approaches to effective problem solving			
		2.7	Recognise problems and seek technical solutions to them			
		2.8	Critically evaluate the evidence base that underpins own technical practice			
3	Be able to participate in drafting Standard Operating Procedures (SOPs)	3.1	Explain the purpose of Standard Operating Procedures			
		3.2	Explain the requirements for drafting Standard Operating Procedures			
		3.3	Participate in drafting Standard Operating Procedures in own area of work			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to perform a range of equipment management skills	4.1	Discuss each stage of the equipment management life cycle and its implementation in own area of work			
		4.2	Explain the importance of control of infection and decontamination within the equipment management life cycle			
		4.3	Comply with local decontamination procedures in own area of work			
		4.4	Perform a range of equipment management skills			
5	Understand the terminology and process that underpins a safe, quality-assured healthcare science service	5.1	Explain the terms: • quality management • quality control • quality assurance • quality improvement • quality methodologies • quality processes and procedures			
		5.2	Explain the principles and practice of quality control, external quality assessment and quality management in own work area			
		5.3	Explain the processes for the distribution of documentation			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to apply and maintain quality standards to assure the validity of routine scientific and technical investigations	6.1	Apply and maintain quality standards to assure the validity of routine scientific and technical investigations			
		6.2	Perform required quality control, assessment and management techniques in own area of work			
		6.3	Explain the common causes of error in own area of practice			
		6.4	Participate in quality-assurance programmes			
		6.5	Define the terms clinical governance and clinical effectiveness			
		6.6	Discuss how clinical governance contributes to the quality of healthcare services			
7	Be able to perform risk assessments	7.1	Explain the approach to risk management in own organisation and department			
		7.2	Discuss own role and responsibilities for risk assessment			
		7.3	Perform risk assessments in accordance with the standard operating procedure			
		7.4	Monitor the effectiveness of the action plan			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 6: Effective Communication in Healthcare

Level:	**4**
Unit type:	**Mandatory**
Credit value:	**4**
Guided learning hours:	**35**

Unit summary

Effective communication skills are fundamental to healthcare and healthcare science. In this unit, you will develop the knowledge and skills needed to communicate effectively with people across a range of situations in the workplace. This unit includes some of the core knowledge and skills required to meet the Level 4 apprenticeship standard.

Additional information

AC1.4 includes:

- the importance of observing and being receptive to an individual's reactions when communicating with them.

AC1.5 includes:

- use of interpreters.

AC2.2 includes:

- the adjustments needed for patients/carers/service users who do not have English as a first language
- the adjustments needed to communicate with people with sensory and/or cognitive impairments.

AC3.1 includes[2]:

- verbal
  - tone
  - volume
  - use of scientific language appropriate to the audience

[2] Source: The Care Certificate Standards adjusted to Level 4 and the healthcare science associate role

- non-verbal
    - position/proximity
    - eye contact
    - body language
    - touch
    - signs
    - symbols and pictures
- writing
- objects of reference
- human and technical aids.

AC3.2 includes:

- face-to-face
- by telephone or text
- by email, internet or social networks
- by written reports or letters
- communication in workplace and academic setting
- developing skills in listening, observing and using feedback.

AC3.4 includes:

- social media[3] and networking sites.

AC3.5 includes:

- providing patients with the information they want or need to know in a way they can understand.

AC4.1 includes:

- feedback in the context of:
    - personal development
    - appraisal
    - healthcare services.

AC5.2 could include:

- audit findings
- teaching
- job interview
- research findings.

AC5.3 includes:

- different technological options for oral presentation.

[3] Social media describes web-based applications that allow people to create and exchange content. In this guidance, we use the term to include blogs and microblogs (such as Twitter®), internet forums, content communities (such as ®, flickr™, YouTube™), and social networking sites (such as Facebook®, LinkedIn®).

AC5.5 could include:

- presentation software
- interactive whiteboards
- tablets
- online collaboration tools, such as those in Google™Apps

AC6.1 includes:

- selecting the technology appropriate to the subject and audience.

AC7.3 includes:

- drawing on personal experience, where possible.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles that underpin effective communication in a healthcare science and academic setting	1.1	Analyse the principles that underpin effective verbal and written communication within own role			
		1.2	Explain the meaning and importance of non-verbal communication and how this can support effective communication			
		1.3	Evaluate the barriers to effective communication and ways to reduce barriers to effective communication			
		1.4	Explain how to check whether information or advice has been understood			
		1.5	Explain where to find information and support or services to help with effective communication			
		1.6	Discuss how effective communication can promote patient-centred care and improve safety and quality of the patient experience			
2	Understand how to meet the communication and language needs, wishes and preferences of individuals	2.1	Explain how to establish an individual's communication and language needs, wishes and preferences			
		2.2	Discuss a range of communication methods and styles that could help meet an individual's communication needs, wishes and preferences			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to use appropriate verbal and non-verbal communication in own role	3.1	Explain the importance of active listening, observation and the use of appropriate language and feedback			
		3.2	Communicate effectively with patients and colleagues, adapting communication methods as appropriate to the situation			
		3.3	Develop skills in listening, observing and using feedback in own area of work			
		3.4	Use all forms of spoken, written and digital communication responsibly when communicating with patients and colleagues			
		3.5	Ensure that arrangements are made, wherever possible, to meet patients' language and communication needs			
		3.6	Explain how patient leaflets and other appropriate media methods can be used to engage with patients, donors and carers and the public			
4	Be able to give effective feedback	4.1	Explain the importance of giving and receiving feedback			
		4.2	Discuss the characteristics of effective feedback			
		4.3	Analyse a range of feedback models appropriate to own role			
		4.4	Use a feedback model to give effective feedback to colleagues or patients			
		4.5	Convey scientific and technical information to agreed protocols to the public, patients, carers, colleagues, including giving and receiving feedback			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Understand the use of technology to present information orally	5.1	Explain scenarios where an oral presentation may be required			
		5.2	Explain the type of audience you might encounter and how that could impact on the presentation			
		5.3	Discuss different formats for oral presentations using technology			
		5.4	Discuss strategies to actively engage the audience			
		5.5	Discuss potential pitfalls in using technology to present information orally			
6	Be able to use technology to present information orally in accordance with best practice guidelines	6.1	Plan an oral presentation appropriate to the purpose and audience			
		6.2	Design a method of collecting audience feedback			
		6.3	Rehearse the presentation, including timings			
		6.4	Deliver the presentation to the audience using appropriate technology and communicating effectively			
		6.5	Evaluate feedback to inform future oral presentations			
		6.6	Produce a development plan to use to deliver future presentations			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Understand how to deal with confrontation and difficult situations in own area of work	7.1	Explain the factors and difficult situations that may cause confrontation			
		7.2	Explain how communication can be used to solve problems and reduce the likelihood or impact of confrontation			
		7.3	Explain how to assess and reduce risks in confrontational situations			
		7.4	Discuss how and when to access support and advice about resolving conflicts			
		7.5	Explain the agreed ways of working within your role for reporting any confrontations			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 7: Audit, Research, Development and Innovation

Level: 4

Unit type: Mandatory

Credit value: 5

Guided learning hours: 20

Unit summary

Audit, research, development and innovation are an important part of the work of the healthcare science workforce, contributing to the creation of new scientific knowledge and driving innovation for patient benefit. In this unit, you will be introduced to audit, research, development and innovation, and the contribution made by healthcare science and the healthcare science associate to these areas of practice. This is a requirement of the Level 4 apprenticeship standard.

Additional information

AC1.2 includes:

- the evaluation of treatment efficacy, the research process and research methodologies, and the benefits of research to the critical evaluation of practice.

AC1.4 includes:

- creating new knowledge
- driving innovation, including new technology, new scientific techniques (e.g. genomics and personalised medicine; diagnostics)
- new ways of working
- innovation in education
- new models of care.

AC2.1 includes:

- contribution to patient care
- the effectiveness of services
- service improvement.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to undertake appropriate research, development and innovation activities which support quality improvement in own area of work	1.1	Explain the scientific research process			
		1.2	Explain how and why research and development is undertaken within governance and ethical frameworks			
		1.3	Describe the principles and applications of scientific enquiry			
		1.4	Explain the principles of developing and introducing innovation into practice			
		1.5	Discuss the contribution of the healthcare science workforce to research, development and innovation			
		1.6	Explain ways in which the individual healthcare science associate can support the wider healthcare team in the spread and adoption of innovative technologies and practice			
		1.7	Assess the value of research to the critical evaluation of practice			
		1.8	Perform research and innovation activities which support quality improvement in own area of work			
		1.9	Perform research and innovation activities in accordance with ethical and research governance approval			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the principles and practice of audit in healthcare science	2.1	Explain the role of audit and the audit cycle in healthcare science			
		2.2	Discuss the ethical and governance framework applied to audit			
		2.3	Explain how audit contributes to patient care, the effectiveness of services and service improvement			
3	Be able to participate in scientific and technical audit in own area of work	3.1	Assist in the design, data collection, data analysis and reporting within the clinical audit cycle			
		3.2	Participate in service improvement programmes in own area of work			
		3.3	Lead a quality-management technical audit process			
		3.4	Communicate the outcome of audit and service improvement to senior colleagues to inform future actions			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 8: Leadership and Team Work

Level: 4

Unit type: Mandatory

Credit value: 3

Guided learning hours: 24

Unit summary

The NHS Leadership Academy states that: 'The Healthcare Leadership Model is to help those who work in health and care to become better leaders. It is useful for everyone – whether you have formal leadership responsibility or not, if you work in a clinical or other service setting, and if you work with a team of five people or 5,000.'

In this unit, you will be introduced to the key concepts of leadership, including looking at the skills, qualities and abilities of effective leaders and how your personal qualities affect the experiences of patients and service users, the organisation, the quality of care provided, and the reputation of the organisation itself. You will be expected to have the skills to lead and work effectively in a healthcare science team. This is a requirement of the Level 4 apprenticeship standard.

Additional information

Learning outcome 2

This learning outcome requires learners to consider the personal qualities of leaders from areas such as politics, sport, healthcare, the voluntary sector.

AC2.2 includes:

- patients/carers/service users
- the organisation
- the quality of care provided
- the reputation of the organisation itself.

AC3.1 includes:

- generic principles of effective team work
- how these generic principles translate into your own organisation:
    - the composition of the teams within own area of work:
        - team structure
        - team objectives
        - lines of reporting
        - responsibilities, including limits of own responsibility
        - when and how to seek support and advice
    - how to develop trust and accountability
    - the leadership of teams within own area of work
    - the values of own organisation
    - the values of teams within own area of work
    - the contribution of each team member
    - how to communicate effectively within teams, and the impact of both positive and negative communication
    - potential barriers to effective multidisciplinary team working
    - how conflict may arise in teams and affect team and personal performance
    - strategies to resolve/overcome conflict.

AC4.2 could include:

- leading quality-management processes
- leading technical audit
- planning the work of a team and the individuals within it
- assessing the work of a team and the individuals within it
- supporting others to provide good patient care and better services
- chairing small group activities and seeking feedback on effectiveness
- holding office and gaining respect, e.g. as an officer in a course committee, professional body
- supporting and motivating others within own team, group learning etc.
- leading on a departmental initiative
- acting as a positive role model
- providing feedback about teaching and learning experiences in order to improve education provision
- taking opportunities to question more senior staff about future directions and scenarios
- attending relevant national and regional events
- researching appropriate sources of information to support learning
- taking part in student/staff committees, e.g. to review the effectiveness of initiatives.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles underpinning the current NHS leadership framework	1.1	Analyse the difference between leadership and management			
		1.2	Discuss the structure of the leadership of the NHS			
		1.3	Discuss the structure of the leadership of the healthcare science workforce			
		1.4	Explain the concept of leadership and its application to practice			
2	Understand the personal qualities associated with effective leaders	2.1	Discuss the skills, qualities and abilities of effective leaders			
		2.2	Discuss how what the learner does and how they behave affects the experiences of others and the organisation			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand how team work contributes to high-quality, safe and patient-centred services and care in own area of work	3.1	Evaluate the underpinning principles of effective team work and working within and across professional boundaries			
		3.2	Explain the key roles of the healthcare professions that contribute to the multi-disciplinary team in own work area			
		3.3	Evaluate how own role contributes to the work of teams in own area of work			
		3.4	Analyse the stages of team development			
		3.5	Evaluate the contribution of the multi-disciplinary team to patient care, patient safety and quality outcomes			
		3.6	Explain how to promote a 'no-blame culture' within a team			
4	Be able to work constructively and effectively within multi-disciplinary teams	4.1	Plan and monitor the work of a team and individuals within it to ensure routine work is completed to the required standard			
		4.2	Lead an activity of a team to support effective patient care and provision of services			
		4.3	Support team members in own area of work			
		4.4	Work as part of a multidisciplinary team to ensure effective patient care, patient safety and quality outcomes			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 9: Teaching, Learning and Assessing Practical Skills

Level: 4

Unit type: Mandatory

Credit value: 4

Guided learning hours: 32

Unit summary

In this unit, you will develop the knowledge and skills needed to teach and assess a range of practical skills required by new and junior team members. You will train junior staff in relevant health, safety and security practices, including infection control. This is a requirement of the Level 4 apprenticeship standard.

Additional information

AC1.3 includes:

- the key principles of adult learning
- the key principles of learner-centred teaching and learning
- how people learn
- active learning
- the process of teaching and learning practical skills.

AC1.4 includes:

- the importance of the learning environment:
  - specific aspects of the learning environment
  - importance of a positive and supportive environment
- Maslow's Hierarchy of Needs and relationship to teaching and learning practical skills.

AC2.3 includes:

- selection criteria.

AC4.4 includes:

- setting out an action plan to inform future practical skills teaching and assessment sessions.

AC5.2 includes:

- the characteristics of effective feedback.

Learning outcome 6 includes infection control.

AC6.5 includes:

- self-assessment
- learner feedback.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand how people learn and key theories of teaching, learning and assessing practical skills	1.1	Define the terms teaching and learning			
		1.2	Explain the three domains of learning: Psychomotor, Cognitive and Affective			
		1.3	Discuss the key theories of teaching, learning and assessment of practical skills			
		1.4	Discuss the physical and psychological conditions that support learning			
2	Understand the process of teaching, learning and assessing a practical skill	2.1	Compare different skills frameworks for teaching and learning practical skills			
		2.2	Discuss the principles underpinning the assessment of practical skills			
		2.3	Evaluate the range of tools available to assess practical skills			
3	Be able to plan for practical skills teaching sessions in own area of work	3.1	Explain a range of frameworks for planning teaching of practical skills			
		3.2	Use a framework to plan to meet the objectives of the practical skills teaching sessions			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to teach and assess junior staff a range of practical skills in own area of work	4.1	Deliver effective practical teaching sessions to meet the needs of own area of work			
		4.2	Plan the assessment of a range of practical skills to meet identified criteria for the area			
		4.3	Assess junior staff performing practical skills in own area of work			
		4.4	Critically reflect on each teaching and assessment session to inform future practice			
5	Be able to use a learner-centred approach to feedback to support learning of practical skills	5.1	Define the term feedback in the context of improving/maintaining learning			
		5.2	Discuss the role of feedback in healthcare science			
		5.3	Assess a range of feedback models appropriate to teaching and learning practical skills			
		5.4	Use a learner-centred approach to feedback following each practical skills teaching session			
		5.5	Use a learner-centred approach to provide feedback for practical skills teaching sessions			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to train junior staff in relevant health, safety/security practices in own area of work	6.1	Discuss own role in training junior colleagues and how this contributes to the delivery of high-quality healthcare			
		6.2	Explain competence and how it can be assessed in own area of work			
		6.3	Plan training sessions for junior staff in relevant health, safety, security practices			
		6.4	Deliver training sessions for junior staff in relevant health, safety, security practices			
		6.5	Evaluate training sessions for junior staff in relevant health, safety, security practices to inform future practice			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 10: Continuing Personal and Professional Development

Level: 4

Unit type: Mandatory

Credit value: 3

Guided learning hours: 20

Unit summary

In this unit, you will develop the knowledge and skills required to engage in continuing personal and professional development. This is a requirement of the Level 4 apprenticeship standard.

Additional information

AC1.3 could include:

- interesting or challenging events
- specific cases or patients you have seen
- feelings or emotions that you have had
- problems you have encountered
- professional situations
- practical skills acquired
- knowledge and understanding acquired
- attitudes challenged or changed
- ethical dilemmas encountered
- dealing with death or dying patients.

AC1.4 and 1.5 include:

- use of each reflection to plan, modify and monitor own professional development.

AC2.1 includes:

- the importance of personal health and wellbeing to fitness to practice
- the need to maintain high standards of personal, professional and business conduct
- the importance of protecting patients from risk or harm
- own role in the diagnostic and therapeutic process, and in maintaining health and well-being

- ensuring personal performance and judgement are not affected by own health
- the risks presented by another person's conduct, performance, or health
- what to do when concerns are identified or raised
- acting without delay on concerns raised by patients or carers, or if you have good reason to believe that you or a colleague may be putting people at risk
- making sure that own conduct justifies the trust of patients, carers and colleagues at all times
- maintaining the public's trust in the scientific profession.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to critically reflect on own practice to support continuing personal and professional development (CPPD)	1.1	Evaluate the process and models of critical reflection			
		1.2	Discuss the range of experiences that could form the basis of reflection			
		1.3	Critically reflect on own practice as part of a commitment to regular CPPD			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to demonstrate continuing personal and professional development (CPPD)	2.1	Explain the importance of maintaining own fitness to practice			
		2.2	Maintain own fitness to practice as a healthcare science associate			
		2.3	Explain the rationale for engaging in CPPD and critical reflective practice			
		2.4	Evaluate methods for recording, learning, developing and evaluating CPPD action plans			
		2.5	Use appropriate methods to keep own professional, scientific and technical knowledge and skills up to date			
		2.6	Assess the range of experiences that can contribute to continuing personal and professional development			
		2.7	Develop a personal development action plan			
		2.8	Monitor own personal and professional development to adapt to changing situations as required			
		2.9	Respond constructively to the outcome of appraisals and performance reviews			
		2.10	Evaluate sources of information and advice on own occupational training and career			
		2.11	Develop a career plan appropriate to own position			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to supervise and mentor junior members of the team	3.1	Explain the purpose of supervision and mentoring junior members of the team			
		3.2	Discuss how supervision and mentoring relate to own role			
		3.3	Explain the underpinning theories of mentoring to support good mentoring practice			
		3.4	Supervise junior members of the team to carry out duties effectively/efficiently and support quality of patient care and provision of services			
		3.5	Mentor junior members of the team to support their CPPD			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 11: Scientific Basis of Healthcare Science: Clinical Science

Level: 4

Unit type: Optional

Credit value: 25

Guided learning hours: 200

Unit summary

In this unit, you will add a broad base to your scientific knowledge, laying the foundation on which to build your knowledge, skills and professional practice as you move through this programme of learning. You will be expected to consolidate your knowledge of embryology anatomy, physiology, pathology and the sociology of health and disease that underpin the practice of healthcare science.

You will be introduced to each subject area through the learning outcomes and associated additional information. You will then deepen, develop and apply your learning in the context of the healthcare science division and specialism in which you are working.

Additional information

AC1.1 to 1.7 include:

- structural
- chemical
- cellular
- tissue
- skin
- cellular, tissue and systems' responses to disease:
    - cell death
    - inflammation
    - neoplasia, e.g. carcinoma
    - hypertrophy
    - hyperplasia
    - tissue responses to injury and repair
- how the body changes from birth to old age.

Learning outcome 2 is designed to provide learners with a broad scientific foundation to their practice. This is a key principle of all healthcare science education and training programmes. Learners at Level 4 are expected to have this broad knowledge across all body systems but will then develop the knowledge that is specific to their specialist area of practice.

AC2.1 includes:

- introduction to embryology – key stages of development of the embryo.

AC2.4 includes:

- changes in structure and the resulting changes in function at birth.

AC2.5 includes anatomy, physiology, and pathology:

- skeletal system
- nervous system:
  - spinal cord and spinal nerves
  - brain and cranial nerves
  - sensory and motor systems
- endocrine system
- vision, hearing and equilibrium
- cardiovascular system, including blood and blood vessels
- respiratory system
- lymphatic system
- immune system
- gastrointestinal tract, including digestion and absorption of food, nutrition, the liver and liver function tests
- renal system
- electrolyte and acid-base balance
- hormonal mechanisms and control
- metabolism
- reproductive system:
  - reproductive cycles
  - key features of gametogenesis
  - differences in male and female gametogenesis
  - process of, and differences between mitosis and meiosis
  - the events in fertilisation
- abdomen, pelvis and perineum
- histology and cytology
- microbiology, including infection control
- treatment regimens, including antibiotics and antibiotic resistance
- virology
- biochemistry
- haematology
- immunology and histocompatibility.

AC2.6 requires the learner to apply their knowledge of anatomy and physiology by explaining how each of the body systems is affected by ONE common disease, recognising that some but not all common diseases will affect all systems.

Body systems include:

- skeletal system
- nervous system
- endocrine system
- vision, hearing and equilibrium
- cardiovascular system, including blood and blood vessels
- respiratory system
- lymphatic system
- immune system
- gastrointestinal tract, including digestion and absorption of food, nutrition, the liver and liver function tests
- renal system
- reproductive system.

AC3.1 includes the sociology of health and illness:

- patients' responses to illness and treatment:
    - the impact of psychological and social factors (including culture, age, ethnicity, gender, socio-economic status and spiritual or religious beliefs) on health and health-related behaviour
- health belief models
- diversity of the patient experience
- disability, including learning disabilities
- mental health
- potential health inequalities
- self-care
- impact of life-threatening and critical conditions
- patient involvement in decisions regarding their healthcare.

AC3.7 includes principles and methods for the rehabilitation of people, e.g.:

- visual impairment
- hearing impairment
- musculoskeletal impairment
- mental health, e.g. the benefits of mindfulness for improving wellbeing and mental health.

This topic area should also include the underpinning theoretical foundations and models, e.g. Health Belief Model, World Health Organisation (WHO) model of activity limitation (disability).

AC4.1 includes keeping up to date with developments in healthcare and healthcare science, identifying new and innovative scientific and technical developments and their application in healthcare science.

- Identifying, reading and evaluating the literature.
- Innovation in the NHS.
- Using innovation to improve services.
- Scientific and technical developments and their application in healthcare science.
- The role of the healthcare science workforce in innovation.

This could be evidenced in the portfolio using a range of activities, including attendance at meetings (and critical reflection of learning from the meetings), reading journals etc.

AC4.2 includes the potential impact of ONE innovative scientific and technical development in each of the four divisions of healthcare science:

- life sciences
- physiological sciences
- physical sciences
- clinical bioinformatics.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the structural, chemical, cellular and tissue organisation of the body and the cellular, tissue and systems' responses to disease	1.1	Describe the structural organisation of the body			
		1.2	Describe the chemical level organisation of the body			
		1.3	Describe the cellular level organisation of the body			
		1.4	Describe the tissue level organisation of the body			
		1.5	Explain the cellular responses to disease			
		1.6	Explain the tissue responses to diseases			
		1.7	Explain the systems' responses to diseases			
2	Understand the structure and function of all body systems and the effects of common diseases	2.1	Describe the key stages of development of the embryo			
		2.2	Explain the physiological changes that occur during birth in the mother			
		2.3	Explain the physiological changes that occur during birth in the baby			
		2.4	Describe one condition that results from an error during the embryological stages of development			
		2.5	Describe the anatomy and physiology of each body system			
		2.6	Explain the changes in structure and function that occur in response to a disease for each of the body systems			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the principles and core concepts of the sociology of health and illness	3.1	Explain the principles and core concepts of the sociology of health and illness			
		3.2	Explain the sociology of health and illness relevant to common disorders that result in a patient being referred to healthcare science services			
		3.3	Explain the sociology of health and illness relevant to a patient typically referred to own work place			
		3.4	Discuss the social, personal and economic effects of mental ill health			
		3.5	Discuss the impact of experiencing a mental health problem on individuals, family and society			
		3.6	Describe the biological, psychological and social aspects that predispose, precipitate and perpetuate mental health conditions			
		3.7	Discuss the principles and methods for rehabilitation of people commonly referred to healthcare science services or own area of work			
4	Be able to keep up to date with developments in healthcare and healthcare science	4.1	Discuss recent developments in healthcare and healthcare science			
		4.2	Discuss the potential impact of innovative scientific and technical development in each of the four divisions of healthcare science			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 12: Scientific Basis of Healthcare Science: Genetics, Genomics and Clinical Bioinformatics

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will be introduced to genetics, genomics and clinical bioinformatics, which for healthcare science spans genomics, health informatics science and physical science). This will provide you with a broad base for your scientific knowledge and professional practice, laying the foundation on which to build your knowledge, skills and professional practice as you move through this programme of learning.

You will be introduced to each subject area through the learning outcomes and associated additional information. You will then deepen, develop and apply your learning in the context of the healthcare science division and specialism in which you are working.

Additional information

Learning outcome 1

'Personalised/precision medicine' – as yet there is no standardisation of terms in this new area of science/medicine, so the terms are currently interchangeable.

AC1.1 includes the structure of the healthcare science division of clinical bioinformatics:

- genomics
- health informatics science
- physical sciences.

AC1.2–1.9 includes the principles and core concepts of clinical genetics, genomics and personalised/precision medicine in the context of patients referred to healthcare science services:

- meiosis and Mendelian inheritance
- nucleic acid structure and function
- chromosome structure and function

- nomenclature used to describe the human genome, how it is used and how it can influence a person's health
- common genetic disorders
- impact of genetic disorders on the patient and their families
- genomic technology and the role of the genome in the development and treatment of disease
- personalised medicine
- the role of genomic counselling.

AC2.1 includes an introduction to clinical bioinformatics and health informatics.

Clinical bioinformatics brings together the disciplines of computer science, mathematics, statistics and physics/engineering to influence, analyse and inform clinical and biological practice, so helping to maintain patient safety and the integrity and security of data. Learners should be introduced to the three specialisms of clinical bioinformatics in healthcare science (genomics, health informatics science and physical sciences) in the context of:

- innovation, translation and interpretation of complex genomic data, optimising the benefits this brings to patient care, including personalised medicine
- the development and adoption of technology solutions and biomedically motivated methods for the collection, management, movement, analysis and use of health information in line with government legislation to improve the quality and safety of healthcare practice and delivery
- devices that may have therapeutic, diagnostic or patient monitoring functions and generate ever-increasing amounts of data that contribute to patient management.

Teaching should be tailored to the learner group using examples relevant to health and healthcare science.

- Contribution of clinical bioinformatics genomics, health informatics sciences and physical sciences to:
    - patient safety
    - patient care
    - healthcare
    - healthcare science.
- Governance and ethical frameworks.
- Storage and sharing of images, Digital Imaging and Communications in Medicine (DICOM).
- Picture Archiving and Communications Systems (PACS).
- Clinical information systems and applications.
- Clinical information systems and applications, e.g. Health Level 7 (HL7).
- Database management.
- Direct patient access to test results.

AC2.2 should be assessed in the context of:

- patients referred to healthcare science services
- laboratory/investigative techniques.

AC2.3 includes:

- Digital Imaging and Communications in Medicine (DICOM)
- Picture Archiving and Communications Systems (PACS).

AC2.4 could include:

- Health Level 7 (HL7).

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and core concepts of clinical genetics, genomics and personalised/ precision medicine	1.1	Describe the structure of the Healthcare Science Division of Clinical Bioinformatics			
		1.2	Explain the terms genomics, genetics and personalised medicine			
		1.3	Explain the terms gene, DNA, chromosome, mutation			
		1.4	Explain the process of meiosis and Mendelian inheritance			
		1.5	Explain the structure and function of nucleic acid and chromosomes			
		1.6	Explain the fundamentals of the human genome			
		1.7	Explain the principles and core concepts of clinical genetics, genomics and personalised/precision medicine			
		1.8	Evaluate the potential impact of genetic disorders on patients and their families			
		1.9	Discuss some of the ethical issues that may arise in the use of genetic and genomic data			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the principles of clinical bioinformatics and the impact on health, healthcare and healthcare science services	2.1	Explain the contribution of clinical bioinformatics (genomics, health informatics sciences and physical sciences) to healthcare			
		2.2	Explain the governance and ethical frameworks underpinning clinical bioinformatics			
		2.3	Explain the principles of systems for the storage and sharing of images			
		2.4	Evaluate clinical information systems and applications within healthcare and healthcare science services			
		2.5	Explain the purpose and principles of database management within healthcare and healthcare science services			
		2.6	Discuss the advantages and disadvantages for patients and healthcare staff of providing direct patient access to test results			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 13: Scientific Basis of Healthcare Science: Pharmacology and Therapeutics

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

In this unit, you will be introduced to pharmacology and therapeutics in the context of patients referred to healthcare science services. This will provide you with a broad base on which to build your knowledge, skills and professional practice as you move through this programme of learning.

You will be introduced to each subject area through the learning outcomes and associated additional information. You will then deepen, develop and apply your learning in the context of the healthcare science division and specialism in which you are working.

Additional information

Learning outcome 1, includes:

- pharmaceutics
- pharmacokinetics
- pharmacodynamics
- therapeutics.

For AC2.5 give **three** common adverse drug reactions.

For AC2.8 give **three** different medications commonly prescribed for patients in own area of practice.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the general principles of pharmacology	1.1	Explain what is meant by generic and proprietary names of drugs			
		1.2	Know routes by which drugs can enter the body			
		1.3	Explain how drugs are absorbed into the body across cell membranes			
		1.4	Explain how drugs are distributed within the body, including barriers to their distribution			
		1.5	Explain the principles of drug interactions, biotransformation, detoxification and excretion			
		1.6	Explain the principles of drug effects on the body, for example how they can interact with receptors or interfere with enzyme function			
		1.7	Explain how the effect of a drug is related to its concentration			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand operational drug policies	2.1	Discuss the practical application of operational drug policies			
		2.2	Explain the role of the pharmacist in primary and secondary care			
		2.3	Know the regulatory requirements for the storage and disposal of medicines			
		2.4	Describe the mechanism and management of common adverse drug reactions			
		2.5	Describe the procedures for documentation and reporting adverse drug reactions			
		2.6	Know how to find information about a drug in a drug formulary			
		2.7	Explain the mode of action, the indications and contraindications, possible interactions and adverse effects and drug dosage for medication commonly prescribed for patients in own area of practice			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 14: Scientific Basis of Healthcare Science: Epidemiology and Public Health

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will be introduced to epidemiology and public health in the context of patients referred to healthcare science services. This will provide you with a broad base on which to build your knowledge, skills and professional practice as you move through this programme of learning.

You will be introduced to each subject area through the learning outcomes and associated additional information. You will then deepen, develop and apply your learning in the context of the healthcare science division and specialism in which you are working.

Additional information

AC1.4 includes:

- Public Health England and related UK organisations
- World Health Organisation.

AC2.1 includes:

- public health surveillance
- health protection
- health improvement
- infectious disease control and emergency planning.

AC2.2 includes:

- public health surveillance
- health protection
- health improvement.

For AC4.1 discuss the prevalence of **one** condition.

For AC4.3 evidence of the effectiveness of public health intervention should be assessed.

AC4.4 could include:

- vision impairment.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand basis of epidemiology, public health and evidence-based medicine	1.1	Define epidemiology and public health, and the relationship between them			
		1.2	Explain how the scientific methods of epidemiology and those methods used to study health conditions and diseases complement each other and contribute to evidence-based medicine			
		1.3	Discuss the incidence and prevalence of a common disease experienced by patients referred to own area of work			
2	Understand public health functions and how these can improve the health of populations	2.1	Explain the local, national and international role of the public health function			
		2.2	Compare public health functions in own UK country			
		2.3	Explain how changes in population demographics impact on public health			
		2.4	Explain the role of public health infectious disease services in control of infection and responding to infection outbreaks			
		2.5	Discuss the process and applications of health needs assessments			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the principles and applications of disease prevention and disease screening	3.1	Explain the three levels of disease prevention			
		3.2	Discuss criteria for disease screening programmes and limitations of screening			
		3.3	Explain the differences between screening tests and diagnostic tests			
		3.4	Assess screening programmes in the UK, their organisation and quality assurance			
		3.5	Explain the factors that lead to effective screening programmes			
4	Understand the relevance of epidemiology and the impact of public health programmes on own area of practice	4.1	Discuss the prevalence of a condition affecting patients referred to healthcare science services in the UK and internationally			
		4.2	Explain international, national and local initiatives to positively affect the conditions described in 4.1			
		4.3	Assess the evidence of the effectiveness of public health interventions			
		4.4	Explain procedures for certification and registration of people with a disability			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 15: Scientific Basis of Healthcare Science: Mathematics, Statistics and Physical Sciences

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will be introduced to mathematics, statistics and physical sciences in the context of the investigations and data analysis undertaken within healthcare science services. This will provide you with a broad base on which to build your knowledge, skills and professional practice as you move through this programme of learning.

You will be introduced to each subject area through the learning outcomes and associated additional information. You will then deepen, develop and apply your learning in the context of the healthcare science division and specialism in which you are working.

Additional information

AC1.1 and 1.2 include an introduction to mathematical and statistical techniques:

- SI metric system
- percentages
- mean
- median
- mode
- standard deviation
- interquartile range
- simple probability
- samples and population distributions
- reasons for sampling
- sample size
- data interpretation, including the variability of biological data and application of statistics
- generation of reference ranges and their limitations.

AC2.5 includes summarising data numerically:

- mean
- median
- mode
- standard deviation
- interquartile range.

AC2.6 includes summarising data graphically:

- histogram
- bar chart
- pie chart
- line graph (time-series)
- scatter graph.

AC3.1 and 3.2 include:

- structure of matter (atomic and nuclear models)
- radiation: nature and its measurement and radiation safety
- radiation dosemeters – personal dosemetry
- basic physics and mathematics of image formation
- imaging techniques:
    - ultrasound
    - magnetic resonance imaging
    - computerised tomography
    - positron emission computed tomography
    - single-photon emission computed tomography
- basic electricity and magnetism as it relates to the measurement of physiological signals
- viscous and inertial flow of simple liquids
- use of radiotherapy.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand mathematical and statistical techniques that underpin the practice of healthcare science	1.1	Explain common mathematical and statistical techniques that underpin the practice of healthcare science			
		1.2	Explain the strengths and weaknesses of the common mathematical and statistical techniques used in own area of work			
		1.3	Describe common presentation techniques for mathematical and statistical data			
2	Be able to apply mathematical and statistical techniques and present data in own area of practice	2.1	Explain how mathematical and statistical techniques are used in own area of practice			
		2.2	Apply mathematical and statistical techniques to data in own area of practice			
		2.3	Summarise healthcare science data numerically and graphically for presentation purposes			
		2.4	Discuss how to select a suitable data presentation technique to communicate the important messages in the data to the audience			
		2.5	Present data using presentation software			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the basic principles of physics and clinical engineering that underpin healthcare science	3.1	Explain the basic principles of physics that underpin healthcare science			
		3.2	Explain the basic principles of clinical engineering that underpin healthcare science			
		3.3	Discuss how physics principles are used within healthcare science services			
		3.4	Discuss how clinical engineering principles are used within healthcare science services			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 16: Point-of-care Testing

Level: 4

Unit type: Optional

Credit value: 5

Guided learning hours: 40

Unit summary

This unit gives you a foundation on which to build your knowledge, skills, experience and attitudes while undertaking point-of-care testing in a range of settings, which could include a hospital bedside, primary care facilities, the home, a workplace etc. You are required to demonstrate appropriate attitudes and behaviours, and integrate your learning as you develop your professional practice.

Additional information

While this unit has been developed for the BTEC Level 4 Diploma in Healthcare Science, the knowledge and skills it covers are relevant to any healthcare profession that includes undertaking point-of-care testing. Examples of diagnostic investigations that might be used at the point of care include:

cardiovascular risk assessment:

- blood-pressure measurement
- measurement of height, weight, waist-hip ratio etc.
- measurement of lipids
- urine testing

chronic disease monitoring:

- blood-pressure measurement
- measurement of height, weight, waist-hip ratio etc.
- measurement of lipids, fasting glucose, HbA1c
- spirometry

sexual health clinics/genitourinary medicine:

- rapid HIV testing
- nucleic acid amplification tests for chlamydia trachomatis and Neisseria gonorrhoeae
- detecting, managing and monitoring haemostasis and determining whether bleeding is a result of coagulopathies
- monitoring patients in acute settings, e.g. intensive care units, operating theatres.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.1 should include the perspectives of the service provider and patient.

Advantages

- Bringing the test conveniently and immediately to the patient.
- Results are available more quickly, enabling clinicians to support the timely diagnosis, monitoring and treatment of patients.
- Testing has been shown to:
    - reduce the length of a hospital stay
    - improve adherence to treatment
    - reduce complications.
- Opportunities to undertake opportunistic screening, including in patients who have traditionally been difficult to reach, e.g. people with mental health issues; people with physical disabilities.
- Testing is effective only if action is taken on the result.

Disadvantages that directly affect patient results and care include the following.

- Point-of-care testing requires trained operators to ensure a good-quality service.
- Poor quality of analysis.
- Poor record keeping.
- Lack of report interpretation.
- Failure to detect abnormal results.
- Unauthorised processing.
- Inappropriate testing.
- Result quality is often directly related to sample quality; a poor sample or incorrect analytical technique will yield poor results.

AC1.4 includes:

- calibration and quality measures (IQC and EQA) underpinning point-of-care testing.

AC2.2 includes:

- communicating effectively with the patient/carer
- explaining the procedure/s to the patient
- gaining and documenting informed consent.

AC2.4 – the results from **two** clinical presentations should be discussed.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in their own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the advantages and disadvantages of point-of-care testing	1.1	Discuss the advantages and disadvantages of point-of-care testing in healthcare			
		1.2	Evaluate the use of innovative technology for point-of-care-testing			
		1.3	Evaluate the benefits and limitations of a healthcare science point-of-care service in own work area			
		1.4	Explain how quality standards can be maintained for point-of-care testing			
		1.5	Explain the procedure for reporting and responding to problems identified with point-of-care equipment			
2	Be able to perform routine point-of-care testing as appropriate to own area of work	2.1	Explain the principles and practice of quality control, external quality assessment and quality management that underpin point-of-care testing in own area of work			
		2.2	Perform routine point-of-care testing to required quality standards			
		2.3	Discuss the result with the patient, completing all required documentation			
		2.4	Discuss the results obtained from point-of-care testing in the context of clinical presentations in own area of work			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 17: The Building Blocks of Life

Level: 4

Unit type: Optional

Credit value: 20

Guided learning hours: 160

Unit summary

In this unit, you will develop an understanding of the classification, structure and function of the human body, together with a knowledge of health, disease, disorder and dysfunction relevant to life sciences. You are expected to apply and contextualise your knowledge and skills, performing routine technical skills and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1–1.3 should include:

- glucose synthesis and storage, gluconeogenesis, glycolysis
- cholesterol synthesis and metabolism
- fatty acid synthesis and metabolism; triglycerides
- the assembly of amino acids into peptides and proteins
- essential amino acids.

AC1.4 requires **one** example, which could include:

- acquired, e.g.
  - diabetic ketoacidosis
  - hyperosmolar coma
  - hypoglycemia
- rare inborn errors of metabolism (i.e. genetic defects), e.g. episodic lactic acidosis.

AC1.5 requires **one** example, which could include:

- Gaucher's disease
- Tay-Sachs disease
- Niemann-Pick disease.

AC1.6 requires **one** example, which could include:

- oculocutaneous albinism
- phenylketonuria
- homocystinuria
- tyrosinemia
- maple syrup urine disease.

AC2.6 includes:

- definition of the term 'genetic mutation'.

AC2.10 includes the difference between:

- genetics
- genomics
- the term 'human genome'.

AC2.11 requires **two** examples, which could include:

- Down syndrome
- cystic fibrosis
- Huntington's disease
- sickle-cell disease
- haemophilia
- Turner syndrome
- Klinefelter syndrome
- Rett syndrome.

AC3.2 should include:

- protein synthesis; transcription
- translation
- post-translational modification.

AC3.3 should include:

- cell membrane
- enzymes
- antigens and antibodies
- receptors
- functional proteins:
    - haemoglobin
    - albumin
    - transport proteins
    - lipoproteins
    - immunoglobulins
    - hormones
    - cytokines etc.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the structure and function of the major classes of carbohydrates, lipids and amino acids, nucleic acids, genes and chromosomes	1.1	Explain the structure and function of the major classes of carbohydrates			
		1.2	Explain the structure and function of the major classes of lipids			
		1.3	Explain the structure and function of the major classes of amino acids			
		1.4	Discuss how disease leads to abnormal carbohydrate structure and function			
		1.5	Discuss how disease leads to abnormal lipid structure and function			
		1.6	Discuss how disease leads to abnormal amino acid structure and function			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the underpinning of genetics and the human genome	2.1	Explain the term 'cell biology' and how knowledge of cell biology contributes to own role			
		2.2	Explain the structure and function of chromosomes			
		2.3	Compare the process of meiosis and mitosis			
		2.4	Explain the process of chromosome segregation			
		2.5	Explain nucleic acid structure and function			
		2.6	Explain how gene mutations can be classified			
		2.7	Explain each mode of inheritance			
		2.8	Describe a genetic condition that illustrates each mode of inheritance			
		2.9	Explain sources of genetic variation			
		2.10	Discuss the ethical, legal and social implications of the development of genomics in healthcare			
		2.11	Explain the potential impact of genetic diseases on the patient and their families			
3	Understand the classification and role of proteins in the structure, integrity and function of biological systems	3.1	Explain how proteins are classified			
		3.2	Explain the process of biological systems			
		3.3	Explain the structure and function of biological systems			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 18: The Science Behind the Cure

Level: 4

Unit type: Optional

Credit value: 20

Guided learning hours: 160

Unit summary

In this unit, you will develop an understanding of how the life sciences are organised into scientific and clinical specialties, and how they interrelate. You will also gain an understanding of the nature of work performed in these specialties and the basics of good laboratory and/or departmental practice as applied to life sciences; spanning blood sciences; cellular sciences, including reproductive sciences; infection science, including decontamination science; genetic science and transfusion, and transplantation science. You will be expected to apply and contextualise your knowledge and skills, performing routine technical skills and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1 should include:

knowledge of the specialist areas of life sciences:

- anatomical pathology
- blood sciences (clinical biochemistry; haematology; clinical immunology; histocompatibility and immunogenetics)
- cellular sciences (cytology; histology)
- reproductive sciences (embryology and andrology)
- infection science (clinical microbiology, virology, serology, decontamination science)
- genetic and genomics science
- transfusion and transplantation science

and:

- scope and core practice
- equipment and systems used, including automation, robotics, analytical platforms, modular systems
- data generation, processing and reporting

- point-of-care testing systems or patients using medical devices in their home (e.g. renal dialysis, infusion devices), or hospital-based practice, e.g. in endoscopy
- provision of 24/7 services
- causes and investigation of common diseases where specimens are sent to life science departments, or decontamination of reusable medical devices as appropriate to the life science setting
- scope and core practice of molecular science in each healthcare science life science specialism.

Learning outcome 2

This should be contextualised to either a laboratory or decontamination science department, depending on own area of life science practice.

AC2.1 includes:

- quality standards
- quality management
- quality assurance
- Standard Operating Procedures
- audit
- accreditation.

AC2.1 – accreditation for blood, cellular, infection (microbiology, virology) and genetic science includes:

- United Kingdom Accreditation Service (UKAS) – Clinical Pathology Accreditation (CPA)
- Medicines and Healthcare products Regulatory Agency (MHRA).

Standards and accreditation for decontamination science includes:

- Medical Devices Regulations 2002
- Medical Devices Directive 93/42/EEC as amended by Directive 2007/47 EC (CE Marking Accreditation)
- BS EN ISO 13485:2016 Medical Device: Quality Management
- Health and Social Care Act 2008
- Joint Advisory Group on Gastrointestinal Endoscopy (JAG).

AC3.2 – the centre will need to provide case studies.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the role of life science services in healthcare	1.1	Discuss the role of life science services in the diagnosis, treatment and management of disease			
		1.2	Discuss the contribution of life science specialisms to screening programmes			
		1.3	Explain the equipment and methods used for decontaminating reusable medical devices			
2	Understand the basis of good laboratory/ departmental practice, including the handling of biological specimens	2.1	Evaluate the mechanisms that underpin the delivery of a quality-assured laboratory or departmental service			
		2.2	Evaluate the Standard Operating Procedures for handling biological specimens			
		2.3	Discuss the overall contribution of life sciences to healthcare and patient-centred care			
		2.4	Evaluate the role of professional bodies in life sciences for staff and patient care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of pathology services on patients and the patient care pathway	3.1	Evaluate the benefits and limitations of pathology services for patients and the patient care pathway			
		3.2	Discuss the improvements made to patient care following a critical incident			
		3.3	Evaluate how effective patient–practitioner partnerships operate in life sciences			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 19: General Laboratory Practice

Level: 4

Unit type: Optional

Credit value: 11

Guided learning hours: 88

Unit summary

In this unit, you will develop the knowledge, skills, experience and attitudes needed to work in a laboratory setting, often within life sciences. This unit will build on your learning from *Unit 2: Professional Practice and Person-centred Care*, and it will begin to integrate and embed many of the professional practice learning outcomes to support safe, quality-assured working practice in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP) and good manufacturing practice (GMP).

Learning outcomes and assessment criteria should be contextualised to either laboratory or decontamination science depending on own area of life science practice.

AC1.1 includes:

- control infection risks and hazards in accordance with departmental protocols.

AC1.3 includes, appropriate to own area of work:

- small volume (repeat pipetting of 0.5 microlitre samples and pipetting viscous fluids)
- maintenance
- calibration.

AC2.1 includes:

- use of both manual and automatic pipettes.

AC3.1 includes:

- temperature of storage facilities
- accurately recording conditions
- identifying if conditions are within required range
- reporting/responding to any errors/alarms
- seeking advice from senior staff when required.

AC3.2 includes:

- accurately recording conditions
- identifying if conditions are within required range
- reporting/responding to any errors/alarms
- seeking advice from senior staff when required.

AC3.3 includes:

- ensuring like lot numbers are stored together.

AC4.1 includes:

- known high-risk specimens
- paediatric specimens
- insufficient specimens
- unlabelled or inadequately labelled samples (including blood, cerebrospinal fluid (CSF), tissue samples).

AC4.2 includes:

- demonstrating correct handling according to health and safety, quality assurance and trust governance procedures.

AC4.6 includes:

- urgent specimens
- deteriorating specimens
- maintaining patient confidentiality.

AC4.7 includes:

- labelling
- insufficient preservative/anticoagulant
- incorrect preservative/anticoagulant
- unfixed.

AC4.8 includes:

- other sections of the laboratory
- other departments.

AC5.1 includes:

- ensuring maintenance records are up to date.

AC5.3 includes (appropriate to own area of work):

- balances
- centrifugation devices
- fridges and freezers
- microscopes
- plasma thawers
- safety cabinets
- water baths and other heating devices
- weighing equipment.

AC7.2 includes:

- how to safely dispose of specimens, including sharps
- Standard Operating Procedures for the disposal of biological specimens
- health and safety issues and use of personal protective equipment (PPE).

AC12.1 includes:

- written
- electronic
- verbal
- non-verbal
- adapting communication style and language to meet the needs of the listener.

AC12.2 includes:

- assist in identifying problems accurately
- increase patient satisfaction
- enhance treatment adherence
- reduce patient distress and anxiety.

AC12.3 includes:

- signposting
- listening
- language
- non-verbal behaviour
- ideas, beliefs, concerns, expectations
- summarising.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to perform laboratory techniques using a range of equipment in own work area	1.1	Demonstrate use of a range of laboratory/departmental apparatus in own work area			
		1.2	Explain the purpose of performing maintenance and calibration procedures on automatic pipettes			
		1.3	Use manual and automatic pipettes to prepare dilutions as appropriate to own work area			
2	Be able to prepare general laboratory/ departmental reagents, consumables or raw materials	2.1	Prepare dilutions and reagents appropriate to own area of work			
		2.2	Explain the importance of lot numbers and expiry dates for reagents, consumables or raw materials			
		2.3	Ensure storage and health and safety requirements are met in own area of work			
3	Be able to store laboratory equipment and consumables correctly and correct stock rotation is maintained	3.1	Record conditions and identify if within required range for specific assays			
		3.2	Correctly store reagents, kits and consumables			
		3.3	Demonstrate the ability to complete the required laboratory equipment and consumables storage documentation			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to perform the safe and secure receipt, handling and storage of biological specimens	4.1	Explain the correct procedures for dealing with biological specimens			
		4.2	Demonstrate the correct handling of specimens and request forms safely			
		4.3	Determine specimen processing requirements and prioritise according to specimen type and local standard operating procedures			
		4.4	Identify the specimen, container, anticoagulant, or preservative required			
		4.5	Perform procedures within own scope of practice for dealing with incorrect or inadequate samples and forms			
		4.6	Ensure other samples are sent to correct destination			
		4.8	Safely and correctly separate the sample if necessary			
		4.9	Place specimens in correct location and storage conditions before analysis or further processing			
		4.10	Access information management systems to enter patient and specimen data			
		4.11	File and archive data in accordance with data security and protection protocols			
		4.12	Explain the need to maintain confidentiality and data protection laws			
		4.13	Use specimen preparation equipment safely and correctly			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Understand the purpose and processes required for equipment maintenance	5.1	Explain how to identify operational status of equipment			
		5.2	Explain how equipment is maintained by external agencies			
		5.3	Discuss the difference between planned preventative maintenance, breakdown and testing and validation of equipment			
		5.4	Explain the role of the user and their responsibilities			
6	Be able to perform regular monitoring, checks and maintenance	6.1	Perform regular monitoring checks			
		6.2	Perform planned preventative maintenance			
		6.3	Perform validation procedures			
		6.4	Respond to breakdowns of equipment and where appropriate take remedial action			
		6.5	Complete appropriate records relevant to work area			
7	Be able to retrieve specimens from storage and correctly deal with add-on requests, completing appropriate documentation	7.1	Evaluate the SOPs for retrieving specimens/blood components from storage			
		7.2	Correctly deal with add-on requests			
		7.3	Complete appropriate documentation for the retrieval of stored specimens accurately			
		7.4	Evaluate the legislation and regulations covering the transport of specimens/blood components			
		7.5	Transport samples appropriately			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
8	Be able to safely dispose of biological specimens	8.1	Explain the requirements of the Human Tissue Act 2004 with respect to the safe disposal of biological specimens			
		8.2	Explain the principles and application of laboratory/departmental SOPs for safe disposal of biological specimens			
		8.3	Select appropriate personal and protective equipment for handling biological specimens			
		8.4	Identify biological specimens for disposal and retrieve from storage			
		8.5	Correctly dispose of specimens and medical devices			
		8.6	Complete all required documentation for the disposal of biological specimens			
9	Be able to evaluate the performance of one or more analysis methods	9.1	Justify the principles and practice of quality control, external quality assessment and quality management			
		9.2	Evaluate the performance of two analysis methods in own area of practice, including internal quality control and external quality assurance			
		9.3	Recommend corrective action where appropriate			
		9.4	Complete all required quality-control documentation			
10	Be able to draft routine reports for validation	10.1	Draft routine reports for validation			
		10.2	Prioritise reports in accordance with standard operating procedures (SOPs)			
		10.3	Identify cases for referral to senior colleagues			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
11	Be able to validate results from a range of routine procedures to inform repeat analysis or processing	11.1	Explain the purpose of validation of results for routine analyses			
		11.2	Validate results from a range of routine procedures to inform repeat analysis or processing			
12	Be able to perform a health and safety risk assessment of a defined area	12.1	Explain the reasons for performing risk assessment			
		12.2	Explain the key legislation, regulations and sources of advice relevant to the risk assessment			
		12.3	Explain the process of risk assessment			
		12.4	Justify the choice of area in which risk assessment is undertaken			
		12.5	Perform the health and safety risk assessment			
		12.6	Solve problems within scope of practice			
		12.7	Seek advice as required			
		12.8	Document the risk assessment in accordance with departmental guidelines			
13	Be able to use effective communication skills within the healthcare environment	13.1	Explain the principles of effective communication			
		13.2	Explain the positive impact of effective communication on patients and care			
		13.3	Explain the importance of key ideas underpinning effective communication			
		13.4	Communicate effectively within the healthcare environment			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 20: Procedures for Witnessing in the HFEA-licensed Fertility Clinic

Level:	**3**
Unit type:	**Optional**
Credit value:	**2**
Guided learning hours:	**15**

Unit summary

In this unit, you will gain the knowledge and understanding of the principles and practice of procedures used when acting as a witness within the HFEA-licensed fertility clinic.

There is a statutory requirement to have robust and effective processes to ensure that no mismatches of gametes, embryos or identification occur within the HFEA-licensed fertility clinic. Identification of samples must be double-witnessed and the witness step recorded at all critical points of the clinical and laboratory process. This includes, but is not limited to, witnessing for: procurement of gametes; mixing of sperm and oocytes; transfer of gametes or embryos between tubes, dishes or cryopreservation carriers; transfer of gametes or embryos to a patient in a clinical procedure; disposal of gametes or embryos; the placing into or retrieving from long-term storage vessels of cryopreserved gametes or embryos.

The witnessing of laboratory and clinical procedures is undertaken using local policies and procedures to verify and document compliance with regulatory requirements.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures and in accordance with the Human Fertilisation and Embryology Act 2008 and HFEA licence.

Training must be performed under the supervision of a designated assessor and with the approval of the person responsible within the HFEA-licensed Fertility Clinic. All activities during the training period require direct supervision of learners by a suitably qualified member of the multidisciplinary team.

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

The evidence presented to demonstrate the achievement of the assessment criteria must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

AC1.1 includes:

- policies, protocols, Standard Operating Procedures and professional guidelines
- the Human Fertilisation and Embryology Authority Code of Practice for witnessing procedures.

AC1.2 includes:

- carrying out all relevant aspects of witnessing procedures
- noting, reporting and following up any discrepancies or omissions in witnessing.

AC1.10 includes:

- the effect of omission or irregularity.

AC2.1 includes:

- where to find the local Standard Operating Procedures and standard laboratory documentation relating to witnessing
- how to check that the consent for the procedure to be witnessed is in place. Where consent is required from more than one individual for a single procedure, describe how to check that consents for each individual are in agreement and in accordance with the proposed procedure
- the checks performed to ensure that the specific procedure to be witnessed is the correct procedure, for the correct individual(s), with the correct partner, with all items, on the right day and at the right time
- the use of personal protective equipment (PPE) if required, to be used when acting as a laboratory witness
- the current local documentation used to record the witnessing of laboratory procedures
- the reference points used to verify patient/vessel identity during witnessing steps.

AC2.2 includes:

- following the local Standard Operating Procedures for witnessing
- verbally confirming the identifying information, which is being examined in different process steps, with the practitioner
- checking that the unique identifier corresponds to the individual's details
- checking that the unique identifiers for each individual are in accordance with the proposed procedure, where gametes or embryos from more than one individual are involved in the process step
- taking action in the event of a requirement for non-confirmation with the practitioner, for example a mismatch of information or deviation from local policy/procedure
- act if a documentation error or omission is noted.

AC2.5 includes:

- updating records in accordance with local policies and procedures
- communicating effectively on all aspects of witnessing in accordance with local policies and procedures
- acting on any event that requires immediate action in accordance with local policies and procedures
- compiling reports on witnessing for audit or quality-assurance purposes.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work, in accordance with Standard Operating Procedures (SOPS)** and in accordance with the **Human Fertilisation and Embryology Act 2008, HFEA licence and the clinic's HFEA licence** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand current national guidelines, local protocols, Standard Operating Procedures (SOPs) and professional guidelines relating to witnessing procedures in the HFEA-licensed Fertility Clinic	1.1	Summarise the requirements of current national and local guidelines relating to witnessing procedures in the HFEA-licensed Fertility Clinic			
		1.2	Evaluate the SOP relating to witnessing procedures			
		1.3	List the circumstances where laboratory witnessing is mandatory			
		1.4	Describe how witnessing tasks are scheduled and why they are completed contemporaneously			
		1.5	Describe the steps to ensure that the requirements for consent are in place for the procedure which is to be witnessed, in line with local and HFEA requirements			
		1.6	Discuss the concept of involuntary automaticity in relation to witnessing procedures			
		1.7	Describe manual and electronic witnessing systems and how these may be used in the HFEA-licensed Fertility Clinic			
		1.8	Describe local witnessing procedures, including but not limited to: • an oocyte collection procedure • preparation of a sperm sample • IVF insemination • embryo transfer • cryopreservation of embryos			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		1.9	Summarise the local health and safety information and risk assessment(s) relating to witnessing procedures			
		1.10	Describe the factors that might influence the quality and validity of witnessing procedures			
		1.11	Describe the witnessing events that might give rise to risks for the safety and quality of gametes or embryos			
		1.12	Summarise the elements of the local quality management system that relate to witnessing procedures in the HFEA-licensed Fertility Clinic			
2	Be able to perform laboratory witnessing following standard operating procedures	2.1	Prepare to act as a laboratory witness			
		2.2	Perform laboratory witnessing			
		2.3	Keep contemporaneous records of the witnessing event in accordance with local policies and procedures			
		2.4	Maintain and update records in accordance with local policies and procedures			
		2.5	Report and conclude the witnessing procedure			
		2.6	Describe the actions taken for any items requiring disposal after the witnessing procedure, including any necessity for further witnessing			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the context, troubleshooting and when to take advice in relation to witnessing procedures	3.1	Explain when and why a discrepancy in witnessing should be reported			
		3.2	Describe the remedial action to take when adverse situations, problems or events occur			
		3.3	Describe the contingency arrangements in the event of an unforeseen problem arising			
		3.4	Describe limits of own authority and who to report to			
		3.5	Describe the context where events occurring or observations made while acting as a witness may become an incident to be reported to the Human Fertilisation and Embryology Authority			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 21: Check Documentation of Consent in the HFEA-licensed Fertility Clinic

Level:	**3**
Unit type:	**Optional**
Credit value:	**3**
Guided learning hours:	**17**

Unit summary

In this unit, you will gain the knowledge and understanding of the principles and practice of checking the documentation used to take effective consent within the HFEA-licensed Fertility Clinic.

There is a statutory requirement to obtain consent on specified consent forms. This includes but is not limited to consent in advance of licensed fertility treatment; storage of gametes or embryos; donation of gametes or embryos for treatment; use of gametes or embryos for training in embryological techniques; use of gametes and embryos for research. Consent for storage also specifies the storage time and encompasses the wishes of the individual in the event of death or mental incapacity. In addition to specified consent forms provided by the HFEA, licensed fertility clinics may use local consent forms that may include but are not limited to forms recording consent for: use of micromanipulation techniques such as ICSI, assisted hatching or embryo biopsy; consent to the number of embryos for transfer.

The skill to check documentation used to take consent, is undertaken using local policies and procedures to verify and document compliance with regulatory requirements.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures, the Human Fertilisation and Embryology Act 2008 and HFEA licence.

Training must be performed under the supervision of a designated assessor and with the approval of the person responsible within the HFEA-licensed Fertility Clinic. All activities during the training period require direct supervision of learners by a suitably qualified member of the multidisciplinary team.

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

The evidence presented to demonstrate the achievement of the assessment criteria must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

AC1.1 includes:

- policies, protocols, Standard Operating Procedures and professional guidelines relating to consent and consent forms
- the Human Fertilisation and Embryology Authority Code of Practice relating to consent and consent forms.

AC1.3 includes:

- carrying out all relevant aspects of the consent process are carried out
- noting, reporting and following up any discrepancies or omissions in consent are.

AC1.7 includes:

- the effect of omission or irregularity.

AC2.2 includes checking:

- for the correct procedure
- for the correct individual
- with the correct partner or any other person
- in advance of any proposed procedure.

AC3.2 includes:

- selecting the correct HFEA consent forms for each relevant procedure
- selecting the correct current local consent for each relevant procedure.

AC3.3 includes:

- following Standard Operating Procedures for checking documentation of consent
- checking that the unique identifier and other identifying information correspond with the individual's details
- ensuring that, where the consent of more than one individual is required for a single procedure, the unique identifiers for each individual, the other identifying information and the consent given are in accordance with each other and with the proposed procedure
- checking that all necessary consent is documented, valid and in place in advance of all relevant HFEA-licensed procedures
- acting if a documentation error or omission is noted.

AC3.5 includes:

- updating records in accordance with local and national policies and procedures
- communicating effectively on all aspects of the documentation of consent in accordance with local policies and procedures
- compiling reports on the documentation of consent for audit or quality-assurance purposes.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work, in accordance with Standard Operating Procedures (SOPS)** and in accordance with the **Human Fertilisation and Embryology Act and the clinic's HFEA licence** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand current national guidelines, local protocols, Standard Operating Procedures and professional guidelines relating to consent and consent forms in the HFEA-licensed Fertility Clinic	1.1	Summarise the requirements of current national and local guidelines relating to consent and consent forms in the HFEA-licensed Fertility Clinic			
		1.2	Describe the principles of informed consent			
		1.3	Evaluate the SOP relating to consent and consent forms			
		1.4	Explain what each current HFEA consent form should be used for and when they are used			
		1.5	Describe how the documentation of consent is scheduled and time scales for validity of consent forms			
		1.6	Describe how to access, and then summarise, the local health and safety information and risk assessment(s) relating to consent and consent forms			
		1.7	Describe the factors that might influence the quality and validity of consent			
		1.8	Describe the factors that might give rise to risks for the safety and quality of gametes or embryos as a consequence of events relating to the consent of the gamete providers			
		1.9	Summarise the elements of the local quality management system that relate to consent and consent forms			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the requirements for checking the documentation of consent, in preparation for undertaking the check	2.1	Describe where to find the local Standard Operating Procedures and standard laboratory documentation used to record the checking of documentation of the consent given by individuals attending the HFEA-licensed Fertility Clinic			
		2.2	List the checks performed to ensure that the documentation of consent is correct			
		2.3	Describe any other checks which may be required that are specific to the proposed procedure			
3	Be able to check documentation of consent in the HFEA-licensed Fertility Clinic	3.1	Select the current documentation used to record the checking of documentation of consent in your workplace			
		3.2	Select the correct consent forms for each relevant procedure			
		3.3	Check that valid consents are documented in preparation for HFEA-licensed procedures			
		3.4	Keep contemporaneous records in accordance with local policies and procedures			
		3.5	Report and conclude on the checks made on the validity of consents for individual cases			
		3.6	Describe how to deal with confidential waste in accordance with local policies and procedures and according to Standard Operating Procedures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Understand the context, troubleshooting and when to take advice in relation to the documentation of consent	4.1	Explain when and why a discrepancy in consenting should be reported			
		4.2	Describe the remedial action to take when adverse situations, problems or events occur			
		4.3	Describe the contingency arrangements in the event of an unforeseen problem arising			
		4.4	Describe limits of own authority and who to report to			
		4.5	Describe the context within which a lack of valid consent may become an incident to be reported to the Human Fertilisation and Embryology Authority			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 22: Identify and Instruct Individuals Providing Semen Samples in the HFEA-licensed Fertility Clinic

Level: 3

Unit type: Optional

Credit value: 3

Guided learning hours: 17

Unit summary

In this unit, you will gain the knowledge and understanding of the principles and practice required to identify and instruct individuals providing semen samples within the HFEA-licensed Fertility Clinic.

Individual men may attend the clinic to provide semen samples for a number of purposes, including: for assessment; for use in treatment with a named partner; for cryopreservation; for donation; for research. The individual may produce the sample using on-site facilities within the Clinic, or may produce the sample off-site. The HFEA Code of Practice specifies a number of safeguards to give assurance that samples are correctly obtained, identified and used. The task to identify and instruct individuals providing semen samples is undertaken using local policies and procedures to verify and document compliance with regulatory requirements.

The skill to identify and instruct individuals providing semen samples is undertaken using local policies and procedures to verify and document compliance with regulatory requirements.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures, the Human Fertilisation and Embryology Act 2008 and HFEA licence.

Training must be performed under the supervision of a designated assessor and with the approval of the person responsible within the HFEA-licensed Fertility Clinic. All activities during the training period require direct supervision of learners by a suitably qualified member of the multidisciplinary team.

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

The evidence presented to demonstrate the achievement of the assessment criteria must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

AC1.1 includes:

- policies, protocols, Standard Operating Procedures and professional guidelines
- the Human Fertilisation and Embryology Authority Code of Practice.

AC1.2 includes:

- the requirement that all relevant aspects of the identification and instruction of individuals providing semen samples are carried out
- the requirement that any discrepancies or omissions in the identification and instruction of individuals providing semen samples are noted, reported and followed up.

AC1.4 includes:

- how appointments are scheduled
- how to locate the correct person to be identified
- how to ensure timely processing of the sample will occur after its production.

AC1.5 must be in line with local and HFEA requirements.

AC1.6 includes:

- the specific risks inherent in sample identification that are checked through the witnessing procedure.

AC1.8 includes instructions with respect to:

- the production of the sample
- abstinence
- use of lubricants
- the purpose for the sample
- how any results will be given
- the local policy with regard to informing the patient of the assessment result and subsequent use of the semen sample.

AC2.1 includes:

- where to find the local Standard Operating Procedures, standard laboratory documentation and any information sheets for the identification and instruction of individuals providing semen samples
- the checks performed to ensure that the individual's identity can be verified and the purpose of sample provision is known
- selection of the appropriate standard laboratory documentation for identification of the individual and the sample container
- checking that the unique identifier corresponds to the individual's details and that all labelling, witnessing and consents are in line with legal and regulatory requirements
- ensuring the weight of the empty sample container is known, if using weight as a measure of sample volume (WHO guidelines 2010)
- ensuring that the sample production room is clean, comfortable and supportive of semen sample collection.

AC2.2 includes:

- demonstrating the witnessing requirements for verification of the sample with the patient or donor and how this is appropriately documented
- ensuring all criteria for semen sample acceptance/rejection comply with procedures and recommended guidelines
- keeping contemporaneous records in accordance with local policies and procedures
- acting if a concern or query is raised by the patient or donor
- acting if a documentation error or omission is noted.

AC2.4 includes:

- ensuring the sample is delivered promptly to the laboratory for assessment, preparation or cryopreservation
- ensuring effective communication on all aspects of the semen sample appointment in accordance with local policies and procedures
- acting on any event that requires immediate action in accordance with local policies and procedures.

AC2.5 includes:

- compiling reports on any aspect of semen sample appointments for audit or quality-assurance purposes.

AC3.6 includes:

- events at the time of the appointment
- future events.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work, in accordance with Standard Operating Procedures (SOPs)** and in accordance with the **Human Fertilisation and Embryology Act and the clinic's HFEA licence** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand current national guidelines, local protocols, Standard Operating Procedures (SOPs) and professional guidelines relating to the identification and instruction of individuals providing semen samples in the HFEA-licensed Fertility Clinic	1.1	Summarise the requirements of current national and local guidelines relating to the identification and instruction of individuals providing semen samples in the HFEA-licensed Fertility Clinic			
		1.2	Evaluate the SOP relating to the identification and instruction of people providing semen samples			
		1.3	List the different reasons for attending the clinic to provide a semen sample			
		1.4	Explain the administration and planning processes			
		1.5	Describe the steps to ensure that the requirements for consent are in place for the proposed appointment			
		1.6	Describe the requirements for witnessing of the sample and the mitigation of the inherent risks			
		1.7	Explain how confidentiality, privacy and comfort are achieved			
		1.8	Describe the instructions given prior to the appointment and at the time of sample production			
		1.9	Describe the steps required to ensure the chain of custody if a sample is produced off-site			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		1.10	Summarise the local health and safety information and risk assessment(s) relating to the identification and instruction of individuals providing semen samples			
		1.11	Describe the factors that might influence the quality and validity of the procedure, including the effect of omission or irregularity			
		1.12	Describe the factors that might give rise to risks for the safety and quality of gametes and embryos			
		1.13	Explain the elements of the local quality management system that relate to the identification and instruction of individuals providing semen samples in the HFEA-licensed Fertility Clinic			
2	Be able to identify and instruct individuals providing semen samples following standard operating procedures	2.1	Prepare to identify and instruct individuals providing semen samples			
		2.2	Instruct the individual in the process of sample production, collection and identification of semen sample			
		2.3	Manage workload taking into account the prioritisation timing of the procedure, the efficient use of resources and the multidisciplinary team			
		2.4	Report and conclude the instruction of the individual after the semen sample has been provided			
		2.5	Maintain and update records in accordance with local policies and procedures			
		2.6	Describe the actions to take in the sample production room, including disposal of any waste, in accordance with local policies and procedures and according to Standard Operating Procedures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the context, troubleshooting and when to take advice in relation to identifying and instructing individuals providing semen samples	3.1	Explain when and why any concerns raised during semen sample appointments should be reported			
		3.2	Explain how to escalate concerns that an individual may be having difficulty providing a semen sample			
		3.3	Explain how to escalate concerns that may be raised by the patient or donor			
		3.4	Describe the remedial action to take when adverse situations, problems or events occur			
		3.5	Describe the contingency arrangements in the event of an unforeseen problem arising			
		3.6	Describe limits of own authority and who to report to			
		3.7	Describe the context within which events concerning the identification and instruction of individuals providing semen samples may become an incident to be reported to the Human Fertilisation and Embryology Authority			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 23: Laboratory Practice in the HFEA-licensed Reproductive Science Laboratory

Level:	**4**
Unit type:	**Optional**
Credit value:	**3**
Guided learning hours:	**25**

Unit summary

In this unit, you will be introduced to the multidisciplinary team in the workplace of the HFEA-licensed Fertility Clinic, and to the key roles of a healthcare science associate in reproductive science. You will build professional practice in accordance with Good Scientific Practice.

The Human Fertilisation and Embryology Act 1990, as amended, 2008, provides a highly specialised working environment where all staff are required to understand the legal framework in order to safeguard the requirements of the Human Fertilisation and Embryology Act, the Human Fertilisation and Embryology Authority (HFEA) licence conditions and the requirements of the EU Tissues and Cells Directives.

On completion of this unit, you will be able to operate safely within a defined role, which may include tasks for laboratory administration, cleaning, stock control, assistance with audit and witnessing of clinical procedures. You will also undertake tasks requiring sterile techniques and the use of specialised laboratory equipment, and other duties, including semen assessment. You will have a patient-facing role. You will be aware of the legislative framework of services within the HFEA-licensed reproductive sciences laboratory and the safety implications of working in the laboratory and the cryostorage facility, including infection control. You will use effective communication skills in the context of patient-centred care and will recognise the role of the specialism in patient care. You will be expected to adhere to health and safety procedures, and work safely in the workplace adhering to the HFEA Code of Practice and local procedures and governance, including patient confidentiality and the Data Protection Act 1998.

The knowledge acquired in this unit underpins the delivery of the care pathways for patients attending the HFEA-licensed Fertility Clinic. This knowledge is required to support the role of the healthcare science associate in the HFEA-licensed reproductive science laboratory.

Additional information

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

Evidence must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality and a breach of this provision is a criminal offence.

All learners must complete formal training in the safe use of liquid nitrogen.

AC1.1 includes:

- how Standard Operating Procedures are structured, how to access them and the importance of their use
- the procedures required to safeguard the quality and safety of human gametes and embryos
- how the security of the laboratory is ensured
- the clothing policy for the different areas within the laboratory
- the requirements for air quality for different areas within the laboratory
- how the environment is maintained, including cleaning, movement of stock and waste disposal
- the types of cleaning products and their appropriate use within the laboratory.

AC1.2 includes:

- the requirements for quality management as specified by the HFEA Code of Practice
- the methods used to track the use of laboratory equipment
- the methods used to track the use of laboratory consumables
- the methods used to track the status of the laboratory environment
- the purpose and methods for daily monitoring undertaken within own laboratory
- how audit procedures are used in own laboratory.

AC1.3 includes:

- completion of formal training in the safe use of liquid nitrogen
- the operational principles and requirements for safe operation within the cryopreservation facility of the HFEA-licensed Fertility Clinic, to include:
    - risks of liquid nitrogen
    - action to take in the event of an emergency
    - personal protective equipment (PPE)
    - low-oxygen alarms
    - cross-contamination risks for samples
    - storage under liquid nitrogen
    - storage in vapour phase
    - alarm systems
    - security of the cryopreservation facility
- the functions and purpose of the equipment located in the cryopreservation facility
- the specific safety considerations for each piece of equipment in the cryopreservation facility.

AC1.4 includes:

- the communication methods used in the context of delivery of services within the HFEA-licensed Fertility Clinic. This includes examples of communication:
    - in the laboratory team
    - in the wider multidisciplinary team
    - with external agencies, including HFEA
- tasks that require the use of effective communication
- use of communication skills:
    - in the laboratory
    - in the wider multidisciplinary team
- effects of poor communication
- the definition of 'an incident' and a 'near miss' as specified by the HFEA Code of Practice
- how to report an incident at both local level and to the Human Fertilisation and Embryology Authority.

AC1.5 includes:

- the role of the healthcare science associate in the HFEA-licensed reproductive science laboratory:
    - the context
    - troubleshooting
    - when to seek advice
- the limits of the learners' own authority and to whom they should report if they encounter problems that they cannot resolve.

AC2.1 includes:

General reproductive science laboratory skills: applies to all procedures, including those specified in AC2.2–2.5.

- Working safely at all times, complying with health and safety and other relevant regulations and guidelines.
- Keeping contemporaneous records in accordance with local policies and procedures.
- Checking batch/lot numbers and expiry dates for items that could affect the quality and safety of gametes or embryos.
- Selecting appropriate cleaning products to use within the laboratory.
- Using cleaning products within the laboratory.
- Disposing of used items in accordance with local policies and procedures.
- Taking appropriate remedial action when adverse situations, problems or events occur.
- Acting on any events that require immediate action in accordance with local policies and procedures.
- Ensuring effective and appropriate communication in the laboratory team and in the multidisciplinary team, in accordance with local policies and procedures.

AC2.2 includes the safe use of centrifuges:

- requirements for safe operation and use of a centrifuge
- selecting the correct method for use of a centrifuge
- how to check centrifuges are working within operational limits
- following the Standard Operating Procedures for any procedure requiring the use of a centrifuge
- following the Standard Operating Procedures for cleaning and decontamination of a centrifuge
- ensuring effective communication on all aspects of centrifuge use in accordance with local policies and procedures.

AC2.3 includes safe use of laboratory workstations:

- the different types and appropriate use of the workstations in the laboratory
- the operational principles and requirements for operation of the workstations in own laboratory, including the features that safeguard the culture system and the quality and safety of gametes, embryos and the operator
- safe and appropriate use of each workstation in own laboratory
- selecting the appropriate workstation for tasks, to ensure sterile technique
- how to check workstations are working within operational limits
- following the Standard Operating Procedures for:
    - sterile technique within the workstation
    - cleaning and decontamination of workstations
- ensuring effective communication on all aspects of use of workstations in accordance with local policies and procedures.

AC2.4 includes the safe use of incubators:

- the different types and appropriate use of the incubators in the laboratory
- the operational principles and requirements for operation of incubators in own laboratory, including the features that safeguard the culture system and the quality and safety of gametes and embryos
- safe and appropriate use of each incubator in own laboratory
- selecting the appropriate incubator for tasks, to ensure correct culture of gametes, embryos and the operator
- how to check incubators are working within operational limits
- following the Standard Operating Procedures for:
    - use of an incubator
    - cleaning and decontamination of incubators
- monitoring of the incubators and alarm systems
- ensuring effective communication on all aspects of use of incubators in accordance with local policies and procedures.

AC2.5 includes:

- the operational principles and requirements for operation of microscopes in own laboratory, including the features that safeguard the culture system and the quality and safety of gametes and embryos
- safe and appropriate operation and use of microscopes, to include:
    - bright field binocular dissecting microscope
    - bright field and phase contrast compound microscope
    - inverted microscope with Hoffman modulation contrast
    - other microscopes in use in own laboratory
- following the Standard Operating Procedures for:
    - use of a microscope
    - cleaning and decontamination of a microscope
- equipment for temperature control during microscopy and its monitoring
- equipment for acquisition of images during microscopy
- ensuring effective communication on all aspects of the use of microscopes in accordance with local policies and procedures.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of working within the HFEA-licensed reproductive science laboratory	1.1	Evaluate how adherence to Standard Operating Procedures underpins a safe laboratory environment and safeguards the quality and safety of human gametes and embryos			
		1.2	Explain the key components of quality management in the HFEA-licensed reproductive science laboratory			
		1.3	Explain the requirements for safe working within a cryopreservation facility			
		1.4	Explain the requirements for reporting and communication within the HFEA-licensed Fertility Clinic			
		1.5	Discuss the role of the healthcare science associate in the HFEA-licensed reproductive science laboratory			
2	Be able to use equipment within the HFEA-licensed reproductive science laboratory	2.1	Work safely in the HFEA-licensed reproductive science laboratory			
		2.2	Use a centrifuge in the HFEA-licensed reproductive science laboratory			
		2.3	Operate using sterile technique within a workstation to protect both the culture system and the operator			
		2.4	Use incubators in the HFEA-licensed reproductive science laboratory			
		2.5	Operate microscopes used in the HFEA-licensed reproductive science laboratory			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 24: Principles and Organisation of Services in the HFEA-licensed Fertility Clinic

Level:	**4**
Unit type:	**Optional**
Credit value:	**3**
Guided learning hours:	**25**

Unit summary

In this unit, you will be introduced to the multidisciplinary team in the workplace of the HFEA-licensed Fertility Clinic and the key roles of a healthcare science associate in reproductive science. You will build professional practice in accordance with Good Scientific Practice.

The Human Fertilisation and Embryology Act 1990, as amended, 2008, provides a highly specialised working environment where all staff are required to understand the legal framework in order to safeguard the requirements of the Human Fertilisation and Embryology Act, the Human Fertilisation and Embryology Authority (HFEA) licence conditions and the requirements of the EU Cells and Tissues Directives.

On completion of this unit, you will be able to operate safely in a defined role within the legal framework of the Human Fertilisation and Embryology Act, to participate in the delivery of care to patients attending the HFEA-licensed Fertility Clinic and to act as part of the multidisciplinary team. You will use effective communication skills in the context of patient-centred care and will recognise the role of the specialism in patient care. You will be expected to adhere to health and safety procedures and to work safely in the workplace, adhering to the HFEA Code of Practice and local procedures and governance, including patient confidentiality and the Data Protection Act 1998.

The knowledge you gain in this unit underpins the delivery of the care pathways for patients attending the HFEA-licensed Fertility Clinic. This knowledge is required to support the role of the healthcare science associate in the HFEA-licensed reproductive science laboratory.

Additional information

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

Evidence must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

AC1.1. includes:

- the role of the Human Fertilisation and Embryology Authority (HFEA)
- how the Code of Practice is implemented and adhered to in the HFEA-licensed Fertility Clinic
- the purpose of the HFEA Register and the information supplied by clinics
- the additional requirements for patient confidentiality provided in the Human Fertilisation and Embryology Act and how it is safeguarded in the HFEA-licensed Fertility Clinic, including the precautions:
    - that ensure confidentiality is not breached when telephoning a patient concerning any aspect of licensed treatment
    - that apply particularly to confidential reporting of an individual's test results
    - that apply to visitors to the centre and to the laboratory
- the roles of the professional bodies, associations and patient support organisations that support the work of a licensed fertility clinic
- the multidisciplinary roles in the workplace to include:
    - person responsible
    - licence holder
    - laboratory manager
    - embryologist
    - other members of the healthcare science workforce
    - consultant in charge
    - fertility nurse
    - quality manager
    - counsellor
- the relationships in:
    - the unit's organisational chart
    - the wider organisation
    - external organisations.

AC1.2 includes:

- the structure of the National Health Service (NHS) fertility services
- the provision of fertility services in the independent sector
- the patient journey for fertility treatment from GP referral to treatment outcome.

AC1.3 includes:

- the clinical care pathway for a variety of clinical treatments, including:
    - investigations
    - initial referral
    - medical consultation
    - treatment options
    - obtaining informed consent
    - counselling
- the procedures required for the clinical care pathway for an IVF/ICSI treatment cycle at own clinic

- the laboratory care pathway for a variety of clinical treatments, including the requirements for consent and witnessing, the records to be kept and the reports to be made to the HFEA register, to include:
    - IVF/ICSI treatment cycles
    - IUI treatment cycles
    - use of donated gametes
    - surgical sperm retrieval
    - cryopreservation and storage of gametes
    - cryopreservation and storage of embryos
    - use of cryopreserved gametes in treatment
    - use of cryopreserved embryos in treatment
- factors that might influence the quality of the care pathways described above and any risks to the safety of gametes or embryos.

AC1.4 includes:

- the communication methods used in the context of delivery of services within the HFEA-licensed Fertility Clinic. Include examples of communication:
    - in the laboratory team
    - in the wider multidisciplinary team
    - with external agencies, including HFEA
- tasks that require the use of effective communication
- examples of the learners' use of communication skills:
    - in the laboratory
    - in the wider multidisciplinary team
- the effects of poor communication
- the limits of the learners' own authority
- the definition of 'an incident' and 'a near miss' as specified by the HFEA Code of Practice
- the process of incident reporting at both local level and to the Human Fertilisation and Embryology Authority.

AC1.5 includes:

- the records kept within the HFEA-licensed Fertility Clinic
- how to keep accurate laboratory records
- how to make an appropriate entry in clinical case notes
- the specific requirements for records within the HFEA-licensed Fertility Clinic.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and organisation of the HFEA-licensed reproductive science laboratory	1.1	Explain current national legislation and local guidelines relating to operation of the HFEA-licensed fertility clinic			
		1.2	Discuss the provision of NHS-funded and self-funded fertility services in the UK			
		1.3	Evaluate the patient-care pathways offered at the HFEA-licensed Fertility Clinic			
		1.4	Discuss the requirements for reporting and communicating in the HFEA-licensed Fertility Clinic			
		1.5	Evaluate the specific requirements for record keeping in the HFEA-licensed Fertility Clinic			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 25: Reproductive Sciences: Human Body Systems – Biological Basis of Reproductive Systems

Level:	**4**
Unit type:	**Optional**
Credit value:	**4**
Guided learning hours:	**30**

Unit summary

In this unit, you will gain knowledge and understanding of the biological basis of reproductive systems in the male and female, including anatomy, physiology and how infertility may arise. This understanding supports the role of a healthcare science associate in reproductive science within the HFEA-licensed Fertility Clinic. You will build professional practice in accordance with Good Scientific Practice. On completion of this unit, you will understand elements of reproductive anatomy and physiology in the male and female, and recognise how pathology of reproductive systems can affect fertility.

The knowledge gained in this unit underpins the delivery of the care pathways for patients attending the HFEA-licensed Fertility Clinic. This knowledge is required to support the role of the healthcare science associate in the HFEA-licensed reproductive science laboratory.

Additional information

AC4.1 includes the spatial and temporal development in vivo from fertilisation to implantation.

AC5.1 is in the context of:

- knowledge of the biological basis of the female reproductive system.

AC5.2 includes:

- surgical sperm retrieval.

AC5.4 includes:

- temperature
- osmolarity
- pH
- ionic composition
- supply of nutrients.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the anatomy and function of the female reproductive system	1.1	Describe the anatomy of the female reproductive system			
		1.2	Explain the structures and function of the components of the female reproductive system			
		1.3	Explain the endocrine control of the menstrual cycle			
		1.4	Describe the processes of oogenesis and meiosis			
		1.5	Discuss how a dysfunction of the female reproductive system can lead to infertility			
		1.6	Explain how lifestyle factors contribute to female reproductive health			
		1.7	Discuss how a disease of the female reproductive system can affect fertility			
		1.8	Explain the influence of female age on natural conception			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the anatomy and function of the male reproductive system	2.1	Describe the anatomy of the male reproductive system			
		2.2	Explain the structures and function of the components of the male reproductive system			
		2.3	Explain the endocrine control of spermatogenesis			
		2.4	Describe the process of spermatogenesis and meiosis			
		2.5	Discuss how a dysfunction of the male reproductive system can lead to infertility			
		2.6	Explain how lifestyle factors contribute to male reproductive health			
		2.7	Discuss how a disease of the male reproductive system can affect fertility			
3	Understand the processes of fertilisation	3.1	Explain the process of ovulation and oocyte transport			
		3.2	Explain the process of ejaculation and sperm transport			
		3.3	Explain the fertilisation process and where this occurs in vivo			
4	Understand the processes of embryo development, implantation and early pregnancy in vivo	4.1	Describe the morphological development of the pre-implantation embryo			
		4.2	Explain the metabolic requirements of the pre-implantation embryo from fertilisation to implantation			
		4.3	Describe the process of embryo implantation			
		4.4	Explain how pregnancy is detected and monitored			
		4.5	Explain how a twin pregnancy may arise			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Understand how the processes of reproduction in vivo are reflected, monitored and performed in the HFEA-licensed laboratory	5.1	Describe using knowledge of the biological basis of the female reproductive system how oocytes are collected and cultured			
		5.2	Describe using knowledge of the biological basis of the male reproductive system how sperm are collected following ejaculation or surgical retrieval and processed			
		5.3	Describe how in vitro embryo development carried out in the HFEA-licensed laboratory may differ from in vivo development			
		5.4	Explain how the culture environment of embryos is constituted and maintained to replicate in vivo conditions			
		5.5	Explain why it is important to have an uninterrupted electricity supply to critical equipment in the laboratory			
		5.6	Explain why sterile conditions are needed in the laboratory and how this is achieved during in vitro culture of embryos			
		5.7	Explain the importance of synchrony of the uterine environment with embryo development in treatment cycles using embryos that have been cryopreserved			
		5.8	Explain the possible causes of failure of fertilisation and how this may relate to infertility in human reproductive systems			
		5.9	Explain the possible causes of embryo arrest and how this may relate to infertility in human reproductive systems			
		5.10	Explain the possible causes of failure of embryo implantation and how this may relate to infertility in human reproductive systems			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 26: Prepare Culture Systems for Gametes and Embryos in the HFEA-licensed Reproductive Science Laboratory

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

In this unit, you will gain knowledge and understanding of the principles and practice of preparing culture systems for gametes and embryos in the HFEA-licensed reproductive science laboratory within the HFEA-licensed Fertility Clinic. Culture systems are highly specialised to meet the needs of human gametes and embryos, and preparation requires the highest standards of laboratory practice.

Underpinning knowledge includes: an understanding of sterile technique, the control of temperature, pH and osmolarity of solutions, and the metabolic requirements of the gametes and embryos. This knowledge is required to ensure that the correct solutions are selected. Timely preparation of sufficient materials is a key laboratory activity, and is critical to the successful running of the clinical service. Omission can jeopardise treatment, while excess preparation can waste resources and lead to future insufficiency. To ensure the task is completed as required by caseload, excellent communication is essential.

The task, to prepare the culture systems for the service, is undertaken using local policies and procedures to verify and document compliance with requirements.

Training will be performed under the supervision of a designated assessor and with the approval of the person responsible within the HFEA-licensed Fertility Clinic. All activities during the training period require direct supervision by a suitably qualified member of the multidisciplinary team.

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

Evidence must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

Additional information

AC1.1 includes:

- current national and local guidelines, policies, protocols, Standard Operating Procedures and professional guidelines relating to the preparation of culture systems for human gametes and embryos
- requirements of the Human Fertilisation and Embryology Authority Code of Practice relating to the preparation of culture systems for human gametes and embryos
- how adherence to Standard Operating Procedures ensures that:
    - all relevant aspects of preparation of the culture systems for human gametes and embryos are considered and undertaken
    - any discrepancies or omissions in any aspect of the preparation of culture systems are noted, reported and followed up
- how sterility is safeguarded during the preparation of culture systems, including but not limited to:
    - sterile working practice
    - identification of potential sources of contamination
    - how to monitor and record the required environmental parameters
    - how to ensure environmental parameters are within set limits
- how the constituents of culture systems and their correct preparation are designed to meet the needs of gametes and the stage-specific needs of embryos, including but not limited to:
    - control of temperature
    - control of pH and buffer systems
    - control of osmolarity
    - provision of nutrients
    - provision of macromolecules
    - supplementation with antibiotics
- the importance of accurate and timely preparation of culture systems, including:
    - time required for pre-equilibration prior to use for culture
    - quantities and types related to planned clinical activities
- the features of a variety of culture systems, the containers and the media and methods of patient identification, including but not limited to:
    - containers
    - media
    - oil
    - incubators
    - labelling for patient identification
- the requirements for traceability specified by the HFEA Code of Practice and the methods used for consumables tracking, appropriate storage, stock rotation, ordering and disposal
- the requirements for recording the critical equipment used and the type and batch of consumables used during preparation of culture systems
- how to minimise the risk of introducing contamination during preparation of culture systems

- the operational principles and requirement for operation of workstations within the laboratory, including the features that safeguard the culture system and the quality and safety of gametes and embryos, and the features that protect the safety of the operator
- the function of all critical laboratory equipment used during setting up culture systems and how to check they are within operational limits
- health and safety information and risk assessment(s) relating to the preparation of culture systems
- procedure-related risks to the operator, gametes, embryos and patients
- the factors that might influence the preparation of culture systems, including the effect of omission or irregularity
- the factors that might give rise to risks for the safety and quality of gametes or embryos
- the elements of the local quality-management system that relate to preparation of culture systems
- the relevance of quality control and quality assurance to the culture of human gametes and embryos.

AC1.2 includes:

- how and when to report with regard to preparation of culture systems, including but not limited to:
    - equipment malfunction
    - shortage of culture media
    - shortage of consumables
    - deficiencies in communication
- the preventative maintenance routines for relevant critical equipment within the laboratory that are required for the preparation of culture systems
- the laboratory key performance indicators that relate to culture conditions and how they may be used to monitor the preparation of culture systems
- the remedial action to take when adverse situations, problems or events occur
- the contingency arrangements in the event of an unforeseen problem arising
- the limits of the learner's authority and who to report to
- the context within which an event connected with the preparation of culture systems may become an incident to be reported to the Medicines and Healthcare Products Regulatory Agency
- the context within which an event connected with the preparation of culture systems may become an incident to be reported to the Human Fertilisation and Embryology Authority.

AC2.1 includes:

- the local Standard Operating Procedures and standard laboratory documentation for the preparation of culture systems

- the methods and checks employed to ensure that the required culture systems are set up in advance of clinical needs, including but not limited to:
    - the planned procedures
    - the correct individuals
    - sufficient items
    - on the right day
    - at the right time
- selection and preparation of laboratory documentation, making clear and accurate entries on documentation as required by local procedures
- selection of appropriate personal protective equipment (PPE)
- confirmation that materials to be used are fit for purpose and are in sufficient quantity
- cleaning the environmental area using correct cleaning materials
- preparation of the laboratory workstation and consumables used during the setting up of culture systems, including selection of the correct materials and knowledge of batch tracking and expiry dates
- performance of checks on all critical equipment to show that set points are correct and explain how any deviations may affect the integrity of the culture system
- importance of temperature and CO2 equilibration and selection of the correct medium type and batch number according to the planned procedures.

AC2.2 includes:

- following Standard Operating Procedures for the preparation of culture systems
- checking that the unique identifier corresponds to the individual's details where culture elements are required to be pre-labelled
- keeping contemporaneous records in accordance with local policies and procedures
- acting if an error, omission or equipment malfunction is noted
- managing workload, taking into account the prioritisation and urgency of cases, the efficient use of resources and the multidisciplinary team.

AC2.3 includes:

- updating records in accordance with local and national policies and procedures
- using effective communication on all aspects of the preparation of culture systems and reporting completion of setting-up tasks in accordance with local policies and procedures
- acting on any event that requires immediate action in accordance with local policies and procedures
- use of correct local procedure for:
    - documentation of consumables used
    - documentation of batch numbers used
    - documentation of critical equipment used
- disposing of used consumables, clearing the workstation and returning unused consumables to appropriate storage, in accordance with local policies and procedures.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles underpinning the preparation of culture systems	1.1	Evaluate current national guidelines, policies, protocols, Standard Operating Procedures and professional guidelines related to preparation of culture systems for human gametes and embryos in the HFEA-licensed Fertility Clinic			
		1.2	Explain the context, troubleshooting and when to take advice in relation to the preparation of culture systems			
2	Be able to prepare culture systems for gametes and embryos	2.1	Prepare to set up culture systems in the HFEA-licensed reproductive science laboratory			
		2.2	Demonstrate the ability to set up culture systems in the HFEA-licensed reproductive science laboratory			
		2.3	Communicate with colleagues following completion of setting-up tasks according to local policies and procedures			
		2.4	Compile reports on the preparation of culture systems for audit or quality-assurance purposes			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 27: Prepare Documents for the Transport of Gametes and Embryos to and from Other Fertility Clinics

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

In this unit, you will gain knowledge and understanding of the principles and practice of preparing the documents and equipment required for the transport of gametes and embryos to and from other fertility clinics.

Transport of gametes and embryos takes place between fertility clinics. These may be HFEA-licensed fertility clinics in the UK, fertility clinics in the EU or those outside the EU. These transfers occur within the legal framework of the Human Fertilisation and Embryology Act 1990, as amended 2008, and there are detailed requirements to ensure that the transport is within the requirements of the act and that it protects the safety and quality of gametes and embryos.

The task, to prepare documents and equipment for the transport of gametes and embryos, requires the highest standards of laboratory practice and is performed under the direction of suitably qualified and registered staff within the HFEA-licensed fertility clinic.

Underpinning knowledge, including an understanding of the required documentation, patient-consent screening results, the cryopreservation method and conditions for transport are critical to ensure the safety, survival and integrity of gametes and embryos during transit. Control of temperature and labelling of the transport vessel are prerequisites for safe transit. Error or omission can jeopardise the survival of gametes and embryos. Timely preparation of associated documentation and ensuring that effective consent is in place are key activities critical to the transport of gametes and embryos.

Excellent communication between fertility clinics and any courier is essential to ensure that the task is completed as required and within the framework of the act.

Training will be performed under the supervision of a designated assessor and with the approval of the person responsible within the HFEA-licensed fertility clinic. All activities during the training period require direct supervision by a suitably qualified member of the multidisciplinary team.

Any external assessor or trainer must be authorised to access the HFEA-licensed fertility clinic.

Evidence must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

Additional information

AC1.1 includes:

- national and local guidelines
- policies
- protocols
- professional guidelines
- Standard Operating Procedures, including:
    - ensuring that all relevant aspects relating to the transport of gametes and embryos between centres are considered and undertaken
    - the responsibilities of the sending centre and the receiving centres
    - ensuring that any discrepancies or omissions in any aspect of the preparation for the transport of gametes or embryos are noted, reported and followed up
    - the requirement for a third-party agreement to be in place with the centre to which the gametes or embryos are being transported to or from, and with any courier of gametes and embryos
- requirements for authorisation of any individual transportation in own clinic
- requirements of the Human Fertilisation and Embryology Authority Code of Practice relating to documentation and transportation
- requirements of the European Union Tissues and Cells Directive (EUTCD) relating to documentation and transportation.

AC1.3 includes:

- the additional considerations if either gametes or embryos are from donors
- how the aspects of arranging the documentation and the physical transport is scheduled to ensure timely completion of each element of the arrangements for the transport of gametes and embryos.

AC1.6 includes:

- the effect of any omissions or irregularities.

AC2.1 includes:

- Standard Operating Procedures, standard laboratory documentation, patient information and consent forms required for the transport of gametes and embryos to and from other centres
- making a plan for the transfer of gametes and embryos, listing the methods and checks performed to ensure the transport is prepared in advance of clinical need
- checking the arrangements to ensure that effective consent has been given by the patient(s) and/or donors for the use, storage and transport of all gametes or embryos to be transported

- where the consent of more than one individual is required for a single procedure, checking that the consents of each individual are in accordance with the proposed use, storage and transport
- listing the checks performed to ensure that transport is undertaken for the correct individual and includes all items on the right day and at the right time
- communicating effectively between own clinic and:
    - patient(s) wishing to carry out the transport
    - patient(s) wishing for transport to be arranged
    - clinics involved in the transport of the gametes or embryos
- selection of the current documentation for transport into another centre and preparation of the documentation, explaining the need for the following:
    - documenting appropriate consent for transport
    - documenting agreement from the other centre, which may be outside of the EU
    - confirming which screening test results and what dates are required
    - confirming screening status of the storage vessel
    - documenting patient consent for storage and/or treatment
    - describing the materials and cryopreservation methods
    - confirming the safety checks on the transport vessel, including temperature monitoring and security
    - checking labelling of the transport vessel
    - provision of consumable batch-tracking information
- selection of the current documentation for transport from another centre and preparation of the documentation, explaining the need for the following:
    - documenting appropriate consent for transport
    - documenting agreement from the other centre, which may be outside of the EU
    - confirming which screening test results and what dates are required
    - confirming screening status of the storage vessel
    - documenting patient consent for storage and/or treatment
    - obtaining information about the materials and cryopreservation methods
    - confirming the safety checks on the transport vessel, including temperature monitoring and security on arrival
    - providing information for the labelling of the transport vessel
    - obtaining consumable batch-tracking information
- managing workload, taking into account the progress of the arrangements for transport, the efficient use of resources and the multidisciplinary team.

AC2.2 includes:

- following Standard Operating Procedures to demonstrate competence in:
    - the safe use and safe handling of liquid nitrogen
    - preparing a dry shipper for use, including how to confirm it is suitable for use
    - the correct labelling of the shipper in preparation for transport.

AC2.3 includes:

- following Standard Operating Procedures to demonstrate competence in:
    - the correct procedures for witnessing the movement of gametes and embryos into the dry shipper for transport
    - the correct procedures for witnessing the movement of gametes and embryos out of the dry shipper for cryostorage
    - checking that the unique identifier corresponds to the individual's details
    - where gametes or embryos from more than one individual are transported, check that the unique identifiers for each individual are in accordance with all records and documentation
    - keeping contemporaneous records
- acting if a documentation error or omission is noted.

AC2.4 includes:

- following Standard Operating Procedures to demonstrate:
    - the correct recording of the transport and updating of records
    - ensuring the transport of gametes or embryos is reported to the HFEA
    - acknowledging receipt of gametes or embryos with the other clinic and with the patient
    - the storage or return of the empty dry shipper
- demonstrating effective communication on all aspects of the transport of gametes and embryos
- acting on any event that requires immediate action in accordance with local policies and procedures
- compiling reports on the transport of gametes and embryos for audit or quality-assurance purposes.

AC3.2 to include but is not limited to:

- mismatch of labelling
- mismatch of consent
- concern that the shipper has been tampered with
- concern that the shipper has not maintained at a low temperature
- contingency arrangements in the event of an unforeseen problem arising
- recall procedure for gametes and embryos
- limits of the learner's authority and who to report to.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand HFEA Code of Practice requirements relating to the documents required before transport of gametes and embryos to and from other fertility clinics	1.1	Summarise current legislation and guidance that must be adhered to before transporting gametes and embryos to and from HFEA-licensed fertility clinics			
		1.2	Evaluate the HFEA decision tree, summarising what centres must consider when transporting gametes and embryos between centres inside and outside of the EU			
		1.3	Explain the importance of checking that effective consent has been given by the patient(s) for the use, storage and transport of all gametes or embryos to be transported			
		1.4	Assess the local health and safety information and risk assessment(s) relating to the transport arrangements for gametes and embryos			
		1.5	Discuss the witnessing requirements at each stage of the arrangements and the specific inherent risks that are checked through the witnessing procedure			
		1.6	Describe the factors that might give rise to risks for the safety and quality of gametes or embryos			
		1.7	Summarise the elements of the local quality-management system relating to the transport arrangements for gametes and embryos			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to prepare documents for the transport of gametes and embryos to and from other fertility clinics	2.1	Prepare the necessary documents for the transport of gametes and embryos to and from other fertility clinics			
		2.2	Perform safe preparation and use of the transport vessel			
		2.3	Act as a witness when gametes or embryos are transported			
		2.4	Report and conclude the transport procedure in line with local policies			
3	Understand how to deal with adverse incidents and emergencies	3.1	Explain when and why a discrepancy in delivery time should be reported			
		3.2	Explain the remedial action to be taken when adverse situations, problems or events occur			
		3.3	Explain the context within which an event during the transport of gametes or embryos becomes an incident to be reported to the Human Fertilisation and Embryology Authority			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 28: Semen Assessment

Level: 4

Unit type: Optional

Credit value: 5

Guided learning hours: 40

Unit summary

In this unit, you will gain knowledge and understanding of the principles and practice of semen assessment within the HFEA-licensed fertility clinic, and will be able to perform semen assessment.

Semen assessment within the HFEA-licensed fertility clinic is performed in order to provide a report in the setting of the fertility service and to indicate the suitability of any sample for use in licensed fertility treatment, cryopreservation or for donation. You may carry out and report the technical steps for the assessment of semen parameters. The report should be signed off by a suitably qualified and registered member of the multidisciplinary team, according to local policies and procedures.

Semen assessment is the term chosen by the Association of Clinical Embryologists and the Association of Biomedical Andrologists to describe the investigation of a semen sample to provide clinical advice to the multidisciplinary team and to the patient (and with the patient's consent, to his partner if applicable) regarding the suitability of that sample for use in licensed fertility treatment, or as an indication of the type of treatment required in the future, or suitability for donation or cryopreservation. Semen assessment is distinct from a diagnostic semen analysis. A diagnostic semen analysis should be performed and reported by an accredited diagnostic laboratory, using the policies and procedures described in the latest WHO laboratory manual for the examination and processing of human semen. Some, but not all, HFEA-licensed fertility centres offer full diagnostic semen analysis.

The task in this unit, performing a semen assessment, is undertaken using local policies and procedures.

Training will be performed under the supervision of a designated assessor and with the approval of the person responsible within the HFEA-licensed fertility clinic. All activities during the training period require direct supervision of the learner by a suitably qualified member of the multidisciplinary team.

Any external assessor or trainer must be authorised to access the HFEA-licensed fertility clinic.

Evidence must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

Additional information

AC1.1 includes:

- guidelines and training schemes of the Association of Biomedical Andrologists
- the requirements of the Human Fertilisation and Embryology Authority Code of Practice relating to semen assessment
- the local health and safety information and risk assessment(s) relating to semen assessment
- how Standard Operating Procedures ensure that:
    - all relevant aspects of performing a semen assessment are considered and undertaken
    - any discrepancies or omissions in any aspect of a semen assessment are noted, reported and followed up
- the guidelines for collection of a semen sample
- the information provided for individuals prior to sample production
- the considerations for individuals that relate to protected characteristics
- the requirements for ensuring confidentiality, privacy and comfort for individuals providing semen samples, including ensuring the sample production room is clean, comfortable and supportive of semen sample collection
- the documents required for collection and assessment of a semen sample and their purpose
- the current WHO criteria of a normal semen analysis
- the steps to ensure that the requirements for consent are in place for the proposed appointment, in line with local and HFEA requirements, to include but not limited to:
    - consent for use with a named partner
    - consent for use in donation
    - consent for storage
    - consent for use for training purposes.

AC1.6 includes:

- the correct identification of the individual providing the sample
- the purpose for which the sample is provided.

AC1.7 includes:

- additional considerations for sample identification and chain of custody
- cases where off-site procurement is not advised.

AC1.9 includes but is not limited to:

- ensuring that samples do not become misidentified
- ensuring that samples do not become contaminated
- ensuring that samples do not become cross-contaminated
- the effect of time and post-procurement on sperm
- the effect of temperature on sperm
- the requirement for sterile practice when assessing samples prior to use in treatment, donation or cryopreservation
- the requirement for following witnessing procedures when assessing samples prior to use in treatment, donation or cryopreservation.

AC2.1 includes:

- Standard Operating Procedures and standard laboratory documentation for semen assessment
- the confirmation of consent as required for the proposed procedure
- how to prepare the room for an individual to provide a semen sample
- the instructions given to patients and donors prior to sample production, including abstinence, use of lubricants, the purpose of the sample and how any results will be given
- identifying and instructing individuals providing semen samples
- identifying and instructing individual patients wishing to provide an off-site sample
- receiving semen samples into the laboratory for a range of purposes
- receiving a semen sample into the laboratory that has been produced off-site
- describing the checks performed to ensure that the assessment of the sample matches the proposed intention for the sample, for the correct individual, with the correct partner assigned, and is undertaken on the right day and at the right time
- describing the procedures carried out before and after production of the sperm sample to ensure correct identification of the purpose or intended use for the sample
- describing the procedures carried out before and after production of the sperm sample to ensure correct identification and labelling of the sample
- selecting appropriate personal protective equipment (PPE) used for semen assessment
- selecting the current documentation used to record the semen assessment
- summarising the principles and practice of microscopy for semen assessment, including the selection and safe use of the appropriate microscope and Standard Operating Procedures for basic maintenance, such as changing the bulb
- summarising the equipment required to perform a semen assessment and explaining how to confirm that it is within operational limits and suitably calibrated
- selecting the appropriate reagents and equipment to perform the semen assessment.

AC2.3 includes the ability to:

- follow Standard Operating Procedures for semen assessment
- demonstrate participation in witnessing procedures for sample identity and purpose, and ensure the absence of other samples or consumables from previous analyses in the work area
- check that the unique identifier corresponds to the individual's details
- perform macroscopic measures and observations of a semen sample
- perform semen volume assessment
- perform semen pH assessment

- perform sperm concentration assessment
- perform sperm motility assessment
- perform sperm vitality assessment (or discuss methodology)
- perform sperm morphology assessment
- perform antisperm antibody tests (or discuss methodology)
- perform round cell concentration assessment (or discuss methodology)
- perform assessment for retrograde ejaculation (or discuss methodology)
- demonstrate how to assess a sample that appears to be azoospermic (or discuss methodology)
- keep contemporaneous records in accordance with local policies and procedures
- demonstrate the ability to act if an error or omission is noted
- manage workload, taking into account the prioritisation timing of the procedure, the efficient use of resources and the multidisciplinary team.

AC2.4 includes the ability to:

- update records in accordance with local and national policies and procedures
- demonstrate effective communication on all aspects of semen assessment in line with the proposed purpose of the sample and in accordance with local policies and procedures
- explain how semen assessment results are reported and communicated to the patient
- act on any event that requires immediate action in accordance with local policies and procedures
- demonstrate disposal of sperm samples in accordance with local policies and procedures and according to Standard Operating Procedures
- list local diagnostic thresholds for treatment
- describe the patient-specific factors that might influence the semen assessment results
- describe the sources of laboratory error in semen assessment
- explain the principles of quality assurance for semen assessment
- participate in laboratory internal and external quality assurance for semen assessment
- compile reports on semen assessment for audit or quality-assurance purposes.

AC3.1 includes:

- the contingency arrangements in the event of an unforeseen problem arising
- how to escalate concerns that an individual may be having difficulty in providing a sample and the options for an individual unable to provide a sample at the appointment
- the limits of the learner's authority and who to report to.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practices related to performing semen assessment	1.1	Summarise current national guidelines, policies, protocols, Standard Operating Procedures and good practice underpinning semen assessment			
		1.2	Compare a 'semen analysis' in a diagnostic laboratory and a 'semen assessment' in the HFEA-licensed reproductive science laboratory			
		1.3	Explain why diagnostic semen analysis is important as an initial fertility investigation			
		1.4	Discuss the occasions when a semen analysis or assessment occurs during a patient or donor's care pathway in the local service			
		1.5	Describe how semen assessment is scheduled to ensure timely completion of the assessment			
		1.6	Explain the requirements for witnessing and the specific risks inherent in semen assessment checked through the witnessing procedure			
		1.7	Describe the particular requirements for samples that are produced off-site			
		1.8	Explain the factors that might influence the quality and validity of a semen assessment, including the effect of omission or irregularity			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		1.9	Explain the factors giving rise to risks for the safety and quality of gametes or embryos arising from use of those gametes			
		1.10	Explain how batch tracking of media and consumables ensures items are fit for purpose, ensuring quality and safety in relation to a semen assessment			
		1.11	Summarise the elements of the local quality-management system relating to semen assessment			
2	Be able to perform semen assessment	2.1	Prepare the working environment for handling semen specimens			
		2.2	Obtain semen specimens in line with local policies and procedures			
		2.3	Perform a semen assessment according to local policies and procedures			
		2.4	Report and conclude the semen assessment in line with local policies and procedures			
3	Understand the context, troubleshooting and when to take advice in relation to performing and reporting semen assessments	3.1	Explain the remedial action to take when adverse situations, problems or unforeseen problems occur			
		3.2	Explain the context within which semen assessment gives rise to or is implicated in an incident to be reported to the Human Fertilisation and Embryology Authority			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 29: Clinical Biochemistry in Practice

Level:	**4**
Unit type:	**Optional**
Credit value:	**30**
Guided learning hours:	**240**

Unit summary

In this unit, you will apply the knowledge and skills gained in *Unit 19: General Laboratory Practice* to work in a clinical biochemistry setting. You will also be required to demonstrate appropriate attitudes and behaviours and integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice.*

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

Learning outcome 2: the type of equipment that learners will be assessed using (automated/semi-automated or manual equipment) will depend on their own specific area of clinical biochemistry.

AC2.4 could include:

- liver function (LFTs)
- thyroid function (TFTs)
- urea and electrolytes (U&Es)
- cardiac markers
- lipid profiles
- fasting glucose, HbA1c and osmolality
- glomerular filtration rate (GFR)
- urinalysis
- blood gases
- tumour markers for cancer biochemistry
- protein markers; electrophoresis etc.
- uric acid
- vitamins and trace metals

- GI tract
- therapeutic drugs, poisons, toxicology, drugs of abuse
- more general endocrine systems such as pituitary, adrenal and reproductive axes
- inherited disease.

AC2.15 includes:

- liver function (LFTs)
- thyroid function (TFTs)
- urea and electrolytes (U&Es)
- calcium, phosphate and magnesium
- cardiac markers
- lipid profiles
- fasting glucose and HbA1c
- kidney function.

AC3.1 requires learners to describe **three** examples.

AC3.2 requires learners to use the same **three** examples as used in 3.1.

AC3.3 requires learners to use **one** patient pathway.

AC3.4 includes contribution to the delivery of high-quality, safe, patient-centred services.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of clinical biochemistry	1.1	Compare the pre-analytical, analytical and post-analytical functions in a clinical biochemistry setting			
		1.2	Explain the principles of spectrophotometry, immunoassay and electrochemistry			
		1.3	Explain the purpose of reference ranges in relation to routine clinical biochemistry analyses			
		1.4	Explain the derivation of reference ranges in relation to routine clinical biochemistry analyses			
		1.5	Discuss safe handling and preparation of human blood in a clinical biochemistry setting			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on equipment in clinical biochemistry to specified quality standards	2.1	Explain the maintenance procedures required on chemistry and immunoassay analysers			
		2.2	Explain the principles and practice of quality control, external quality assessment and quality management in clinical biochemistry			
		2.3	Explain the role of audit and laboratory accreditation in supporting quality-assured services			
		2.4	Explain the common indications for clinical biochemistry measurements			
		2.5	Demonstrate the measurement of liver function tests (LFTs)			
		2.6	Demonstrate the measurement of thyroid function (TFTs)			
		2.7	Demonstrate the measurement of urea and electrolytes (U&Es)			
		2.8	Demonstrate the measurement of calcium, phosphate and magnesium			
		2.9	Demonstrate the measurement of cardiac markers			
		2.10	Demonstrate the measurement of lipid profiles			
		2.11	Demonstrate the measurement of fasting glucose and HbA1c			
		2.12	Demonstrate the performance of a urinalysis test			
		2.13	Demonstrate the measurement of blood gases			
		2.14	Maintain quality standards and related quality control, assessment and management techniques in own area of work			
		2.15	Describe common conditions where a clinical biochemistry result is below or above the reference range			
		2.16	Separate clinical trial samples in accordance with the clinical trial protocol and the ethical and governance approvals in place			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of clinical biochemistry on patients and the work of the multidisciplinary team	3.1	Describe patient pathways where clinical biochemistry services contribute to diagnosis and long-term monitoring			
		3.2	Explain how clinical biochemistry results are used in patient pathways			
		3.3	Explain the common symptoms experienced by a person in a patient pathway			
		3.4	Explain the work of multidisciplinary teams in own area of work			
		3.5	Discuss how personalised medicine can be used in the diagnosis and treatment of conditions appropriate to own work area			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 30: Haematology in Practice

Level: 4

Unit type: Optional

Credit value: 30

Guided learning hours: 240

Unit summary

In this unit, you will apply the knowledge and skills gained in *Unit 19: General Laboratory Practice* to work in a haematology setting. You will also be required to demonstrate appropriate attitudes and behaviours, and to integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice.*

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

Learning outcome 2: the type of equipment that learners will be assessed using (automated/semi-automated or manual equipment) will depend on their specific area of clinical haematology.

AC2.3 includes:

- full blood count (FBC)
- when should a blood film be assessed
- plasma viscosity
- International normalised ratio (INR)
- D-dimers
- an infectious mononucleosis screen.

AC2.13 includes for:

- haemoglobin
- platelets
- neutrophils
- eosinophils
- red blood cells
- ESR/PV
- coagulation screen.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of haematology	1.1	Compare the pre-analytical, analytical and post-analytical functions in a haematology setting			
		1.2	Explain the derivation and purpose of reference ranges in relation to routine haematology analyses			
		1.3	Describe the main cell types seen in normal blood			
		1.4	Discuss safe handling and preparation of human blood in a haematology setting			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on equipment in haematology to specified quality standards	2.1	Explain the principles and practice of quality control, external quality assessment and quality management in haematology			
		2.2	Explain the role of audit and laboratory accreditation in haematology laboratories			
		2.3	Explain the common indications for routine measurements in haematology			
		2.4	Carry out a full blood count (FBC) and spread a blood smear			
		2.5	Carry out the measurement of plasma viscosity (PV) or erythrocyte sedimentation rate (ESR)			
		2.6	Carry out a manual differential count, recognising normal cells and referring samples with abnormal cells appropriately			
		2.7	Carry out the measurement of international normalised ratio (INR)			
		2.8	Carry out the measurement of D-dimers			
		2.9	Carry out a coagulation screen			
		2.10	Carry out an infectious mononucleosis screen			
		2.11	Maintain quality standards and related quality control, assessment and management techniques in haematology			
		2.12	Explain which FBC parameters are measured and which are calculated			
		2.13	Explain the steps needed to rectify a problem when an automated haematology analyser has 'flagged' that the white blood cells have not produced a differential count			
		2.14	Explain why different anti-coagulants are used for different tests			
		2.15	Describe common haematology conditions where a result is below or above the reference range			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of haematology on patients and the work of the multidisciplinary team	3.1	Describe a common condition that results in a raised plasma viscosity or Erythrocyte Sedimentation Rate and how this measurement contributes to the patient pathway			
		3.2	Describe a common condition that results in a raised D-dimer			
		3.3	Explain how the measurement of D-dimer contributes to the patient pathway			
		3.4	Explain the common symptoms experienced by a person who has infectious mononucleosis			
		3.5	Explain how an infectious mononucleosis screen contributes to the patient pathway			
		3.6	Describe partnership working in haematology settings as part of the delivery of a high-quality, safe, patient-centred services			
		3.7	Discuss how personalised medicine is/could be used in the diagnosis and treatment of conditions appropriate to own work area			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 31: Clinical Immunology in Practice

Level: 4

Unit type: Optional

Credit value: 30

Guided learning hours: 240

Unit summary

In this unit, you will apply the knowledge and skills you gained in *Unit 19: General Laboratory Practice* to work in a clinical immunology setting. You will be required to demonstrate appropriate attitudes and behaviours, and to integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice*.

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs).

Learning outcome 2, the type of equipment that the learner will be assessed using (automated/semi-automated or manual equipment) will depend on their specific area of clinical immunology.

AC3.1 requires the learner to describe **three** examples.

AC3.2 requires the learner to use the same **three** examples as used in AC3.1.

AC3.3 requires the learner to use **one** patient pathway.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of clinical immunology	1.1	Compare the pre-analytical, analytical and post-analytical functions in a clinical immunology setting			
		1.2	Explain the derivation of reference ranges in relation to routine clinical immunology analyses			
		1.3	Explain the purpose of normal ranges in relation to routine clinical immunology analyses			
		1.4	Explain the principles of protein electrophoresis in clinical immunology			
		1.5	Discuss safe handling and preparation of human blood in clinical immunology			
		1.6	Explain the role of audit and laboratory accreditation in clinical immunology			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on equipment in clinical immunology to specified quality standards	2.1	Explain the principles and practice of quality control, external quality assessment and quality management in clinical immunology			
		2.2	Explain the role of audit and laboratory accreditation			
		2.3	Carry out protein electrophoresis for myeloma screening			
		2.4	Carry out allergy testing			
		2.5	Carry out the investigation of auto-immune disease			
		2.6	Apply and maintain quality standards and related quality-control assessment in clinical immunology			
3	Understand the impact of clinical immunology on patients	3.1	Describe patient pathways where clinical immunology services contribute to diagnosis and/or long-term monitoring			
		3.2	Explain how clinical immunology results are used in patient pathways			
		3.3	Explain the common symptoms experienced by a person in a patient pathway			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 32: Histocompatibility and Immunogenetics in Practice

Level:	**4**
Unit type:	**Optional**
Credit value:	**30**
Guided learning hours:	**240**

Unit summary

This unit will enable learners to apply the knowledge and skills they gained in *Unit 19: General Laboratory Practice* to work in a histocompatibility and immunogenetics setting. Learners will be required to demonstrate appropriate attitudes and behaviours and to integrate their learning as they develop their professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice.*

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs).

AC1.4 includes:

- serum separation
- preparation of lymphocytes from peripheral blood and other tissues
- freezing and thawing of lymphocytes
- DNA extraction.

AC1.5 – core techniques include:

- solid phase HLA antibody detection and definition
- HLA typing using polymerase chain reaction (PCR)-based techniques.

AC1.6 – specialist techniques including **one** from the following:

- complement-dependent cytotoxicity (CDC)
- flow cytometry crossmatching
- post-haematopoietic stem cell transplantation (HSCT) engraftment monitoring by short tandem repeat (STR).

AC1.7 – core techniques include:

- solid phase HLA antibody detection and definition
- HLA typing using polymerase chain reaction (PCR)-based techniques.

AC1.8 – specialist techniques includes **one** from the following:

- complement-dependent cytotoxicity (CDC)
- flow cytometry crossmatching
- post-haematopoietic stem cell transplantation (HSCT) engraftment monitoring by short tandem repeat (STR).

Learning outcome 2: the type of equipment that learners will be assessed using (automated/semi-automated or manual equipment) will depend on their specific area of clinical immunology.

AC2.2 includes:

- requirements for sample identification
- appropriate sample/specimen for each histocompatibility and immunogenetics investigation
- use of a laboratory information system
- understanding the importance of accurate transcription of patient/donor details.

AC2.3 includes performing the skills of:

- serum separation
- preparation of lymphocytes from peripheral blood and other tissues
- freezing and thawing of lymphocytes
- DNA extraction

and knowledge with respect to the:

- importance of accurate transcription of patient/donor details
- assessment of cell viability and purity
- preparation of correct cell concentration
- quantification of DNA and adjustment of DNA concentration.

AC2.4 includes performing the core skills of:

- solid phase HLA antibody detection and definition
- HLA typing using polymerase chain reaction (PCR)-based techniques

and knowledge with respect to the:

- preparation of reagents used in each histocompatibility and immunogenetics technique
- awareness of risk assessments for each histocompatibility and immunogenetics technique
- understanding the importance of instrument calibration
- understanding the problems of PCR contamination.

AC2.5 includes performing **one** specialist skill from the following:

- complement-dependent cytotoxicity (CDC)
- flow cytometry crossmatching
- post-haematopoietic stem cell transplantation (HSCT) engraftment monitoring by short tandem repeat (STR)

and knowledge with respect to:

- sample purity
- sample contamination
- false positive or negative reactions.

AC2.6 should be assessed for **one** core histocompatibility and immunogenetics laboratory technique:

- solid phase HLA antibody detection and definition
- HLA typing using polymerase chain reaction (PCR)-based techniques

and include knowledge with respect to:

- assessment of internal controls
- completion of appropriate documentation.

AC2.7 should be assessed for **one** specialist histocompatibility and immunogenetics laboratory technique:

select ONE from the following:

- complement-dependent cytotoxicity (CDC)
- flow cytometry crossmatching
- post-haematopoietic stem cell transplantation (HSCT) engraftment monitoring by short tandem repeat (STR).

AC2.8 should be assessed for the **two** core histocompatibility and immunogenetics laboratory techniques:

- solid phase HLA antibody detection and definition
- HLA typing using polymerase chain reaction (PCR)-based techniques.

AC2.9 should be assessed for **one** specialist histocompatibility and immunogenetics laboratory technique from the following:

- complement-dependent cytotoxicity (CDC)
- flow cytometry crossmatching
- post haematopoietic stem cell transplantation (HSCT) engraftment monitoring by short tandem repeat (STR).

AC2.10 should be assessed for **one** core histocompatibility and immunogenetics laboratory technique:

- solid phase HLA antibody detection and definition
- HLA typing using polymerase chain reaction (PCR)-based techniques.

AC2.11 should be assessed for **one** specialist histocompatibility and immunogenetics laboratory technique from the following:

- complement-dependent cytotoxicity (CDC)
- flow cytometry crossmatching
- post haematopoietic stem cell transplantation (HSCT) engraftment monitoring by short tandem repeat (STR).

AC3.1, 3.2 and 3.3 include **three** from the following:

- patient referred from solid organ transplantation
- patient referred for haematopoietic stem cell transplantation
- patient referred for investigation of platelet refractoriness
- patient referred for immunogenetics testing for disease association or drug hypersensitivity.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of histocompatibility and immunogenetics (H&I) in support of transplantation and immunogenetic services	1.1	Explain the range of services provided by the H&I laboratory			
		1.2	Explain the organisation and flow of samples within the H&I laboratory			
		1.3	Explain how samples are received in the H&I laboratory and their safe handling			
		1.4	Explain the principles of sample preparation in the H&I laboratory			
		1.5	Explain the principles of core techniques undertaken in the H&I laboratory			
		1.6	Explain the principles of a specialist technique undertaken in the H&I laboratory			
		1.7	Explain the common indications for the use of core H&I techniques			
		1.8	Explain the common indications for the use of a specialist H&I technique			
		1.9	Explain the role of audit and laboratory accreditation			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on equipment in histocompatibility and immunogenetics setting (H&I) to specified quality standards	2.1	Explain the principles and practice of quality control, external quality assessment and quality management in H&I			
		2.2	Carry out sample reception procedures for samples received in the H&I laboratory			
		2.3	Carry out the preparation of samples for use in H&I laboratory techniques			
		2.4	Carry out core H&I laboratory techniques			
		2.5	Carry out a specialist H&I laboratory technique			
		2.6	Explain the use of internal test controls for a core H&I laboratory technique			
		2.7	Explain the use of internal test controls for a specialist H&I laboratory technique			
		2.8	Resolve common problems in routine H&I laboratory techniques			
		2.9	Resolve common problems with procedures for a specialist H&I laboratory technique			
		2.10	Analyse the results of core H&I laboratory techniques			
		2.11	Analyse the results of a specialist H&I laboratory technique			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of Histocompatibility and Immunogenetics (H&I) on patients and the work of the multidisciplinary team	3.1	Describe patient pathways where H&I services contribute to patient management and/or long-term monitoring			
		3.2	Explain how the results of H&I tests contribute to H&I patient pathways			
		3.3	Explain the common symptoms experienced by a person in H&I patient pathways			
		3.4	Describe how multidisciplinary teams work in H&I settings as part of the delivery of a high-quality, safe, patient-centred service			
		3.5	Discuss how personalised medicine is/could be used in the diagnosis and recommended treatment of H&I conditions appropriate to own area of work			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 33: Transfusion Science – Blood Transfusion in Practice

Level:	**4**
Unit type:	**Optional**
Credit value:	**30**
Guided learning hours:	**240**

Unit summary

In this unit, you will apply your knowledge and skills gained in *Unit 19: General Laboratory Practice* to work in a transfusion setting. You will also be required to demonstrate appropriate attitudes and behaviours and integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice*.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.6 (Explain the principles of a group of procedures) and AC2.7 (Perform analyses from a group of procedures) must be completed for **one** of the groups of procedures listed below.

Group 1

Explain the principles of and perform the following:

- blood grouping and phenotyping
- antibody screening and identification
- microbiology screening of blood donations, including ELISA/chemiluminescence and nucleic acid amplification testing.

Or

Group 2

Explain the principles of and perform the following:

- blood grouping and phenotyping
- blood group genotyping
- pre-transfusion testing
- antenatal testing to monitor for haemolytic disease of the foetus and newborn (HDFN).

Or

Group 3

Explain the principles of and perform the following:

- manufacturing blood components from blood donations
- irradiation of blood components ensuring that components meet the required quality standards throughout the supply chain
- performing the processes relating to labelling, storage and issue of routine and non-routine products
- quality monitoring of blood components, including blood counts by flow cytometry.

Or

Group 4

Explain the use of panel cells and reagents in blood transfusion and perform the following:

- processing reagents and panel cells from blood donations
- performing the processes relating to labelling and storage and issue of panel cells and reagents
- perform validation and quality-control checks on panel cells and reagents.

AC1.6 should include **one** group of procedures.

AC2.1 should not include stem cell and tissue transplantation methods in healthcare.

AC2.7 should include **one** group of procedures.

AC3.1 should include **three** patient pathways.

AC3.2 should include **three** patient pathways.

AC3.3 should include **two** patient pathways.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of transfusion science	1.1	Explain the range of services provided by NHS Blood and Transplant			
		1.2	Discuss the safe handling of samples and blood donations			
		1.3	Explain the range and uses of blood components processed from whole blood			
		1.4	Explain the main functions of the principal blood cells and tissues			
		1.5	Explain sources and uses of human stem cells and tissues			
		1.6	Explain the principles of a group of procedures within transfusion sciences			
		1.7	Explain the principles of quality control and quality management			
		1.8	Explain the role of audit and laboratory accreditation			
		1.9	Explain the derivation and purpose of normal reference ranges in relation to routine transfusion science analyses			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on automated and/or manual equipment in transfusion science working to Good Manufacturing Practice	2.1	Discuss the application of transfusion science methods in healthcare			
		2.2	Explain the MHRA and Human Tissue Authority requirements for transfusion services			
		2.3	Perform quality control as required in departmental Standard Operating Procedures			
		2.4	Perform sample reception procedures for samples or donations received in your department			
		2.5	Demonstrate the ability to safely handle and prepare human blood			
		2.6	Perform sample/donation preparation following Standard Operating Procedures			
		2.7	Perform analyses from a group of procedures within transfusion sciences			
		2.8	Identify common laboratory errors and problems that may be encountered			
		2.9	Perform maintenance and troubleshooting following standard operational procedures			
		2.10	Perform final checks to ensure processes, results or products meet requirements for patient safety			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of transfusion science services on patients and the work of the multidisciplinary team	3.1	Describe patient pathways where transfusion science services contribute to diagnosis and/or long-term monitoring of diseases			
		3.2	Explain how transfusion science results are used in patient pathways			
		3.3	Explain the common symptoms experienced by a person in transfusion science patient pathways			
		3.4	Explain how multidisciplinary teams work in transfusion science settings as part of the delivery of high-quality, safe, patient-centred services			
		3.5	Discuss how personalised medicine is/could be used in the diagnosis and recommended treatment of conditions appropriate to this specialist area of healthcare science practice			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 34: Transfusion Science – Stem Cell and Tissue Transplantation

Level:	**4**
Unit type:	**Optional**
Credit value:	**30**
Guided learning hours:	**240**

Unit summary

In this unit, you will apply the knowledge and skills gained in *Unit 19: General Laboratory Practice* to work in a stem cell or tissue transplantation setting. You will also be required to demonstrate appropriate attitudes and behaviours and integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice.*

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.7 (Explain the principles of a group of procedures) and AC2.7 (Perform analyses from a group of procedures) must be completed for **one** of the groups of procedures listed below.

Group 1

Explain the principles of and perform the following:

- identifying different sources of stem cells (principles only)
- evaluation of CD34 doses in stem cell donations
- clean room practices
- processing/manipulation of stem cells in closed systems or controlled environments
- long-term storage of stem cells by cryopreservation
- issuing of stem cells
- perform validation and quality-control checks.

Or

Group 2

Explain the principles of and perform the following:

- consent for tissue donation (principles only)
- retrieval of tissues from a deceased donor (principles only)
- clean room practices, including clean room gowning
- processing of tissues, including dissection, decontamination and cryopreservation
- labelling and storage of tissue allografts
- separation and dispensing of serum eye drops
- ordering and issuing of tissues
- perform validation and quality-control checks.

AC1.7 should include **one** group of procedures.

AC2.7 should include **one** group of procedures.

AC3.1 should include **three** patient pathways.

AC3.2 should include **three** patient pathways.

AC3.3 should include **two** patient pathways.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of transfusion science in the fields of stem cells and tissues	1.1	Explain the range of services provided by NHS Blood and Transplant			
		1.2	Explain the role of audit and laboratory accreditation			
		1.3	Discuss the safe handling of samples, stem cells and tissues			
		1.4	Explain the range and uses of blood components and tissues			
		1.5	Explain the main functions of the principal blood cells and tissues			
		1.6	Explain sources and uses of human stem cells and tissues			
		1.7	Explain the principles of a group of procedures within transfusion science – stem cell and tissue transplantation			
		1.8	Explain the principles of quality control and quality management			
		1.9	Explain the derivation and purpose of normal reference ranges in relation to routine transfusion/transplantation science analyses			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on automated and/or manual equipment in transfusion and transplantation science working to good manufacturing practice	2.1	Discuss the application of transfusion science – stem cell and tissue transplantation methods in healthcare			
		2.2	Explain the MHRA and Human Tissue Authority requirements for transfusion or transplantation services			
		2.3	Perform quality control as required in departmental standard operating procedures			
		2.4	Perform sample reception procedures for samples or donations received in your department			
		2.5	Demonstrate the ability to safely handle and prepare human blood			
		2.6	Perform sample/donation preparation following Standard Operating Procedures			
		2.7	Perform analyses from a group of procedures within transfusion and transplantation sciences			
		2.8	Identify common laboratory errors and problems that may be encountered			
		2.9	Perform maintenance and troubleshooting following standard operational procedures			
		2.10	Perform final checks to ensure processes, results or products meet requirements for patient safety			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of transfusion and transplantation science services on patients and the work of the multidisciplinary team	3.1	Describe patient pathways where transfusion science – stem cell or tissue transplantation services – contribute to diagnosis and/or long-term monitoring of diseases			
		3.2	Explain how transfusion and transplantation science results are used in patient pathways			
		3.3	Explain the common symptoms experienced by a person in transfusion science patient pathways			
		3.4	Explain how multidisciplinary teams work in transfusion and transplantation science settings as part of the delivery of a high-quality, safe, patient-centred service			
		3.5	Discuss how personalised medicine is/could be used in the diagnosis and recommended treatment of conditions appropriate to this specialist area of healthcare science practice			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 35 Histology in Practice

Level: 4

Unit type: Optional

Credit value: 30

Guided learning hours: 240

Unit summary

In this unit, you will apply the knowledge and skills gained in *Unit 19: General Laboratory Practice* to work in a histology setting. You will also be required to demonstrate appropriate attitudes and behaviours and integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice.*

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.1 includes:

small biopsy type specimens:

- endoscopic biopsies
- skin
- breast cores
- prostate cores
- bladder biopsies
- liver cores
- gynaecology specimens, e.g. endometrial curetting

surgical resection specimens:

- breast
- bowel
- prostate
- gynaecology, e.g. uterus.

AC2.7 examples include:

- gut
- breast
- prostate

and stains

- haemotoxylin
- eosin (H&E).

AC3.1 requires the learner to describe **three** examples.

AC3.2 requires the learner to use the same **three** examples as used in 3.1.

AC3.3 requires the learner to use **one** patient pathway.

AC3.4 includes contribution to the delivery of a high-quality, safe, patient-centred service.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of histology	1.1	Explain the range of common small biopsy and surgical resection specimens sent to a histology department for analysis			
		1.2	Discuss safe handling and preparation of samples			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on automated/semi-automated and/or manual equipment in histology to specified quality standards	2.1	Explain the principles and practice of quality control, external quality assessment and quality management in histology			
		2.2	Explain the role of audit and laboratory accreditation in supporting quality-assured services histology			
		2.3	Use tissue processors and embedding equipment in histology			
		2.4	Perform appropriate local maintenance of equipment to specified quality standards in histology			
		2.5	Perform embedding techniques for common tissue samples in histology			
		2.6	Assist in cutting samples in histology			
		2.7	Perform sample staining on a range of sections in histology			
		2.8	Demonstrate loading and uploading immunohistochemistry analysers for a range of tissue antigens (tumour markers)			
		2.9	Explain how histopathology services contribute to molecular pathology			
		2.10	Explain the process of report generation and distribution			
		2.11	Apply and maintain quality standards and related quality control, assessment and management techniques			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of histology services on patients and the work of the multidisciplinary team	3.1	Describe patient pathways where histology services contribute to diagnosis and/or long-term monitoring			
		3.2	Explain how histology results are used in patient pathways			
		3.3	Explain the common symptoms experienced by a person in a patient pathway			
		3.4	Explain the work of multidisciplinary teams in own area of work			
		3.5	Discuss how personalised medicine is/could be used in the diagnosis and treatment of conditions appropriate to own work area			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 36: Cytology in Practice

Level: 4

Unit type: Optional

Credit value: 30

Guided learning hours: 240

Unit summary

In this unit, you will apply the knowledge and skills gained in *Unit 19: General Laboratory Practice* to work in a cytology setting. You will also be required to demonstrate appropriate attitudes and behaviours and integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice*.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.3 could include:

- NHS cervical screening programme inspection.

AC2.7 includes:

- Papanicolaou stain (PAP)
- Romanowsky staining in cytology.

AC3.1 includes:

- patient pathways where cytology services contribute to diagnosis and/or long-term monitoring
- the use of cytology results in patient pathways
- common symptoms experienced by a person in patient pathways.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of cytology	1.1	Describe the range of common samples sent to a cytology department for analysis			
		1.2	Discuss safe handling and preparation of cytology specimens			
2	Be able to perform routine analysis on automated/semi-automated and/or manual equipment in cytology to specified quality standards	2.1	Explain the principles and practice of quality control, external quality assessment and quality management in cytology			
		2.2	Explain the role of laboratory accreditation in cytology			
		2.3	Explain the role of audit in cytology			
		2.4	Apply and maintain quality standards and related quality control, assessment and management techniques			
		2.5	Process a range of gynaecology specimens in cytology			
		2.6	Process a range of non-gynaecology specimens in cytology			
		2.7	Perform sample staining			
		2.8	Prepare specimens (cell blocks) for immunohistochemistry for a range of samples to support the differential diagnosis of malignant disease			
		2.9	Demonstrate the use of molecular pathology techniques on a range of cytology gynaecology samples appropriate to cytology			
		2.10	Compare the process of report generation and distribution in gynaecology and non-gynaecology cytology			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of cytology on patients and the work of the multidisciplinary team	3.1	Discuss the role of cytology in patient care pathways			
		3.2	Discuss how a cytological diagnosis contributes to personalised medicine			
		3.3	Explain how multidisciplinary teams work in cytology settings as part of the delivery of high-quality, safe, patient-centred services			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 37: Microbiology in Practice

Level: 4

Unit type: Optional

Credit value: 30

Guided learning hours: 240

Unit summary

In this unit, you will apply the knowledge and skills that you gained in *Unit 19: General Laboratory Practice* to work in a microbiology setting. You will be required to demonstrate appropriate attitudes and behaviours, and to integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice*.

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs).

AC2.3 should include:

- blood
- urine
- wound swabs
- sputum
- stool
- high vaginal swabs.

AC3.1 requires the learner to describe **three** examples.

AC3.2 requires the learner to use the same **three** examples as used in AC3.1.

AC3.3 requires the learner to use **one** patient pathway.

AC3.4 includes contribution to the delivery of a high-quality, safe, patient-centred service.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of microbiology	1.1	Explain the range of common samples sent to a microbiology department for analysis			
		1.2	Discuss safe handling and preparation of samples in microbiology			
		1.3	Explain the basis of epidemiology, public health, health prevention and health protection in relation to microbiology services			
		1.4	Explain the role of public health bodies in screening and outbreak control			
2	Be able to perform routine analysis on automated/ semi-automated and/or manual equipment in microbiology to specified quality standards	2.1	Explain the principles and practice of quality control, external quality assessment and quality management in microbiology			
		2.2	Explain the role of audit and laboratory accreditation in microbiology			
		2.3	Process a range of microbiology samples			
		2.4	Perform molecular pathology techniques for a range of samples appropriate to microbiology			
		2.5	Explain the process of report generation and distribution in microbiology			
		2.6	Apply and maintain quality standards and related quality-control, assessment and management techniques			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the impact of microbiology on patients and the work of the multidisciplinary team	3.1	Describe patient pathways where microbiology services contribute to diagnosis and/or long-term monitoring			
		3.2	Explain how microbiology results are used in patient pathways			
		3.3	Explain the common symptoms experienced by a person in a patient pathway			
		3.4	Explain the work of multidisciplinary teams in own area of work			
		3.5	Discuss how personalised medicine is/could be used in the diagnosis and treatment of conditions appropriate to own work area			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 38: Virology in Practice

Level: 4

Unit type: Optional

Credit value: 30

Guided learning hours: 240

Unit summary

In this unit, you will apply the knowledge and skills gained in *Unit 19: General Laboratory Practice* to work in a virology setting. You will also be required to demonstrate appropriate attitudes and behaviours and integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice*.

All procedures must be undertaken in accordance with the Standard Operating Procedures/Examination Procedures (SOPs/EPs).

AC2.1 'quality control' should include internal quality control, external quality assessment and quality management.

AC2.3 'quality standards' should include related quality control, assessment and management techniques.

AC2.3 should include:

- swabs
- enteric samples
- blood samples
- CSF samples
- urine samples.

AC3.1 requires the learner to describe **three** examples.

AC3.2 requires the learner to use the same **three** examples as used in 3.1.

AC3.3 requires the learner to use **one** patient pathway.

AC3.4 should include: contribution to the delivery of high-quality, safe, patient-centred services.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures/Examination Procedures (SOPs/EPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of virology	1.1	Explain the range of common samples sent to a virology department for analysis			
		1.2	Explain the basis of epidemiology, public health, health prevention and health protection in relation to virology services			
		1.3	Explain the role of public health bodies in screening and outbreak control			
		1.4	Critically evaluate the principles of infection control			
		1.5	Explain what is meant by a significant result in virology			
		1.6	Discuss examples of significant results in relation to routine virology			
		1.7	Discuss safe handling and preparation of samples			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on automated/semi-automated and/or manual equipment in virology to specified quality standards	2.1	Explain the principles and practice of quality control in virology			
		2.2	Explain the role of audit and laboratory accreditation in supporting quality-assured services			
		2.3	Demonstrate the ability to apply and maintain quality standards in virology			
		2.4	Demonstrate the processing of a range of virology samples			
		2.5	Perform serology techniques for routine samples appropriate to virology			
		2.6	Perform molecular pathology techniques for routine samples appropriate to virology			
		2.7	Explain the process of report generation and distribution			
3	Understand the impact of virology on patients and the work of the multidisciplinary team	3.1	Describe patient pathways where virology services contribute to diagnosis and/or long-term monitoring			
		3.2	Explain how virology results are used in patient pathways			
		3.3	Explain the common symptoms experienced by a person in a patient pathway			
		3.4	Explain the work of multidisciplinary teams in own area of work			
		3.5	Discuss how personalised medicine can be used in the diagnosis and treatment of conditions appropriate to own work area			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 39: Principles and Practice of Decontamination Science

Level: 4

Unit type: Optional

Credit value: 5

Guided learning hours: 26

Unit summary

This unit introduces you to the principles and practice of decontamination science, and the role of the healthcare science associate working in decontamination science services. The unit includes processing methods and the contribution of decontamination science to the provision of safe, quality-assured services. You will be expected to build your professional practice and practice safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP) in own area of work.

AC1.1 includes:

- on-site decontamination services of a range of medical devices
- off-site decontamination services of a range of medical devices
- sterilisation
- disinfection
- processing of reusable medical devices:
    - surgical instruments
    - flexible endoscopes
    - rigid endoscopes
    - power tools
- user's own equipment, e.g. medical devices owned by the service user, processing service only
- fully-managed service, e.g. delivery collection/repairs, supply, maintenance and testing of processing equipment.

AC1.4 includes:

- organisational level
- department level.

AC1.5 includes:

- cleaning
- decontamination
- disinfection
- sterilisation
- medical device.

AC1.6 includes:

- Spaulding's Classification of Medical Devices
- decontamination levels.

AC3.1 includes:

- radioactive and biological material:
    - blood
    - urine
    - faeces
    - other body tissues.

AC3.2 includes:

- water quality
- steam quality
- chemistry
- processing equipment cycle parameters
- processing equipment validation
- processing equipment planned preventative maintenance
- staff training
- correct preparation of medical device prior to washing and sterilisation
- following manufacturers' instructions of each medical device
- environmental control
- work flow.

AC4.1 includes:

- the extent of the role and responsibility of the decontamination science department with respect to the quality management
- methods of quality assurance:
    - internal quality control
    - external quality assessment
- correcting failures in quality systems
- departmental training programmes and competency assessments
- quality standards
- compliance with manufacturers' instructions for use
- audit programmes.

AC4.2 includes:

- Medical Devices Regulations 2002
- Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC (CE marking accreditation)
- BS EN ISO 13485
- 2016 Medical Device Management (Issued by MHRA)
- quality management
- Health and Social Care Act 2008 (code of Practice on the prevention and control of infections and related guidance)
- Joint Advisory Group on Gastrointestinal Endoscopy (JAG)
- Requirements of Hospital Building Notes (HBN) and national guidance:
    - Health Technical Memorandum (HTM)
    - Welsh Health Technical Memorandum (WHTM)
    - Scottish Health Technical Memorandum (SHTM)
    - Northern Ireland Health Technical Memorandum (NIHTM).

AC4.4 includes:

- internal quality control (IQC)
- external quality assessment (EQA) data
- recording the outcome of quality-control assessment
- recommending corrective action where appropriate.

AC4.7 'periodic' refers to daily, weekly, quarterly, annual testing.

AC4.8 includes:

- hospital
- primary care
- community-based decontamination science services.

AC4.9 includes:

- air flows and pressures
- microbiological testing
- particle count.

AC5.1 includes:

- quality control
- quality assurance
- service provision
- meeting the needs of clinical services
- maintaining a safe service.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the healthcare science services provided by decontamination science	1.1	Explain the range of healthcare science services provided by decontamination science			
		1.2	Evaluate how the services provided by decontamination science support safe, high-quality patient care			
		1.3	Discuss the importance of partnership working within own organisation and private providers working with own department			
		1.4	Explain how decontamination science services are organised in own organisation			
		1.5	Explain the meaning of common terms used in decontamination science			
		1.6	Explain the different levels of decontamination			
		1.7	Explain the Control of Substances Hazardous to Health (COSHH) Regulations 2002 requirements in relation to chemicals used in decontamination science			
		1.8	Justify health and safety legislation and guidance underpinning decontamination science services			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the role of the healthcare science associate in decontamination science	2.1	Explain the role of the healthcare science associate in decontamination science			
		2.2	Explain the legislation, policy, quality management systems and good practice underpinning the practice of decontamination science			
		2.3	Justify the regulatory framework underpinning the delivery of healthcare science decontamination science services			
		2.4	Evaluate the purpose and process of incident reporting in own area of work			
		2.5	Discuss the impact a critical incident may have on the diagnosis and treatment of patients and healthcare services in own service			
		2.6	Explain personal responsibilities regarding processes and procedures appropriate to own role as described in Good Scientific Practice			
		2.7	Explain the limits of own authority and to whom they should report unresolvable problems			
3	Understand the principles and practice of processing reusable medical devices	3.1	Explain the different types of waste generated in the department and the appropriate methods of handling and disposal for each			
		3.2	Explain the factors that impact cleaning and disinfection of reusable medical devices			
		3.3	Explain how to select the appropriate cleaning and decontamination procedure			
		3.4	Explain the purpose of medical device Manufacturer's Instructions for Use (IFU)			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to participate in quality control, external quality assessment and quality management in own area of work	4.1	Explain the principles and practice of quality control, external quality assessment and quality management in decontamination science			
		4.2	Explain the current quality standards, management and accreditation legislation underpinning decontamination science services			
		4.3	Evaluate the performance of **two** methods of quality control in own area of work			
		4.4	Demonstrate the ability to participate in quality processes in own area of work			
		4.5	Explain the role of audit and the audit cycle as part of the quality management in decontamination science			
		4.6	Explain the purpose of environmental monitoring and testing in decontamination science services			
		4.7	Describe the purpose of periodic testing and maintenance programmes used in decontamination science services			
5	Understand the medical device journey and stock control	5.1	Compare **two** different medical device journeys through the decontamination process			
		5.2	Explain the purpose, organisation and utilisation of effective stock utilisation in decontamination science services			
6	Be able to use audit to ensure the validity of the information management system	6.1	Perform an audit of the information system to ensure information is retained in the system correctly			
		6.2	Analyse the information and prepare a report setting out the outcome of the audit			
		6.3	Analyse findings and prepare an action plan for information system improvement using feedback from the audit			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 40: Preparation of Medical Devices for the Cleaning and Disinfection Process

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**26**

Unit summary

This unit aims to provide you with the knowledge and skills to enable you to prepare medical devices for the cleaning and disinfection process, including safe collection of devices and the safe disposal of contaminated waste. You will be required to take appropriate reporting action when non-conformances are identified by self and others, including reporting procedures and remedial action within your authority. This knowledge will be extended and applied to specific processing methods as you build your professional practice and practice safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOP) in own area of work.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** and **Quality Management Systems** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice for the collection of medical devices from service users	1.1	Evaluate the standard operating procedure for the collection of medical devices from service users			
		1.2	Explain the requirements of collection trolleys to meet Health and Safety and Control of Infection guidance			
		1.3	Demonstrate the safe collection of medical devices from service users			
2	Be able to perform the preparation of medical devices for the cleaning process	2.1	Evaluate the standard operating procedure for the preparation of medical devices			
		2.2	Explain the different pre-cleaning processes for a range of devices			
		2.3	Explain the different sections of a set checklist and the legislative importance of checklists			
		2.4	Perform the checking of medical devices against the checklist and take appropriate action if a non-conformance is identified			
		2.5	Demonstrate the disassembly of medical devices			
		2.6	Identify the correct cleaning process for a selection of medical devices			
		2.7	Explain the importance of following the medical device manufacturers' instructions for use			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to identify any non-conforming devices received from service users	3.1	Explain when you would raise a non-conformance on a medical device			
		3.2	Perform the reporting of a non-conformance			
		3.3	Describe the actions to be taken with the service user when a non-conformance is identified			
		3.4	Perform the routine required to close an existing non-conformance			
4	Be able to document the receipt of medical devices	4.1	Evaluate the standard operating procedures for documentation in the receipting/wash area			
		4.2	Perform the process of entering data into the department information system			
		4.3	Explain the documentation required within the receipting/wash area and any retention periods that must be met			
5	Be able to perform housekeeping requirements	5.1	Evaluate the standard operating procedure for housekeeping duties within the area			
		5.2	Explain the housekeeping schedule carried out by others			
		5.3	Perform housekeeping duties within your area of responsibility			
		5.4	Describe the requirements of finishes with this area (fabric and furniture) to ensure compliance with infection control standards			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 41: Cleaning and Disinfection of Medical Devices: Manual Processes

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**30**

Unit summary

This unit will give you the knowledge and skills you need to be able to process reusable medical equipment by the various methods available. The unit will enable you to identify the differences between the methods and their advantages and disadvantages. You will extend and apply this knowledge to specific processing methods as you build your professional practice and practice safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) and in own area of work.

AC1.2 includes:

- the reasons why this process would be performed, including manufacturers' instructions for use.

AC1.3 includes:

- effectiveness
- reproducibility
- external influences
- consistency
- time efficient.

AC2.4 includes:

- water temperature
- detergent.

AC4.3 includes:

- effectiveness
- reproducibility
- external influences
- consistency
- time efficient.

AC4.2 includes:

- water temperature
- detergent.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** and **Quality Management Systems** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of processing reusable medical devices by the immersion manual clean	1.1	Evaluate the standard operating procedure for processing all reusable medical devices by the immersion manual clean method			
		1.2	Explain the advantages and disadvantages of the immersion manual clean method			
2	Be able to perform the processing of reusable medical devices by the immersion manual clean	2.1	Perform the cleaning process of a medical device using the immersion manual process			
		2.2	Perform the disinfection process of a medical device after the immersion manual process			
		2.3	Describe the personal protective equipment to be worn during this process, including when to change it during the process			
		2.4	Explain what critical parameters must be met during the cleaning phase to complete an effective process			
		2.5	Perform the process of transferring the device to the inspection and packing room to prevent cross-contamination			
		2.6	Describe the cross-infection risks to staff and the device			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the principles and practice of processing reusable medical devices by the non-immersion manual clean	3.1	Evaluate the standard operating procedure for processing of all reusable medical devices by the non-immersion manual clean method			
		3.2	Describe the reasons why this process would be performed, including Manufacturer's Instructions for Use			
		3.3	Explain the advantages and disadvantages of the non-immersion manual clean process			
4	Be able to perform the processing of reusable medical devices by the non-immersion manual clean	4.1	Perform the cleaning process of a medical device using the non-immersion manual process			
		4.2	Perform the disinfection process of a medical device after the non-immersion manual process			
		4.3	Describe the personal protective equipment to be worn during this process, including when to change			
		4.4	Explain what critical parameters must be met during the cleaning phase to complete an effective process			
		4.5	Perform the process of transferring the device to the inspection and packing room to prevent cross-contamination			
		4.6	Describe the cross-infection risks to staff and the device			
5	Be able to record all tasks in the departmental information system	5.1	Record the task completed into the department information system			
		5.2	Recover information from the information system of previously processed devices, using this method			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 42: Cleaning and Disinfection of Medical Devices: Automated Processes

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

This unit provides you with the knowledge and skills to enable you to process reusable medical equipment by the various automated methods that are available. It will enable you to identify the differences between the methods and their advantages and disadvantages. This knowledge will be extended and applied to specific processing methods as you build your professional practice and practice safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of work.

AC1.3 includes:

- effectiveness
- reproducibility
- external influences
- consistency
- time efficient.

AC3.3 includes:

- effectiveness
- reproducibility
- external influences
- consistency
- time efficient.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** and **Quality Management Systems** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of processing reusable medical devices by the ultrasonic clean	1.1	Evaluate the Standard Operating Procedure for processing of all reusable medical devices by the ultrasonic clean method			
		1.2	Describe the reasons why this process would be performed, including manufacturers' instructions for use			
		1.3	Explain the advantages and disadvantages of the ultrasonic clean method			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform the processing of reusable medical devices by the ultrasonic clean	2.1	Perform the cleaning process of a medical device using the ultrasonic process			
		2.2	Perform the disinfection process of a medical device after ultrasonic process			
		2.3	Describe the personal protective equipment to be worn during this process, including when to change it during the process			
		2.4	Explain what critical parameters must be met during the cleaning phase to complete an effective process, e.g. water temperature detergent			
		2.5	Perform the process of transferring the device to the inspection and packing room to prevent cross-contamination			
		2.6	Explain how an ultrasonic cleaner works, including cavitation			
		2.7	Describe the different phases of an ultrasonic cycle			
		2.8	Describe the cross-infection risks to staff and the device			
3	Understand the principles and practice of processing reusable medical devices by the validated automated process clean	3.1	Evaluate the Standard Operating Procedure for processing of all reusable medical devices by the automated cleaning process method			
		3.2	Describe the reasons why the automated cleaning process method would be performed, including manufacturers' instructions for use			
		3.3	Explain the advantages and disadvantages of the automated cleaning process method			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to perform the processing of reusable medical devices by the validated automated process	4.1	Perform the cleaning process of a medical device using the automated process			
		4.2	Explain what critical parameters must be met during the cleaning phase to complete an effective process			
		4.3	Explain the disinfection process for reusable medical devices by the automated process			
		4.4	Describe the personal protective equipment to be worn during this process, including when to change it during the process			
		4.5	Perform the process of transferring the device to the Inspection and Packing room to prevent cross-contamination			
		4.6	Describe the cross-infection risks to staff and the device			
5	Be able to record all tasks in the departmental information system	5.1	Record the task completed into the departmental information system			
		5.2	Recover information from the information system of previously processed devices using this method			
		5.3	Explain the recording system of the processing equipment and how it monitors the process			
6	Understand the importance and function of an Independent Monitoring System	6.1	Describe the function of an Independent Monitoring System			
		6.2	Explain the critical parameters that the Independent Monitoring System must monitor			
		6.3	Perform product release from the washer/disinfector using the Independent Monitoring System			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 43: Inspection, Assembly, Packaging of Medical Devices in a Controlled Environment

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**76**

Unit summary

This unit will give you the knowledge and skills you need to be able to prepare medical devices for the sterilisation process. You will be required to inspect, assemble and pack medical devices in a safe manner. You will be required to take appropriate reporting action when non-conformances are identified and undertake remedial action. This knowledge will be extended and applied to specific processing methods as you build your professional practice and practice safely in the workplace.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and the requirements of own area of work.

AC3.2 includes:

- power tools
- laparoscopic medical devices
- rigid endoscopes
- generic medical device checks
- robotic medical devices
- purpose: ensuring device is fit for use.

AC4.1 includes:

- power tools
- laparoscopic medical devices
- rigid endoscopes
- generic medical device checks
- robotic medical devices.

AC4.3 includes:

- preparation of device to be sent for repair
- decontamination certificate
- return process for device once repair has been completed.

AC5.2 includes:

- the consequences of not following the manufacturer's instructions for use.

AC7.2 includes:

- tray wrap
- crepe paper
- pouches
- containers
- non on-cellulose wrap.

AC7.3 includes:

- envelope method
- parcel method.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** and **Quality Management Systems** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of product release from the washer/disinfector process	1.1	Evaluate the standard operating procedure for product release of medical devices from washer/disinfectors			
		1.2	Define the purpose and process of product release of medical devices			
		1.3	Explain the criteria required to complete the product release of medical devices			
2	Be able to perform the product release from the washer/disinfection process	2.1	Demonstrate the product release process from the washer/disinfector			
		2.2	Demonstrate the criteria required and how it is checked			
		2.3	Describe the process to be completed should the product release process indicate a fail status			
		2.4	Explain the process to be taken after a fail status has been identified for medical devices post processing and the washer/disinfector			
3	Understand the principles and practice of the inspection process of medical devices	3.1	Evaluate the standard operating procedure for the inspection of medical devices			
		3.2	Explain the purpose of the inspection process and the checks that need to be carried out on a range of devices			
		3.3	Explain the consequences to the clinical colleagues and patients if a device that is unfit for use is released to them			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to perform an inspection process on a range of medical devices	4.1	Demonstrate checks that need to be carried out on each type of device			
		4.2	Demonstrate the process required for a device that fails the checking process			
		4.3	Explain the process that is required to ensure that the remedial work is completed to enable the device to be returned to a fit-for-use condition			
5	Understand the principles and practice of assembly of medical devices	5.1	Evaluate the standard operating procedure for the assembly of medical devices into packs/sets			
		5.2	Describe the reasons for assembly or non-assembly of medical devices prior to sterilisation			
		5.3	Explain the reasons for the checklist and the responsibilities for completion of each section by all decontamination science departments			
		5.4	Explain the construction of the checklist and the importance of following the information contained within it			
6	Be able to perform the assembly process on appropriate medical devices	6.1	Perform the assembly of medical devices as defined in the manufacturer's instructions for use			
		6.2	Perform the assembly of a pack/set following the information contained on the checklist			
		6.3	Demonstrate the process to be followed when non-conformance is identified and take remedial action to resolve the issue			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Understand the principles and practice of wrapping or containerising medical devices	7.1	Evaluate the standard operating procedure for selecting the correct wrapping process			
		7.2	Explain the reason why different wrapping processes and material would be selected			
		7.3	Explain the reason that the wrapping material is folded in a prescribed manner and the purpose of this process			
		7.4	Describe the different criteria for each type of wrap and when it would be used			
		7.5	Explain the advantages and disadvantages of each type of wrap			
		7.6	Describe the checks that would need to be made for each type of wrap to ensure it is fit for purpose			
8	Be able to perform the wrapping or containerisation of medical devices	8.1	Perform the envelop and parcel wrap as appropriate to medical devices			
		8.2	Perform the actions required to pack medical devices into a pouch			
		8.3	Perform the actions required to pack medical devices into a container			
9	Be able to record all tasks carried out in the IAP room in the departmental information system	9.1	Record all tasks in the departmental information systems (tracking and tracing) database			
		9.2	Retrieve information on individual medical devices from the tracking system			
		9.3	Produce departmental information system reports			
		9.4	Describe how the departmental information system assists with meeting contractual arrangements			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
10	Be able to perform the required housekeeping duties in the inspection, assembly and packaging of medical devices	10.1	Explain the housekeeping schedule carried out by others in your area of work			
		10.2	Perform the housekeeping duties within your area of responsibility			
		10.3	Describe the requirements of finishes with this area (fabric and furniture) to ensure compliance with infection control standards			
11	Be able to produce and prioritise reports from activities completed in the IAP room for validation	11.1	Review prepared reports for the environmental monitoring testing for referral to an appropriate senior colleague			
		11.2	Review all housekeeping documentation and highlight areas of concern or gaps to an appropriate senior colleague			
		11.3	Observe an environmental monitoring test being performed			
		11.4	Describe the actions required should the environmental conditions move to fail status			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 44: Terminal Processing Including Sterilisation and High Level Disinfection

Level: 4

Unit type: Optional

Credit value: 5

Guided learning hours: 36

Unit summary

This unit gives you the knowledge and skills you need to be able to process reusable medical equipment using terminal sterilisation or high-level disinfection. You will be able to understand how to use the sterilisers to process medical devices and the safety requirements for their operation. You will also be required to take appropriate reporting action when faults or breakdowns occur with processing equipment. This knowledge will be extended and applied to specific processing methods as you build your professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures and the requirements of own area of work.

AC1.3 includes:

- steam
- gas plasma
- ethylene oxide.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** and **Quality Management Systems** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of processing reusable medical devices by terminal sterilisation	1.1	Evaluate the standard operating procedure for processing of all reusable medical devices terminal sterilisation method			
		1.2	Explain the criteria for loading packs/sets onto the sterilisation carriage			
		1.3	Describe the critical cycle parameters required for a successful sterilisation cycle			
		1.4	Describe the advantages and disadvantages of the various methods of sterilisation			
		1.5	Explain the definition of sterilisation and high-level disinfection, and the difference between the two processes			
		1.6	Describe the role of the independent monitoring system and how it is used to perform product release			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform the processing of reusable medical devices by terminal sterilisation	2.1	Receive a range of reusable medical devices for terminal sterilisation			
		2.2	Perform the checks required prior to accepting the medical devices for processing			
		2.3	Record the devices in the departmental information system			
		2.4	Demonstrate operation of the steriliser to process reusable medical devices			
		2.5	Perform the unloading and checking of the critical parameters of the sterilisation process			
		2.6	Demonstrate the correct cooling process for medical devices			
		2.7	Perform the product release process for medical devices to either store or the service user ensuring all critical parameters are met			
3	Be able to record all tasks in the departmental information system	3.1	Record all tasks in the departmental information system (tracking and tracing) database			
		3.2	Retrieve information on individual medical devices from the tracking system			
		3.3	Produce departmental information system reports			
		3.4	Describe how the departmental information system assists with meeting contractual arrangements			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to perform the housekeeping requirement duties in the terminal processing area	4.1	Explain the housekeeping schedule carried out by others			
		4.2	Perform the housekeeping duties within own area of responsibility			
5	Be able to review and prioritise reports for validation	5.1	Review prepared reports for the testing of the steriliser for referral to an appropriate senior colleague			
		5.2	Review all housekeeping documentation and, when identified, highlight areas of concern or gaps to an appropriate senior colleague			
		5.3	Perform daily and weekly steriliser testing			
		5.4	Describe the actions required should the steriliser not meet acceptance criteria			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 45: Testing, Maintenance and Breakdown Management of Decontamination Equipment

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

In this unit, you will perform periodic testing and planned maintenance of decontamination equipment. You will also gain an understanding of the requirements for quarterly and annual equipment testing within a decontamination science setting. You will gain the knowledge and skills necessary to ensure all the testing and maintenance carried out is in compliance with national and internal guidance and the manufacturer's instructions for the device. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures and the requirements of own area of practice.

AC1.1 includes:

- commissioning
- validation
- testing
- planned maintenance
- breakdown/repair.

AC1.3 includes:

- range of equipment:
    - sterilisers
    - washer/disinfector
    - endoscope washer/disinfectors
    - ultrasonic washers
    - endoscope storage systems
    - heat sealers
    - fume cabinets
    - insulation testing machines
    - automated flushing systems
- the national/international guidance/standards/legislation for each type of equipment.

AC2.1 includes tests on each of the types of equipment listed below:

- sterilisers
- washer/disinfector
- endoscope washer/disinfectors
- ultrasonic washers
- endoscope storage systems
- heat sealers
- fume cabinets
- insulation testing machines.

AC2.4 includes on each of the types of equipment listed below:

- sterilisers
- washer/disinfector
- endoscope washer/disinfectors
- ultrasonic washers
- endoscope storage systems
- heat sealers
- fume cabinets
- insulation testing machines.

AC3.1 includes on each of the types of equipment listed below:

- sterilisers
- washer/disinfector
- endoscope washer/disinfectors
- ultrasonic washers
- endoscope storage systems
- heat sealers
- fume cabinets
- insulation testing machines.

AC3.4 includes on each of the types of equipment listed below:

- sterilisers
- washer/disinfector
- endoscope washer/disinfectors
- ultrasonic washers
- endoscope storage systems
- heat sealers
- fume cabinets
- insulation testing machines.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of daily and weekly testing of decontamination equipment	1.1	Define medical device processing equipment terms			
		1.2	Explain the purpose and importance of planned maintenance of decontamination equipment			
		1.3	Identify all daily and weekly tests for all equipment as detailed in manufacturer's instructions			
		1.4	Explain the importance of having a schedule of all planned testing and maintenance and what considerations should be taken into account when planning the schedule for the year			
		1.5	Discuss the potential impact of equipment failure on service delivery			
		1.6	Explain who should be notified of equipment failure, most crucially where it will impact on service delivery			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform daily testing and housekeeping of equipment to ensure that it is fit for safe use	2.1	Perform the daily tests on equipment used within decontamination science services			
		2.2	Complete all the documentation required for the recording of the daily tests			
		2.3	Review all daily test documentation and highlight areas of concern or gaps to an appropriate senior colleague			
		2.4	Perform all the daily housekeeping and complete all the documentation required for the recording of the tests			
		2.5	Review all documentation and highlight areas of concern or gaps to an appropriate senior colleague			
3	Be able to perform weekly testing of equipment to ensure that it is fit for safe use	3.1	Perform the weekly tests on equipment used within decontamination science services			
		3.2	Complete all the documentation required for the recording of the weekly tests			
		3.3	Review all weekly test documentation and highlight areas of concern or gaps to an appropriate senior colleague			
		3.4	Perform all the weekly housekeeping on equipment used within decontamination science services			
		3.5	Complete all the documentation required for the recording of the weekly tests			
		3.6	Review all documentation and highlight areas of concern or gaps to an appropriate senior colleague			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Record all testing data in the department information system	4.1	Record all testing data into department information system			
		4.2	Discuss the reasons for retaining test results into the information system			
		4.3	Review test data within the department information system to improve performance or reduce equipment downtime			
5	Perform the acceptance procedure for returning equipment back to service after successful testing/planned maintenance	5.1	Review the test data for accuracy and completeness			
		5.2	Identify the appropriate person to sign off report before equipment is placed back into service			
		5.3	Explain the checks that need to be made prior to allowing the equipment to be used for processing of medical devices			
		5.4	Discuss any follow-up actions required after the equipment is returned to service			
		5.5	Review any outstanding areas of concern identified by yourself and others to see they have been completed			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Understand when to notify the appropriate personnel in the event of an equipment failure	6.1	Explain the method used to identify the appropriate personnel that need to be notified to resolve the failure			
		6.2	Discuss the communication process so that updated information is provided regarding the progress of the repair and potential downtime of equipment			
		6.3	Explain business continuity arrangements and implementation process			
		6.4	Discuss the limits of your authority			
		6.5	Identify occasions when it is appropriate to notify a senior colleague			
		6.6	Discuss the information service users would need to receive in the event of a significant breakdown			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 46: Principles and Practice of Flexible Endoscope Decontamination

Level:	**4**
Unit type:	**Optional**
Credit value:	**6**
Guided learning hours:	**50**

Unit summary

In this unit, you will gain a broad knowledge of the processing systems for flexible endoscopes and the information management system, as well as the skills to ensure the information is accurate. This knowledge will be extended and applied to specific processing methods. You will be expected to build your professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures and the requirements of own area of work.

AC1.4 includes:

- sterilisers
- high-level disinfection.

AC2.1 includes:

- requirements of Hospital Building Notes (HBN) and national guidance:
  - Health Technical Memorandum (HTM)
  - Welsh Health Technical Memorandum (WHTM)
  - Scottish Health Technical Memorandum (SHTM)
  - Northern Ireland Health Technical Memorandum (NIHTM).

AC3.8 includes:

- checks to be made to ensure the equipment is ready to operate.

AC5.1 includes:

- vacuum systems
- drying systems
- chemical systems.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principal design and components of a flexible endoscope	1.1	Explain the main components of flexible endoscopes and how to identify potential failure			
		1.2	Describe the accessories that would be used with the flexible endoscope			
		1.3	Describe the reusable and disposable components of a flexible endoscope			
		1.4	Describe the level of decontamination that should be attained in relation to the endoscope			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the principles and practice of processing a flexible endoscope using a validated automated cleaning process	2.1	Evaluate the standard operating procedures for processing of all flexible endoscopes by the automated cleaning process method			
		2.2	Explain the methods used by processing equipment to identify when an endoscope is not fit for use			
		2.3	Identify the checks that are carried out on a flexible endoscope to ensure it is fit for purpose			
		2.4	Describe the limitations of the processing equipment to achieve a fit-for-use flexible endoscope			
		2.5	Explain the purpose of the leak test for flexible endoscopes			
		2.6	Describe the process should a flexible endoscope be identified as having a fault and the action to be taken to remedy the fault			
		2.7	Explain the process of returning flexible endoscopes for repair			
		2.8	Describe the role of the independent monitoring system and how it is used to perform product release			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to perform the receipt, leak test, manual cleaning and preparation for the automated process	3.1	Demonstrate the collection and receipting of a flexible endoscope			
		3.2	Demonstrate the leak test process			
		3.3	Demonstrate a manual wash and rinse of the flexible endoscope			
		3.4	Explain the actions required if at any stage of the receipt, leak test, and manual cleaning stages the endoscope is identified as having a fault			
		3.5	Perform the recording into the departmental information system all data relating to process of the endoscope			
		3.6	Raise any non-conformance onto the departmental information system			
		3.7	Perform the process to load the flexible endoscope into the processing equipment			
		3.8	Demonstrate operation of the processing equipment to clean the flexible endoscope			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to perform the product release from the endoscope washer/disinfector	4.1	Evaluate the standard operating procedures for processing of all flexible endoscopes by the automated cleaning process method			
		4.2	Perform the process of reviewing the critical parameters of the processing cycle of both the equipment and independent monitoring system			
		4.3	Enter the data into the departmental information system			
		4.4	Explain the process when a flexible endoscope fails during processing and take remedial action			
		4.5	Describe the appropriate actions when the processing equipment fails			
		4.6	Ensure all documentation is completed and retained with the flexible endoscope before proceeding to the next process			
		4.7	Perform the product release process when the flexible endoscope is released direct to the service user			
5	Be able to prepare the flexible endoscope so it can be held in an endoscopy storage system	5.1	Perform the process for storing the flexible endoscope in the various storage systems			
		5.2	Enter the data into the departmental information system			
		5.3	Raise any non-conformance onto the departmental information system			
		5.4	Ensure all the documentation is completed			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to perform product release from endoscopy storage systems to the service user	6.1	Evaluate the standard operating procedures for processing of all flexible endoscopes by the automated cleaning process method			
		6.2	Review the critical parameters of the processing cycle of both the equipment and independent monitoring system			
		6.3	Enter the data into the departmental information system			
		6.4	Perform the product release process if the flexible endoscope is released direct to the service user			
		6.5	Perform the process if a flexible endoscope fails during processing and take remedial action			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 47: The Role of the Genetic Counsellor

Level: 4

Unit type: Optional

Credit value: 5

Guided learning hours: 41

Unit summary

In this unit, you will gain an understanding of the role of the genetic counsellor within healthcare science. Learning will include the potential impact of inherited conditions and personalised medicine on the patient and their families, and the role of the genetic counsellor in supporting patients and their families to understand and adjust to receiving genetic information. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to your scope of practice.

Additional information

AC1.1 – the key differences between the term genetic and genomic include:

- genetics scrutinises the functioning and composition of the single gene whereas genomics addresses all genes and their interrelationships, in order to identify their combined influence on the growth and development of the organism.

AC1.2 includes:

- prenatal
- paediatric onset
- adult onset.

AC1.4 should include **two** inherited conditions.

AC1.5 should include **one** inherited condition.

AC2.1 – the purpose of prenatal genetic counselling includes:

- to provide support, information and advice about genetic and genomic conditions
- to use specialist knowledge to support patients and their families
- assessment of the risk of passing an inherited condition on to a child
- gathering a medical history and drawing up a family tree
- requesting genetic and genomic tests to clarify health risks
- supporting patients/families as they incorporate this information into their lives and make decisions about the pregnancy.

AC2.2 – the purpose of genetic counselling if a child is affected by an inherited condition includes:

- support and advice to families
- discussion about genetic tests, which can be arranged if appropriate, including the risks, benefits and limitations of genetic testing
- help understanding the results of genetic tests and what they mean
- information about relevant patient support groups
- support patients/families as they incorporate this information into their lives, including how this may affect future reproductive choices.

AC2.3 – the counselling issues for an adult onset would include:

- understanding the implications for the patient's own heath (e.g. whether they need specific treatment or surveillance)
- how the genetic condition may affect reproductive choices for the patient
- the implications for family members as predictive/pre-symptomatic testing may now be available.

the purpose of genetic counselling if an adult is affected by an inherited condition includes:

- support and advice to families
- discussion about genetic tests, which can be arranged if appropriate, including the risks, benefits and limitations of genetic testing
- help understanding the results of genetic tests and what they mean
- information about relevant patient support groups
- support patients/families as they incorporate this information into their lives, including how this may affect future reproductive choices.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the genetic and genomic conditions affecting patients and their families within own area of practice	1.1	Explain the key differences between the term genetic and genomic			
		1.2	Explain how the diagnosis of a genetic/genomic condition may occur at any stage of life			
		1.3	Explain the role of genomics/genetics in the diagnosis and management of disease, including screening			
		1.4	Explain the patterns of inheritance of inherited conditions with different inheritance patterns in own area of practice			
		1.5	Explain how an inherited condition, where a diagnostic referral is made to own area of practice, may impact on the patient and their family			
		1.6	Explain how personalised medicine provides opportunities to tailor treatment to individual patients based on their predicted response or risk of disease			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the role of genetic/genomic counselling in the diagnosis and management of genetic or genomic conditions	2.1	Explain the purpose of pre-natal genetic counselling			
		2.2	Explain the purpose of genetic counselling if a child is affected by an inherited condition			
		2.3	Explain the purpose of genetic counselling following the diagnosis of an adult-onset condition			
		2.4	Discuss the importance of the partnership between patient and counsellor and collaborative decision making			
		2.5	Discuss the role of the genetic counsellor within the multidisciplinary team			
		2.6	Discuss how the practice of genetic counselling may be used within own area of practice			
		2.7	Discuss the ethical and legal considerations of genetic counselling in own area of practice			
3	Be able to gather and draw a simple family history and interpret the findings	3.1	Explain how family trees can be used to identify inheritance patterns and other family members who may be at risk of inheriting the genetic condition			
		3.2	Gather a patient history from patient notes in the medical record and/or a family history questionnaire to identify a mode of inheritance			
		3.3	Prepare a short presentation summarising the family history			
		3.4	Explain the importance of using standardised symbols when drawing a family history			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 48: Genetics and Genomics in Practice

Level: 4

Unit type: Optional

Credit value: 30

Guided learning hours: 240

Unit summary

In this unit, you will apply the knowledge and skills you gained in *Unit 19: General Laboratory Practice* to work in a genetics and genomics sciences setting. The unit will build on your learning from *Unit 2: Professional Practice and Person-centred care*. You will begin to integrate and embed many of the professional practice learning outcomes to support safe, quality-assured working practice in the workplace. You will also be required to demonstrate the appropriate attitudes and behaviours, and integrate your learning as you develop your professional practice.

Additional information

Learners completing this unit must also complete *Unit 19: General Laboratory Practice*.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.7 includes:

- reverse transcription PCR, sample preparation and validation of the results of the technique.

AC2.3 includes:

- quality-control assessment of DNA extraction
- monitoring of equipment
- performance of routine assays.

AC2.5 and 2.10 include:

- alerting a more senior member of staff or discussions.

AC2.9 could include:

- quantitative fluorescent PCR
- use of kit-based methods to detect genetic variation.

AC3.2 should include **three** examples.

AC3.3 should include **three** patient pathways.

AC3.4 should include **three** common genetic conditions.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of genetics and genomics within healthcare science	1.1	Explain the difference between genetics and genomics			
		1.2	Describe the structure of DNA and the functions of coding and non-coding DNA			
		1.3	Compare the pre-analytical, analytical and post-analytical functions in a clinical biochemistry setting			
		1.4	Explain the derivation and purpose of reference ranges in relation to routine genetic and genomic analyses			
		1.5	Describe the principles of cell culturing, harvesting and staining techniques for chromosome and genetic analysis			
		1.6	Describe the principles of DNA and RNA extraction from a range of patient sample types			
		1.7	Describe a range of polymerase chain reaction (PCR) techniques using both manual and automated technology			
		1.8	Describe the methods used to assess single-point genetic variation			
		1.9	Describe the methods used to assess more complex genetic variation			
		1.10	Explain how to prepare clinical reports for validation			
		1.11	Explain how to prioritise reports that require referral to senior colleagues			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine analysis on automated/ semi-automated and/or manual equipment in genetic and genomic sciences specified quality standards	2.1	Explain the principles and practice of quality control, external quality assessment and quality management in genetic and genomic sciences			
		2.2	Explain the role of audit and laboratory accreditation in supporting quality-assured services			
		2.3	Explain the common indications for routine measurements in genetic and genomic science			
		2.4	Perform constitutional chromosome analysis across a range of clinical settings			
		2.5	Recognise situations when additional banding techniques or fluorescence in situ hybridization (FISH) would provide extra beneficial information, and take appropriate action			
		2.6	Describe the range of chromosome variation and normal and abnormal results			
		2.7	Perform fluorescence in situ hybridization (FISH) to specified quality standards on constitutional preparations			
		2.8	Recognise normal and abnormal results, including suboptimal fluorescence in situ hybridization (FISH) preparations, and take appropriate action			
		2.9	Demonstrate the use of equipment to specified quality standards			
		2.10	Recognise normal and abnormal results and interferences, individual variations and sample integrity issues, and take appropriate action			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		2.11	Perform a range of polymerase chain reaction (PCR) techniques manually, making adjustments to correct for poor PCR quality as necessary			
		2.12	Recognise normal and abnormal results, interferences, individual variations and sample integrity issues as factors that affect polymerase chain reaction quality			
		2.13	Apply and maintain quality standards and related quality-control, assessment and management techniques			
3	Understand the impact of genetic and genomic sciences on patients and the work of the multidisciplinary team	3.1	Discuss some ethical issues associated with the use of genetic and genomic testing			
		3.2	Discuss the changes in body structure and function resulting from common genetic conditions on the affected person			
		3.3	Explain how genetic and genomic science results are used in patient pathways			
		3.4	Discuss the potential impact of common genetic conditions on the daily life of the affected person and, if appropriate, their family			
		3.5	Discuss the role of genomic counselling in own area of work			
		3.6	Explain how multidisciplinary teams work in genetic and genomic science settings as part of the delivery of a high-quality, safe, patient-centred service			
		3.7	Discuss how personalised medicine can be used in the diagnosis and recommended treatment of ONE condition appropriate to own area of work			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 49: Scientific Basis of Cardiovascular, Respiratory and Sleep Science: Cardiac Embryology, Anatomy and Physiology

Level:	**4**
Unit type:	**Optional**
Credit value:	**15**
Guided learning hours:	**120**

Unit summary

In this unit, you will develop the understanding of cardiac embryology, anatomy and physiology of the cardiovascular system, which is needed if you want to work in a cardiac science department. You will be expected to apply and contextualise your knowledge and skills by performing routine technical skills and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

LO1 includes:

- the genomic and/or genetic basis for common congenital cardiac diseases.

AC1.2 should include **two** common congenital heart defects.

AC3.2 includes:

- structure of the pericardium and layers of the heart wall
- structural and functional characteristics of cardiac muscle tissue and the conduction system
- anatomy of the chambers of the heart, septum and conducting system
- position, surface anatomy and importance of the cardiac valves
- anatomy of the four heart valves
- anatomy of the conduction system and fibrous skeleton.

AC3.4 includes:

- arteries and veins.

AC4.6 could include (some are less common):

- mitral stenosis
- mitral regurgitation
- mitral valve prolapse
- aortic stenosis
- aortic regurgitation
- tricuspid stenosis
- tricuspid regurgitation
- tricuspid atresia
- pulmonary stenosis
- pulmonary regurgitation
- pulmonary atresia.

AC5.4 should include:

- autonomic regulation of heart rate
- chemical regulation of heart rate
- age
- gender
- physical fitness
- body temperature.

AC6.2 should include **two** common vascular arterial diseases, e.g.:

- diabetes
- coronary artery disease
- peripheral arterial disease
- stroke
- transient ischaemic attack

and **two** common vascular venous diseases, e.g.:

- deep vein thrombosis
- varicose veins
- venous insufficiency.

AC7.2 should include **three** examples for cardiac and **three** for respiratory and sleep, one of which for both should have a genetic basis.

AC7.5 includes:

- identifying instances of good practice and those where there could be improvements.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand cardiac embryology and common congenital heart defects	1.1	Explain the key stages in cardiac embryology			
		1.2	Explain the resulting anatomical and physiological changes for common congenital heart defects			
		1.3	Discuss the potential impact of congenital heart disease on the patient and their family			
2	Understand the foetal circulation and the circulatory changes that occur at birth	2.1	Discuss the anatomy and physiology of the foetal circulation			
		2.2	Explain the function of the umbilical arteries, umbilical vein, ductus venosus, foramen ovale and ductus arteriosus			
		2.3	Explain the circulatory changes that occur at birth			
		2.4	Discuss a cardiac condition that can result when the normal circulatory changes at birth do not occur			
3	Understand the anatomy of the heart, coronary, systemic and pulmonary circulations	3.1	Describe the location of the surfaces and borders of the heart			
		3.2	Explain the structure and function of the heart			
		3.3	Explain the purpose and structure of the coronary circulation			
		3.4	Explain the flow of blood through the systemic and pulmonary circulations			
		3.5	Explain which areas of the heart are damaged if the main trunk of the right and left coronary artery is blocked			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Understand the cardiac cycle and cardiac conduction system	4.1	Explain the pressure and volume changes that occur during a cardiac cycle			
		4.2	Explain the cardiac conduction system and the relationship to the normal electrocardiogram (ECG)			
		4.3	Explain how cardiac action potentials are generated and propagated			
		4.4	Explain the structure and function of the heart valves			
		4.5	Explain how heart sounds are generated			
		4.6	Describe the physiological changes that occur to blood flow through heart valves in the presence of valvular heart disease			
5	Understand the term cardiac output, the regulation of heart rate and factors affecting cardiac output	5.1	Explain the term cardiac output			
		5.2	Explain how stroke volume is regulated			
		5.3	Explain the relationship between exercise and the heart			
		5.4	Describe factors that affect cardiac output and their effect			
6	Understand the structure and function of blood vessels and the effect of vascular disease	6.1	Compare structure and function of arteries, arterioles, capillaries, venules and veins			
		6.2	Explain the damage caused by common vascular diseases that affect arterial and venous blood vessels			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Understand the practice of cardiac science	7.1	Explain the investigations undertaken by cardiac science services			
		7.2	Explain the pathophysiology of common cardiac diseases where physiological science investigations are indicated			
		7.3	Explain the components of good patient-centred care and why it is important within cardiac science departments			
		7.4	Explain the key features of effective multidisciplinary team working within cardiac services to inform own practice			
		7.5	Critically reflect on personal experience of patient-centred care and effective team working			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 50: Scientific Basis of Cardiovascular, Respiratory and Sleep Science: Anatomy, Histology and Physiology of the Respiratory System

Level:	**4**
Unit type:	**Optional**
Credit value:	**15**
Guided learning hours:	**120**

Unit summary

In this unit, you will develop an understanding of the anatomy, histology and physiology of the respiratory system. You will be expected to apply and contextualise your knowledge and skills by performing routine technical skills and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.3 includes:

- muscles of the chest wall
- blood supply to the chest wall
- ribs
- sternum
- vertebral column.

AC2.2 includes:

- total ventilation
- alveolar ventilation
- physiological dead space.

AC3.2 includes:

- surface area
- partial pressure gradients
- blood flow
- airflow.

AC4.1 includes:

- neurochemical
- regulation of airway smooth muscle
- the influences of higher centres.

AC5.2 includes:

- obstructive lung diseases:
  - chronic obstructive pulmonary disease
  - asthma
- restrictive patterns
- fibrotic lung disease
- mechanical restriction (chest wall, obesity, muscle weakness)
- congenital lung conditions.

AC5.3 includes

- knowing the patient as an individual
- the essential requirements of care, including treating patients with respect, compassion and maintaining their dignity
- tailoring healthcare services for each patient
- continuity of care and relationships
- enabling patients to actively participate in their care, including communication, information and shared decision making.

AC5.5 includes:

- identifying instances of good practice and those where there could be improvements.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the anatomy, histology and physiology of the respiratory system	1.1	Explain the main features of the development of the lungs from conception onwards			
		1.2	Explain the anatomy and histology of the nose, pharynx, larynx, trachea, bronchi and lungs			
		1.3	Explain the anatomy of the chest wall			
		1.4	Explain the anatomy of the spine			
		1.5	Explain the function of the nose, pharynx, larynx, trachea, bronchi and lungs			
		1.6	Explain the lymphatics of the thorax			
		1.7	Explain the non-respiratory functions of the lungs and pulmonary circulation			
		1.8	Explain the effects of ageing, smoking and obesity on the respiratory system			
2	Understand the process of inspiration and expiration	2.1	Explain the process of inspiration and expiration			
		2.2	Explain the mechanics of ventilation and the role of surfactant in the lungs			
		2.3	Explain airflow and airway resistance within the tracheobronchial tree			
		2.4	Discuss how a respiratory disease leads to the modification of breathing			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand gas exchange and the transport of oxygen and carbon dioxide and factors that affect gas exchange	3.1	Explain the process of gas exchange and the transport of oxygen and carbon dioxide to and from the lungs			
		3.2	Explain the mechanism by which factors affect gas exchange			
		3.3	Explain the concept of ventilation and perfusion of the lungs, and the requirement to match ventilation and perfusion			
		3.4	Explain the regulation of acid-base balance			
4	Understand control of respiration and the effects of exercise	4.1	Explain the basics of the control of ventilation			
		4.2	Explain the effects of exercise on the respiratory system			
5	Understand the practice of respiratory physiology	5.1	Explain the investigations undertaken by respiratory physiology services			
		5.2	Explain the pathophysiology of common respiratory diseases where respiratory physiology investigations are indicated			
		5.3	Discuss the components of good patient-centred care and discuss why it is important within respiratory physiology			
		5.4	Explain the key features of effective multidisciplinary team working within respiratory physiology			
		5.5	Critically reflect on personal experience of patient-centred care and effective team working to inform future practice			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 51: Scientific Basis of Cardiovascular, Respiratory and Sleep Science: Scientific Basis of Respiratory Disorders of Sleep

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will develop an understanding of the physiological changes that occur during sleep and methods to assess daytime sleepiness. You will be expected to apply and contextualise your knowledge and skills by performing routine technical skills and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.4 includes:

- cardiovascular system
- respiratory system
- sympathetic nerve activity
- cerebral blood flow
- renal system
- endocrine system.

AC1.6 includes:

- pregnancy
- post-partum
- menopause.

AC2.4 includes:

- methods to assess excessive daytime sleepiness
- Multiple Sleep Latency Test (MSLT)
- maintenance of wakefulness test
- Stanford sleepiness scale.

AC2.5 should include **one** respiratory condition.

AC2.6 should include **one** non-respiratory condition.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the physiology of sleep	1.1	Explain the basic structural organisation of normal sleep			
		1.2	Explain normal and abnormal sleep patterns			
		1.3	Explain the stages of sleep and their characteristics			
		1.4	Explain the physiological changes that occur during sleep and the control of sleep wake cycle			
		1.5	Explain the mechanisms that control normal sleep			
		1.6	Discuss the effects of ageing and hormones on sleep			
2	Understand the routine techniques undertaken by healthcare science services to support the diagnosis and treatment of disorders of sleep	2.1	Explain a range of methods used to assess daytime sleepiness			
		2.2	Explain the basic principles underpinning routine techniques undertaken to investigate common respiratory sleep conditions			
		2.3	Explain the indications and contraindications of positive airway pressure systems used to treat respiratory disorders of sleep			
		2.4	Explain methods used to assess excessive daytime sleepiness			
		2.5	Discuss how a respiratory condition result in a disorder of sleep			
		2.6	Discuss how a non-respiratory condition result in a disorder of sleep			
		2.7	Discuss the impact of disorders of sleep on patients and their families			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 52: Principles of Ultrasound

Level:	**4**
Unit type:	**Optional**
Credit value:	**3**
Guided learning hours:	**24**

Unit summary

In this unit, you will gain an understanding of the principles of ultrasound that underpin many investigations, including those undertaken by the healthcare science workforce. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to your scope of practice.

Additional information

AC1.1 – ultrasound terms include:

- ultrasound
- Doppler ultrasound
- common artefacts
- echogenic
- anechoic
- acoustic enhancement
- acoustic shadowing.

AC1.3 includes:

- A-Mode
- B-Mode
- M-Mode
- 2-D
- 3-D
- Doppler ultrasound.

AC1.5 includes:

- longitudinal and transverse waves.

AC1.7 includes:

- power
- intensity
- pressure
- acoustic output of diagnostic machines
- tissue effects.

AC1.8 includes:

- ultrasound-induced heating
- mechanical bio-effects.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the basic principles of ultrasound	1.1	Explain common ultrasound terminology			
		1.2	Explain how ultrasound is generated and detected			
		1.3	Explain the physical properties of the different types of ultrasound			
		1.4	Explain the principles of Doppler ultrasound			
		1.5	Explain how ultrasound and Doppler ultrasound propagates through tissue			
		1.6	Explain how a transducer works to produce images in own area of work			
		1.7	Describe the risk of ultrasound exposure in own area of work			
		1.8	Describe the biological effects of ultrasound			
2	Understand the applications of ultrasound in healthcare science	2.1	Explain an application of ultrasound in own division of healthcare science or own area of practice			
		2.2	Evaluate the advantages and disadvantages of ultrasound within healthcare science or own area of practice			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 53: Recognising ECG Abnormalities in Adults

Level: 4

Unit type: Optional

Credit value: 10

Guided learning hours: 80

Unit summary

The aim of this unit is to equip you with the knowledge and skill to be able to recognise a wide range of ECG abnormalities in adults. You will be expected to develop a framework for ECG identification. You will be expected to build your patient-centred professional practice to enable you to undertake this skill safely in the workplace.

Additional information

It is suggested that learners will have completed the Level 2 *Unit 73: Performing Routine Electrocardiography in Adults*, or have appropriate experience before completing this unit.

AC3.1 includes recognising the ECG changes associated with:

- sinus arrhythmia
- sinus bradycardia
- sinus tachycardia
- atrial fibrillation
- atrial flutter
- atrial ectopics
- ventricular ectopics
- atrioventricular conduction blocks
- supraventricular tachycardia
- asystole
- ventricular fibrillation
- ventricular tachycardia.

AC3.2 includes recognising the ECG changes associated with:

- myocardial infarction
- myocardial ischaemia
- ST segment depression
- ST segment elevation
- how physiological changes result in ST depression and elevation
- the causes of ST segment elevation
- how to localise the site of the myocardial infarction on the ECG.

AC3.3 includes recognising the ECG changes associated with:

- left and right atrial abnormalities
- left and right ventricular hypertrophy
- left and right bundle branch block
- fascicular blocks.

AC3.4 includes recognising the ECG changes associated with:

- hyperkalaemia
- hypokalaemia
- thyrotoxicosis
- hyperthyroidism
- hypocalcaemia.

AC3.5 includes recognising the ECG changes associated with:

- Long QT syndrome
- Brugada syndrome
- digoxin effect and toxicity
- cardiomyopathies
- pulmonary embolism
- neurological/neuromuscular disorders
- pericarditis
- myocarditis.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of electrocardiography	1.1	Explain the principles of the ECG			
		1.2	Evaluate the strengths and weaknesses of 12-lead ECG recording			
		1.3	Explain the relationship between ECG leads and cardiac anatomy			
		1.4	Explain the relationship between the normal ECG and cardiac physiology			
2	Understand the normal ECG in adults	2.1	Explain the relationship between the electrical and mechanical action of the heart during a normal cardiac cycle			
		2.2	Explain the main waves, complexes, segments, duration and intervals of the normal ECG			
		2.3	Explain the term cardiac axis and how to measure the cardiac axis			
		2.4	Explain how to measure heart rate from an ECG			
		2.5	Know the normal ranges for each component of the ECG in adults			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to identify a range of ECG changes in adults	3.1	Recognise arrhythmias, including life-threatening arrhythmias on a 12-lead ECG recording			
		3.2	Recognise ECG changes associated with myocardial infarction and ischaemia			
		3.3	Recognise ECG changes associated with conditions affecting the left and right sides of the heart			
		3.4	Recognise the ECG changes associated with conditions not primarily affecting the heart			
		3.5	Recognise the ECG changes associated with a range of general disorders			
4	Be able to produce a factual ECG report	4.1	Evaluate ECG reporting frameworks			
		4.2	Produce factual ECG reports on a range of normal and abnormal adult ECGs			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 54: Ambulatory ECG Monitoring

Level:	**4**
Unit type:	**Optional**
Credit value:	**20**
Guided learning hours:	**160**

Unit summary

The aim of this unit is for you to be able to fit and remove ambulatory ECG devices and analyse the recording (excluding pacing and inherited disease). You will also be expected to apply knowledge of abnormal ECG rhythms and produce a factual report. You will be expected to build your patient-centred professional practice to enable you to undertake this skill safely in the workplace.

Additional information

It is suggested that learners will have completed the following units:

- Level 4 – Unit 53: Recognising ECG Abnormalities in Adults
- Level 2 – Unit 76: Fitting a 24hr Ambulatory ECG Monitor

or have appropriate experience before completing this unit.

AC1.2 includes:

- how to choose the correct monitoring period based on the frequency of symptoms
- alternative monitoring for less frequent symptoms, i.e. weeks and months between symptoms.

AC1.3 includes:

- assessment of patients in whom an arrhythmia is suspected, including:
  - syncope
  - near syncope or dizziness
  - palpitations
- patients who have had a cerebrovascular accident in whom paroxysmal atrial fibrillation (AF) or atrial flutter is suspected
- assessment of the potential risk of developing an arrhythmia, e.g. prior to discharge from hospital after a myocardial infarction
- assessment of the response to anti-arrhythmic treatment.

AC1.6 includes:

- all relevant information related to consent, tests, investigations and treatment.

Learning outcome 2 – should be achieved in a range of routine patients and in accordance with the Standard Operating Procedure.

AC2.1 includes:

- infection control
- health and safety, including patient safety.

AC2.2 includes:

- preparing the environment for ambulatory ECG monitoring
- preparing the equipment for ambulatory ECG monitoring
- explaining the test to the patient, adapting communication to meet the needs of the patient
- gaining and documenting informed consent
- explaining the importance of introducing yourself and your role as a learner
- gathering all required information from the patient, including current medication.

AC2.3 includes:

- choosing the appropriate electrodes for ambulatory ECG monitoring
- explaining the reasons for the choice of electrode positioning
- choosing the optimal electrode position for ambulatory ECG monitoring
- preparing the patient's skin and applying electrodes, or explaining to the patient how to prepare their own skin and apply the electrodes
- connecting the ECG leads and recorder to ensure patient comfort
- explaining the use of the patient diary
- explaining how to activate the device as necessary
- explaining any safety issues and the need to protect the monitor from damage
- maintaining records
- minimising artefacts.

AC2.4 includes:

- removing the equipment from the patient
- discussing the patient experiences during the recording, clarifying symptoms and diary entries
- explaining the procedure for receiving results.

AC3.1 includes:

- correlating patient symptoms with ECG findings
- checking the accuracy of automated evaluation
- evaluating the technical quality of ambulatory ECG recordings, identify suboptimal recordings
- selecting ECG tracings sufficient to illustrate and support the final evaluation.

AC3.2 includes:

- using appropriate methods of:
    - analysing
    - summarising
    - displaying information.

AC3.3 includes:

- in accordance with applicable:
    - legislation
    - protocols
    - guidelines.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of ambulatory ECG (AECG) monitoring	1.1	Explain the characteristics of AECG monitoring recording equipment			
		1.2	Explain the limitations and optimisation of AECG monitoring			
		1.3	Explain the indications and contraindications for AECG monitoring of arrhythmias			
		1.4	Discuss the development of AECG ambulatory monitoring as a tool for the detection of myocardial ischaemia			
		1.5	Explain the purpose of continuous and intermittent (event and loop) recorders			
2	Be able to perform ambulatory ECG (AECG) monitoring	2.1	Evaluate the departmental Standard Operating Procedure for AECG monitoring			
		2.2	Prepare for AECG monitoring			
		2.3	Set up AECG recorders in a range of adult patients			
		2.4	Remove the AECG recording equipment			
3	Be able to analyse ambulatory ECG recordings and produce a factual report	3.1	Operate a playback/analyser system and analyse the results in accordance with the Standard Operating Procedure			
		3.2	Produce a factual report			
		3.3	Keep accurate, comprehensive and comprehensible records			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 55: Ambulatory Blood Pressure Monitoring

Level: 4

Unit type: Optional

Credit value: 15

Guided learning hours: 120

Unit summary

The aim of this unit is for you to be able to fit and remove ambulatory blood pressure monitoring (ABPM) devices, analyse the recording and produce a factual report. You will be expected to build your patient-centred professional practice to enable you to undertake this skill safely in the workplace.

Additional information

It is suggested that learners will have completed the following units:

- **Level 2 – Unit 72: Measuring Blood Pressure using an Automatic Machine**
- **Level 3 – Unit 77: Fitting an Ambulatory Blood Pressure Monitor**
- **Level 3 – Unit 78: Manual Blood Pressure Measurement**

or have appropriate experience before completing this unit.

AC1.1 includes:

- observer
- equipment:
  - effect of using BP cuffs that are either too large or too small
- patient
- cardiac arrhythmias.

AC1.6 includes:

- current National Institute for Health and Care Excellence (NICE) Guidelines.

Learning outcome 2 – this should be achieved in a range of routine patients and in accordance with the Standard Operating Procedure.

AC2.2 includes:

- preparing the environment for ABPM monitoring
- programming the equipment for ABPM monitoring
- explaining the test to the patient, adapting communication to meet the needs of the patient
- gaining and documenting informed consent
- explaining the importance of introducing yourself and your role as a learner
- gathering all required information from the patient, including current medication.

AC2.4 includes:

- identifying the site for the placement of the microphone (where applicable)
- choosing and applying the correct size of cuff
- explaining the use of the patient diary
- explaining how to activate the device as necessary
- explaining any safety issues and the need to protect the monitor from damage
- maintaining records.

AC2.5 includes:

- removing the equipment from the patient
- discussing the procedure with the patient, clarifying symptoms and diary entries
- explaining the procedure for receiving results
- cleaning equipment and room.

AC3.1 includes:

- evaluating the technical quality of the recording, identifying errors
- correlating patient symptoms with BP recordings.

AC3.2 includes:

- reviewing the report with senior staff when appropriate.

AC3.3 includes:

- in accordance with applicable legislation, protocols and guidelines.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of Ambulatory Blood Pressure (BP) Monitoring (ABPM)	1.1	Explain the common errors in BP measurement			
		1.2	Explain the characteristics of ABPM equipment			
		1.3	Evaluate the limitations of ABPM			
		1.4	Explain the indications and contraindications for ABPM			
		1.5	Explain the role of ambulatory BP monitoring in patients with autonomic disorders			
		1.6	Know the definition of Stage 1, Stage 2 and severe hypertension			
		1.7	Explain the term white coat hypertension			
		1.8	Discuss the risk factors for hypertension			
		1.9	Evaluate the effectiveness of non-pharmacological measures in reducing blood pressure and cardiovascular risk			
2	Be able to perform Ambulatory Blood Pressure Monitoring (ABPM)	2.1	Evaluate the departmental Standard Operating Procedure for ABPM			
		2.2	Prepare for ABPM			
		2.3	Measure baseline resting BP in accordance with the British Hypertension Society Guidelines			
		2.4	Set up for ABPM			
		2.5	Remove the ABPM equipment			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to analyse Ambulatory Blood Pressure recordings and produce a factual report	3.1	Download the BP data			
		3.2	Present the results of ABPM			
		3.3	Keep accurate, comprehensive and comprehensible records			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 56 Assist in Cardiac Stress Testing

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 48

Unit summary

This unit aims to give you the knowledge, understanding and skills needed to be able to assist the healthcare science practitioner/clinical scientist/medical staff in the performance of cardiac stress testing. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

Learners completing this unit must also complete *Unit 53: Recognising ECG Abnormalities in Adults*.

It is suggested that learners will have completed the Level 2 Unit 72: Measuring Blood Pressure using an Automatic Machine, or have appropriate experience before completing this unit.

It is expected that learners will have the appropriate life support qualification required by their own place of work.

The responsibility for the conduct of the test and gaining informed consent will lie with the healthcare science practitioner/clinical scientist/medical staff.

AC1.1 includes the physiological effect of exercise on the:

- cardiovascular system
- respiratory system
- musculoskeletal system

and

- the effect of exercise on patients with:
  - suspected angina
  - breathless on exertion.

AC1.2 includes:

- the importance of patient-centred practice
- ways to ensure and promote patient-centred care in own area of practice
- indications and contraindications for undertaking cardiac stress testing
- possible symptoms experienced by a patient experiencing angina
- how angina can impact on quality of life
- methods available to exercise patients in own area of practice.

LO2 – in accordance with Standard Operating Procedures.

AC2.5 and 2.6 include:

- measuring the height and weight of the patient
- gathering information on current medication
- assisting in correct positioning of the patient
- setting up all monitoring equipment
- maintaining the highest standards of person-centred care, treating every person with compassion, dignity and respect.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of cardiac stress testing	1.1	Explain the physiological changes that occur during exercise			
		1.2	Explain the principles of cardiac stress testing			
2	Be able to assist with cardiac stress testing	2.1	Evaluate the departmental Standard Operating Procedure underpinning cardiac stress testing			
		2.2	Explain the factors influencing the choice of equipment for the investigation			
		2.3	Select suitable equipment in accordance with the requirements of the test			
		2.4	Explain the principles of measurement for the range of equipment used			
		2.5	Prepare the environment for cardiac stress testing			
		2.6	Prepare the equipment for cardiac stress testing			
		2.7	Prepare the patient treating the patient with respect and compassion			
		2.8	Address any special patient requirements and, if necessary, discuss with senior staff and carers			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to assist following completion of the recording	3.1	Explain how to remove electrodes and clean the site with minimum discomfort			
		3.2	Remove electrodes and clean the site minimising discomfort to the patient			
		3.3	Provide information to the patient with respect to how they will be informed of results of the investigation			
		3.4	Ensure that all the required arrangements are in place for the patient/carer following completion of the cardiac stress test			
		3.5	Clean and decontaminate equipment, leaving in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 57: Introduction to Congenital Heart Disease

Level:	**4**
Unit type:	**Optional**
Credit value:	**4**
Guided learning hours:	**25**

Unit summary

This unit is designed for learners working in a healthcare area where patients with congenital heart disease attend for routine cardiac science investigations. The unit includes an introduction to congenital heart disease and enables you to apply and build your knowledge and understanding of cardiac anatomy, embryology, pathology, genetics and genomics. The knowledge gained in this unit will enable you to build your patient-centred professional practice by performing routine cardiac science investigations requested for patients with congenital heart disease.

Additional information

Within congenital heart disease learners will have appropriate experience in the routine scientific investigations undertaken in own area of work, supported by relevant modules completed in these techniques.

AC1.6: congenital heart defects to include:

- atrial septal defect/patent foramen ovale
- patent ductus arteriosus
- ventricular septal defect
- obstructive defects – stenotic valve disease/coarctation of the aorta

and a basic understanding of more complex pathologies, as relevant to the role:

- Atrioventricular septal defect
- Transposition of the great arteries
- Tetralogy of Fallot.

AC1.9 – learners should be able to provide **one** example of the physiological changes that occur in the cardiovascular system in a person with a cyanotic congenital heart disease.

AC2.2 includes:

- what it means to be a carrier or possess an abnormal gene
- impact of screening tests on the patient
- the patient's family; healthcare staff.

AC2.3/2.5 includes:

- Turner Syndrome
- Down Syndrome
- Noonan Syndrome
- Marfan Syndrome.

AC3.1 – investigations offered by a cardiac science department that could contribute to the diagnosis of patients with congenital heart disease could include:

- ECG
- 24-hour ECG
- exercise and cardiopulmonary exercise testing (for non-subjective symptom assessment and timings of interventions)
- echocardiography overview
- cardiac catheterisation overview
- cardiac electrophysiology and pacing overview.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the anatomy of more common congenital heart conditions referred to cardiac science	1.1	Explain the normal anatomy of the heart			
		1.2	Explain the normal embryological development of the heart			
		1.3	Explain the normal physiological changes that occur in the heart in a newborn baby			
		1.4	Explain the term congenital heart disease			
		1.5	Explain the terms cyanotic and acyanotic congenital heart disease			
		1.6	Know the common congenital heart defects that may result in a referral to cardiac sciences			
		1.7	Give an example of how an error in embryological development results in an anatomical cardiac abnormality			
		1.8	Explain the physiological changes that occur in the cardiovascular system in a person with acyanotic congenital heart disease			
		1.9	Explain the physiological changes that occur in the cardiovascular system in a person with a cyanotic congenital heart disease			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the fundamentals of the human genome, how it is used and how it can influence a person's health	2.1	Define the terms gene, DNA, chromosome, mutation			
		2.2	Discuss the impact of genetic screening			
		2.3	Describe how common genetic syndromes affect the structure and function of the heart			
		2.4	Explain how personalised medicine can be integrated into healthcare in own area of practice			
		2.5	Explain how genetic predisposition can affect a person's health			
		2.6	Explain how shared environmental factors affect a patient with congenital heart disease			
3	Understand the range of services available to patients with congenital heart disease	3.1	Describe the investigations offered by a cardiac science department that contribute to the diagnosis of patients with congenital heart disease			
		3.2	Describe the limitations associated with performing cardiac scientific investigations on patients with congenital heart disease and how these can be overcome			
		3.3	Explain the importance of providing a supportive and informative clinical atmosphere for children, young people and parents/carers			
		3.4	Explain the principles of patient-centred care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Understand the challenges faced by individuals and families affected by congenital heart disease	4.1	Explain the potential psychological impact of a congenital heart condition on the individual and family			
		4.2	Explain the potential social impact of a congenital heart condition on the individual and family			
		4.3	Discuss the range of information resources relating to **one** congenital heart condition in own area of practice			
		4.4	Discuss how patient support groups can support people affected by the diagnosis of a congenital heart disease			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 58: Recognising ECG Abnormalities in Children

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

The aim of this unit is to equip you with the knowledge and skills to be able to recognise common ECG abnormalities in children. You will be expected to develop a framework for ECG identification. You will be expected to build your patient-centred professional practice to enable you to undertake this skill safely in the workplace.

Additional information

It is suggested that learners will have completed the Level 3 – *Unit 74: Performing Routine Electrocardiography in Children*, or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedure in own area of work.

AC2.10 includes:

- normal ECG age-related values, particularly for criteria relating to right or left ventricular hypertrophy.

AC2.11 includes:

- heart rate > 100 beats/min
- QRS axis > 90°
- right precordial T wave inversion
- dominant right precordial R waves
- short PR and QT intervals
- short P wave and short duration of QRS complexes
- inferior and lateral Q waves.

AC2.12 includes:

- syncope or seizure
- exertional symptoms
- drug ingestion
- tachyarrhythmia
- bradyarrhythmia
- cyanotic episodes
- heart failure
- hypothermia
- electrolyte disturbance
- Kawasaki disease
- rheumatic fever
- myocarditis
- myocardial contusion
- pericarditis
- post-cardiac surgery
- congenital heart defects.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of electrocardiography (ECG)	1.1	Explain the principles of the paediatric ECG			
		1.2	Evaluate the strengths and weaknesses of 12-lead ECG recording			
		1.3	Explain the relationship between ECG leads and cardiac anatomy			
		1.4	Evaluate ways to ensure and promote patient-centred, child-friendly care			
		1.5	Evaluate safeguarding procedures and the process for reporting safeguarding issues			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the normal ECG in children	2.1	Explain the relationship between the normal ECG and cardiac physiology in children			
		2.2	Explain the relationship between the electrical and mechanical action of the heart during a normal cardiac cycle			
		2.3	Explain the main waves, complexes, segments, duration and intervals of the normal ECG in children			
		2.4	Explain how the heart develops during infancy and childhood and the impact of development on the ECG			
		2.5	Explain the derivation of the 12 ECG leads			
		2.6	Explain the term cardiac axis			
		2.7	Explain how to measure the cardiac axis			
		2.8	Explain the age-related changes in heart rate from birth to adulthood			
		2.9	Explain how to measure heart rate			
		2.10	Know the normal ranges for each component of the ECG in children			
		2.11	Explain ECG changes that may be abnormal in adults but normal in children			
		2.12	Explain the indications for ECG in children			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to recognise the ECG changes associated with arrhythmias in children	3.1	Recognise the ECG changes associated with: • ventricular fibrillation • asystole • ventricular tachycardia			
		3.2	Recognise the ECG changes associated with: • sinus arrhythmia • sinus bradycardia • sinus tachycardia			
		3.3	Explain the effect of exercise on ectopic activity			
		3.4	Recognise the ECG changes associated with atrial and ventricular ectopics			
		3.5	Recognise the ECG changes associated with supraventricular tachycardia			
		3.6	Recognise the ECG changes associated with atrial fibrillation			
		3.7	Recognise the ECG changes associated with atrial flutter			
		3.8	Recognise the ECG changes associated with atrioventricular re-entrant tachycardia			
		3.9	Recognise the ECG changes associated with ventricular arrhythmias			
		3.10	Recognise the ECG changes associated with Wolff-Parkinson-White syndrome			
		3.11	Recognise the ECG changes associated with atrioventricular conduction blocks			
		3.12	Recognise and escalate arrhythmias that need urgent action			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to recognise the ECG changes associated with conditions affecting the left and right sides of the heart of children	4.1	Recognise the ECG changes associated with left and right atrial abnormalities			
		4.2	Recognise the ECG changes associated with right and left ventricular hypertrophy			
		4.3	Recognise the ECG changes associated with left and right bundle branch block			
		4.4	Recognise the ECG changes associated with fascicular blocks			
		4.5	Recognise the ECG changes associated with conditions affecting the left and right sides of the heart that need urgent action			
5	Be able to produce a factual ECG report	5.1	Evaluate ECG reporting frameworks			
		5.2	Produce factual ECG reports on a range of normal and abnormal results from children			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 59: Spirometry, Static Lung Volumes and Bronchodilator Response in Adults

Level: 4

Unit type: Optional

Credit value: 15

Guided learning hours: 120

Unit summary

In this unit, you will gain the understanding and skills needed to be able to perform the quality-assured measurement of dynamic and static lung volumes, and administer and measure the response to bronchodilator tests safely and accurately. You will also be expected to interpret technical data from patients and generate a technical report. In addition, you will be able to undertake routine maintenance, calibration and quality-assurance procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

AC1.1 includes:

- the communicable diseases and microbiological hazards in a respiratory department
- risks and hazards in compliance with health and safety policies
- control of infection risks pre, during and post investigations, including decontamination of equipment
- importance of hand washing
- adherence to appropriate standards of professional practice as defined in Good Scientific Practice.

Learning outcome 2 – in a range of patients and produce a technical report in accordance with Standard Operating Procedures (SOPs).

AC2.1 includes:

- greeting the patient and checking patient identification
- communicating with patients in a way that respects their dignity, rights, privacy and confidentiality
- introducing self and own role
- reviewing the request form

- explaining the investigation to the patient in appropriate language, addressing any investigation-related questions
- providing information on how the patient will be informed of the results
- evaluating the risks and benefits of undertaking the investigation
- gaining and documenting informed consent
- explaining the principles, guidance and law for gaining informed consent, including the limits of consent
- obtaining and reviewing relevant patient information:
    - medication
    - smoking history
    - recent change in condition
    - any previous test results
- explaining potential special requirements of patients referred for investigations
- treating the patient with respect, compassion and dignity
- acting on any special patient requirements and, if necessary, discussing with senior staff and carers, e.g. learning disabilities.

AC2.2 includes:

- identifying the potential risks of using defective equipment and measures to resolve problems
- the factors influencing the choice of equipment for the investigation
- selecting the correct equipment.

AC2.3 includes:

- the requirements for the investigation environment
- checking the equipment
- calibrating the equipment
- preparing the equipment
- explaining the principles of measurement for the range of equipment used
- identifying common faults
- taking remedial action
- the potential special needs of patients referred for investigation and the relevant action required
- the measurements that may be required pre and post investigation
- measuring height, weight and other appropriate measurements in accordance with standardised procedures, adapting them where necessary
- the impact of incorrect positioning or non-cooperation on the patient, the investigation and the results.

AC2.4 includes:

- measuring:
  - forced expiratory volume in one second (FEV1)
  - forced vital capacity (FVC]
  - peak expiratory flow (PEF)
  - maximal flow volume curves (MFVC)
- identifying errors in patient technique
- correcting errors in patient technique
- providing reassurance to the patient
- allowing sufficient time to enable a patient to recover between or from the test
- recording the results accurately in an appropriate format
- the relevance of investigations to referral request and differential diagnosis
- the importance of supporting patients and encouraging them to perform within their capability
- how to distinguish between poor patient performance, technical faults and deterioration in clinical status
- the reasons a test may be stopped to maintain the safety of the patient
- recording the results in an appropriate format, documenting any technical comments that may influence the test outcome
- documenting any technical comments that may influence the test outcome.

AC2.5 – according to local and national guidelines, including:

- measuring[4]:
  - total lung capacity (TLC)
  - functional residual capacity (FRC) or thoracic gas volume (TGV)
  - residual volume (RV) and all subdivisions
- identifying errors in patient technique
- correcting errors in patient technique
- providing reassurance to the patient
- allowing sufficient time to enable a patient to recover between or from the test
- recording the results accurately in an appropriate format
- the relevance of investigations to referral request and differential diagnosis
- the importance of supporting patients and encouraging them to perform within their capability
- how to distinguish between poor patient performance, technical faults and deterioration in clinical status
- the reasons a test may be stopped to maintain the safety of the patient
- documenting any technical comments that may influence the test outcome
- recording the results in an appropriate format.

[4] using helium dilution, nitrogen washout, or body plethysmography

AC2.6 includes:

- mode of action of common bronchodilation
- the Standard Operating Procedure for bronchodilation, including the patient group directive (PGD) for administering a bronchodilator
- authority required to administer bronchodilators as part of respiratory physiology investigations
- factors influencing the selection of bronchodilator and device
- common side effects of bronchodilators
- preparing the bronchodilator and device
- the purpose and use of bronchodilators to the patient
- the factors that influence the effectiveness of administration that may impact on results.

AC2.7 includes:

- administering the bronchodilator
- documenting any technical comments that may influence the test outcome
- recording the results in an appropriate format.

AC4.1 with respect to reference ranges includes:

- calculation
- use
- limitations
- age-related variations.

AC5.1 includes:

- safety testing
- routine maintenance.

AC5.9 includes:

- volume
- gas concentration calibration.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and application of dynamic and static lung volume measurement in routine clinical practice in adults	1.1	Explain the clinical indications and contraindications for dynamic and static lung volume measurement and bronchodilation			
		1.2	Explain the clinical indications for the use of bronchodilation in adults			
		1.3	Explain the role of inhaled drug therapy in the management of respiratory disease			
		1.4	Evaluate ways to ensure and promote patient-centred care			
		1.5	Evaluate the Standard Operating Procedure for performing quality-assured dynamic and static lung volumes and bronchodilation			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform the measurement of dynamic lung volumes	2.1	Demonstrate the ability to gain informed consent for static and dynamic lung volumes in adults			
		2.2	Demonstrate the ability to select suitable equipment for the investigation in accordance with the requirements of the test			
		2.3	Demonstrate the ability to prepare the environment, equipment and patient for investigations			
		2.4	Perform the measurement of dynamic lung volumes in a range of adult patients in accordance with recommended guidelines and patient capability			
		2.5	Perform the measurement of static lung volumes in adult patients with a range of underlying disorders, recording the results			
		2.6	Demonstrate the ability to administer a bronchodilator(s) to adults			
		2.7	Perform post-bronchodilator measurements according to local and national guidelines			
3	Be able to clean and decontaminate equipment used to measure static and dynamic lung volumes in adults	3.1	Evaluate the protocols for cleaning and decontaminating equipment to measure static and dynamic lung volumes			
		3.2	Clean and decontaminate equipment and leave in a suitable condition for reuse			
4	Be able to produce a technical report for static and dynamic lung volumes	4.1	Demonstrate the ability to use reference ranges for dynamic and static lung volumes			
		4.2	Describe the typical patterns and results for dynamic and static lung volumes and bronchodilation for common respiratory diseases			
		4.3	Demonstrate the ability to produce a technical report for dynamic and static lung volumes, including the effect of bronchodilator therapy			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to perform routine maintenance, calibration and quality-assurance procedures on the equipment used to undertake dynamic and static lung volumes	5.1	Justify current safety standards underpinning the measurement of static and dynamic lung volumes			
		5.2	Justify the requirements for accurate completion of equipment maintenance records			
		5.3	Perform routine maintenance on equipment and accurately complete equipment maintenance records			
		5.4	Explain the use and importance of volume and flow verification for static and dynamic lung volumes			
		5.5	Explain the use of physiological controls as part of the quality-assurance procedures for static and dynamic lung volumes			
		5.6	Perform vital capacity measurements using a calibration syringe			
		5.7	Perform forced vital capacity, forced expiratory volume in one second (FEV1) and peak expiratory flow measurements on a physiological control			
		5.8	Perform functional residual capacity/total gas volume, total lung capacity and vital capacity measurements on a physiological control			
		5.9	Explain the purpose of calibration logs			
		5.10	Explain the purpose of volume calibration verification at differing flow rates on one piece of equipment			
		5.11	Discuss the purpose of quality assurance in respiratory physiology			
		5.12	Explain the procedure to be followed in the event of identifying an issue of quality assurance			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 60: Measurement of Single Breath Gas Transfer

Level: 4

Unit type: Optional

Credit value: 15

Guided learning hours: 120

Unit summary

In this unit, you will gain the understanding and skills needed to be able to perform the quality-assured measurement of single breath gas transfer safely and accurately. You will also be expected to interpret technical data from patients and generate a technical report. In addition, you will be able to undertake routine maintenance, calibration and quality-assurance procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

AC1.5 includes:

- the communicable diseases and microbiological hazards in a respiratory department
- risks and hazards in compliance with health and safety policies
- control of infection risks pre, during and post investigations, including decontamination of equipment
- importance of hand washing
- adherence to appropriate standards of professional practice as defined in Good Scientific Practice.

Learning outcome 2 – in a range of patients with respiratory and non-respiratory disorders in accordance with Standard Operating Procedures.

AC2.1 includes:

- greeting the patient and check patient identification
- communicating with patients in a way that respects their dignity, rights, privacy and confidentiality
- introducing self and own role
- reviewing the request form
- explaining the investigation to the patient in appropriate language, addressing any investigation-related questions
- providing information on how the patient will be informed of the results

- evaluating the risks and benefits of undertaking the investigation
- gaining and documenting informed consent
- explaining the principles, guidance and law for gaining informed consent, including the limits of consent
- obtaining and reviewing relevant patient information:
    - medication
    - smoking history
    - recent change in condition
    - any previous test results
- explaining potential special requirements of patients referred for investigations
- treating the patient with respect, compassion and dignity
- acting on any special patient requirements and, if necessary, discuss with senior staff and carers, e.g. learning disabilities.

AC2.2 includes:

- identifying the potential risks of using defective equipment and measures to resolve problems
- the factors influencing the choice of equipment for the investigation
- selecting the correct equipment.

AC2.3 includes:

- the requirements for the investigation environment
- checking the equipment
- calibrating the equipment
- preparing the equipment
- explaining the principles of measurement for the range of equipment used
- identifying common faults
- taking remedial action
- the potential special needs of patients referred for investigation and the relevant action required
- the measurements that may be required pre and post investigation
- measuring height, weight and other appropriate measurements in accordance with standardised procedures, adapting them where necessary
- the impact of incorrect positioning or non-cooperation on the patient, the investigation and the results.

AC2.4 includes in accordance with recommended guidelines and patient capability and:

- identifying errors in patient technique
- correcting errors in patient technique
- providing reassurance to the patient
- allowing sufficient time to enable a patient to recover between or from the test
- recording the results accurately in an appropriate format
- the relevance of investigations to referral request and differential diagnosis
- supporting patients and encouraging them to perform within their capability
- how to distinguish between poor patient performance, technical faults and deterioration in clinical status
- the reasons a test may be stopped to maintain the safety of the patient
- documenting any technical comments that may influence the test outcome.

AC5.1 includes:

- safety testing
- routine maintenance.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and application of single breath gas transfer	1.1	Explain the structure-function relationships determining gas exchange and carbon monoxide (CO) transfer factor			
		1.2	Explain the methods available for estimating CO transfer factor by single breath			
		1.3	Explain the concepts of the subdivisions of CO transfer factor			
		1.4	Explain the clinical indications and contraindications for single breath gas transfer			
		1.5	Evaluate the Standard Operating Procedure for performing quality-assured single breath gas transfer			
2	Be able to measure the uptake of carbon monoxide (CO) using the single breath technique as a guide to the gas exchange function	2.1	Demonstrate the ability to gain informed consent for the measurement of the uptake of carbon monoxide (CO) using the single breath technique			
		2.2	Demonstrate the ability to select suitable equipment for the investigation in accordance with the requirements of the test			
		2.3	Demonstrate the ability to prepare the environment, equipment and patient for investigations			
		2.4	Perform the measurement of the uptake of carbon monoxide (CO) using the single breath technique			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to clean and decontaminate equipment used to measure the uptake of carbon dioxide (CO)	3.1	Evaluate the protocols for cleaning and decontaminating equipment for measuring the uptake of carbon monoxide (CO) using the single breath technique			
		3.2	Clean and decontaminate equipment and leave in a suitable condition for reuse			
4	Be able to produce a technical report for single breath gas transfer	4.1	Demonstrate the ability to use reference ranges for single breath gas transfer			
		4.2	Describe the typical patterns and results for single breath gas transfer common respiratory diseases			
		4.3	Demonstrate the ability to produce a technical report for single breath gas transfer			
5	Be able to perform routine maintenance, calibration and quality-assurance procedures on the equipment used to undertake single breath gas transfer	5.1	Justify current safety standards underpinning the measurement of single breath gas transfer			
		5.2	Justify the requirements for accurate completion of equipment maintenance records			
		5.3	Perform routine maintenance and accurately complete equipment maintenance records			
		5.4	Perform alveolar volume and transfer test measurements on a physiological control			
		5.5	Explain the purpose of calibration logs			
		5.6	Discuss the purpose of quality assurance in respiratory physiology testing			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 61: Performing Overnight Oximetry

Level: 4

Unit type: Optional

Credit value: 10

Guided learning hours: 80

Unit summary

In this unit, you will gain the understanding and skills needed to be able to perform the quality-assured performance of overnight oximetry safely and accurately. You will also be expected to interpret technical data from patients and generate a technical report. In addition, you will be able to undertake routine maintenance, calibration and quality-assurance procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

AC1.6 includes:

- the communicable diseases and microbiological hazards in a respiratory department
- risks and hazards in compliance with health and safety policies
- control of infection risks pre, during and post investigations, including decontamination of equipment
- importance of hand washing
- adherence to appropriate standards of professional practice as defined in Good Scientific Practice.

AC2.1 includes:

- greeting the patient and checking patient identification
- communicating with patients in a way that respects their dignity, rights, privacy and confidentiality
- introducing self and own role
- reviewing the request form
- explaining the investigation to the patient in appropriate language, addressing any investigation-related questions
- providing information on how the patient will be informed of the results
- evaluating the risks and benefits of undertaking the investigation

- gaining and documenting informed consent
- explaining the principles, guidance and law for gaining informed consent, including the limits of consent
- obtaining and reviewing relevant patient information:
    - medication
    - smoking history
    - recent change in condition
    - any previous test results
- explaining potential special requirements of patients referred for investigations
- treating the patient with respect, compassion and dignity
- acting on any special patient requirements and, if necessary, discuss with senior staff and carers, e.g. learning disabilities.

AC2.2 includes:

- identifying the potential risks of using defective equipment and measures to resolve problems
- the factors influencing the choice of equipment for the investigation
- selecting the correct equipment.

AC2.3 includes:

- checking the equipment
- calibrating the equipment
- preparing the equipment
- identifying common faults
- taking remedial action
- explaining the impact of non-cooperation on the patient, the investigation and the results
- making height, weight, neck circumference and other appropriate measurements in accordance with standardised procedures, adapting them where necessary.

AC2.4 includes:

- confirming that the patient understands the process of overnight oximetry.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand overnight oximetry	1.1	Explain how oxygen is carried in the blood and the role of respiration in maintaining oxygen levels			
		1.2	Explain the principles of overnight oximetry			
		1.3	Explain the applications of overnight oximetry			
		1.4	Explain the clinical indications and contraindications for overnight oximetry			
		1.5	Evaluate the scientific literature with respect to the use of overnight as a screening tool for obstructive sleep apnoea hypopnoea syndrome			
		1.6	Evaluate and justify the Standard Operating Procedure for performing quality-assured overnight oximetry			
2	Be able to prepare, issue, retrieve and store data from overnight oximetry	2.1	Demonstrate the ability to gain informed consent for overnight oximetry			
		2.2	Demonstrate the ability to select suitable equipment for the investigation in accordance with the requirements of the test			
		2.3	Demonstrate the ability to prepare for overnight oximetry			
		2.4	Demonstrate the ability to issue overnight oximeters			
		2.5	Demonstrate the ability to retrieve data from overnight oximeters			
		2.6	Demonstrate the ability to store data from overnight oximeters			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to clean and decontaminate equipment used to measure overnight oximetry	3.1	Evaluate the protocols for cleaning and decontaminating equipment for overnight oximetry			
		3.2	Clean and decontaminate equipment used for overnight oximetry and leave in a suitable condition for reuse			
4	Be able to perform routine maintenance, calibration and quality-assurance procedures on the equipment used for overnight oximetry	4.1	Perform routine maintenance on the equipment used for overnight oximetry			
		4.2	Perform calibration and quality-assurance procedures on the equipment used for overnight oximetry			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 62: Spirometry, Static Lung Volumes and Bronchodilator Response in Children

Level:	**5**
Unit type:	**Optional**
Credit value:	**15**
Guided learning hours:	**120**

Unit summary

In this unit, you will gain the understanding and skills needed to be able to perform the quality-assured measurement of dynamic and static lung volumes, and administer and measure the response to bronchodilator tests in children safely and accurately. You will also be expected to interpret technical data from patients and generate a technical report. In addition, you will be able to undertake routine maintenance, calibration and quality-assurance procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

AC1.5 includes:

- the communicable diseases and microbiological hazards in a respiratory department
- risks and hazards in compliance with health and safety policies
- control of infection risks pre, during and post investigations, including decontamination of equipment
- importance of hand washing
- adherence to appropriate standards of professional practice as defined in Good Scientific Practice.

AC2.1 includes:

- the consent procedures for minors
- greeting the patient and, if appropriate the responsible adult with the child, and checking patient identification
- using effective communication skills and working with children and their parents/carers/responsible adult in a way that respects their dignity, rights, privacy and confidentiality
- introducing self and own role

- reviewing the request form
- explaining the investigation to the patient in appropriate language, addressing any investigation-related questions
- providing information on how the patient will be informed of the results
- evaluating the risks and benefits of undertaking the investigation
- gaining and documenting informed consent
- explaining the principles, guidance and law for gaining informed consent, including the limits of consent
- obtaining and reviewing relevant patient information:
    - medication
    - smoking history
    - recent change in condition
    - any previous test results
- explaining potential special requirements of patients referred for investigations
- treating the patient with respect, compassion and dignity
- acting on any special patient requirements and, if necessary, discuss with senior staff and carers, e.g. learning disabilities.

AC2.2 includes:

- identifying the potential risks of using defective equipment and measures to resolve problems
- the factors influencing the choice of equipment for the investigation
- selecting the correct equipment.

AC2.3 includes:

- the requirements for the investigation environment
- checking the equipment
- calibrating the equipment
- preparing the equipment
- explaining the principles of measurement for the range of equipment used
- identifying common faults
- taking remedial action
- the potential special needs of patients referred for investigation and the relevant action required
- the measurements that may be required pre and post investigation
- measuring height, weight and other appropriate measurements in accordance with standardised procedures, adapting them where necessary
- the impact of incorrect positioning or non-cooperation on the patient, the investigation and the results.

AC2.6 includes:

- measuring:
  - forced expiratory volume in one second (FEV1)
  - forced vital capacity (FVC)
  - peak expiratory flow (PEF)
  - maximal flow volume curves (MFVC)
- identifying errors in patient technique
- correcting errors in patient technique
- providing reassurance to the patient
- allowing sufficient time to enable a patient to recover between or from the test
- recording the results accurately in an appropriate format
- the relevance of investigations to referral request and differential diagnosis
- the importance of supporting patients and encouraging them to perform within their capability
- how to distinguish between poor patient performance, technical faults and deterioration in clinical status
- the reasons a test may be stopped to maintain the safety of the patient
- recording the results in an appropriate format, documenting any technical comments that may influence the test outcome

AC2.7 includes:

- measuring[5]:
  - total lung capacity [TLC]
  - functional residual capacity [FRC] or thoracic gas volume [TGV]
  - residual volume [RV] and all subdivisions
- identifying errors in patient technique
- correcting errors in patient technique
- providing reassurance to the patient
- building up a rapport with the child
- encouraging and supporting the child to perform the test
- allowing sufficient time to enable a patient to recover between or from the test
- recording the results accurately in an appropriate format
- the relevance of investigations to referral request and differential diagnosis
- the importance of supporting patients and encouraging them to perform within their capability
- how to distinguish between poor patient performance, technical faults and deterioration in clinical status
- the reasons a test may be stopped to maintain the safety of the patient
- documenting any technical comments that may influence the test outcome
- recording the results in an appropriate format.

[5] using helium dilution, nitrogen washout, or body plethysmography

AC2.8 includes:

- mode of action of common bronchodilation
- the Standard Operating Procedure for bronchodilation, including the patient group directive (PGD) for administering a bronchodilator
- authority required to administer bronchodilators as part of respiratory physiology investigations
- factors influencing the selection of bronchodilator and device
- common side effects of bronchodilators
- preparing the bronchodilator and device
- the purpose and use of bronchodilators to the patient
- the factors that influence the effectiveness of administration that may impact on results.

AC2.9 includes:

- administering the bronchodilator
- documenting any technical comments that may influence the test outcome
- recording the results in an appropriate format.

AC4.1 with respect to reference ranges includes:

- calculation
- use
- limitations
- age-related variations.

AC5.1 includes:

- safety testing
- routine maintenance.

AC5.9 includes:

- volume
- gas concentration calibration.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and application of dynamic and static lung volume measurement in routine clinical practice in children	1.1	Explain the structure of the respiratory system and the changes that occur from birth to adulthood			
		1.2	Explain physiology of the respiratory system and the changes that occur from birth to adulthood			
		1.3	Explain the clinical indications and contraindications for dynamic and static lung volume measurement and bronchodilation			
		1.4	Explain the clinical indications for the use of bronchodilation in children			
		1.5	Explain the role of inhaled drug therapy in the management of respiratory disease in children			
		1.6	Evaluate ways to ensure and promote patient-centred, child-friendly care			
		1.7	Evaluate the Standard Operating Procedure for performing quality-assured spirometry, static lung volumes and bronchodilation			
		1.8	Evaluate safeguarding procedures and the process for reporting safeguarding issues			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform the measurement of dynamic lung volumes in a range of patients and produce a technical report in children in accordance with Standard Operating Procedures (SOPs)	2.1	Demonstrate the ability to gain informed consent for static and dynamic lung volumes in children			
		2.2	Demonstrate the ability to select suitable equipment for the investigation in accordance with the requirements of the test			
		2.3	Demonstrate the ability to prepare the environment, equipment and patient for investigations			
		2.4	Evaluate the advantages and disadvantages of animated incentives in software intended for both pre-schoolers and older children			
		2.5	Explain the importance of the environment and ways to adapt the environment for testing children			
		2.6	Perform the measurement of dynamic lung volumes in a range of children in accordance with recommended guidelines and patient capability			
		2.7	Perform the measurement of static lung volumes in children with a range of underlying disorders and produce a technical report according to local and national guidelines			
		2.8	Demonstrate the ability to administer a bronchodilator(s) to children			
		2.9	Perform post-bronchodilator measurements according to local and national guidelines			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to clean and decontaminate equipment used to measure static and dynamic lung volumes in children	3.1	Evaluate the protocols for cleaning and decontaminating equipment to measure static and dynamic lung volumes in children			
		3.2	Clean and decontaminate equipment and leave in a suitable condition for reuse			
4	Be able to produce a technical report for static and dynamic lung volumes in children	4.1	Demonstrate the ability to use reference ranges for dynamic and static lung volumes in children			
		4.2	Describe the typical patterns and results for dynamic and static lung volumes and bronchodilation for common respiratory diseases in children			
		4.3	Demonstrate the ability to produce a technical report for dynamic and static lung volumes in children, including the effect of bronchodilator therapy			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to perform routine maintenance, calibration and quality-assurance procedures on the equipment used to undertake dynamic and static lung volumes in children	5.1	Justify current safety standards underpinning the measurement of static and dynamic lung volumes in children			
		5.2	Justify the requirements for accurate completion of equipment maintenance records			
		5.3	Perform routine maintenance and accurately complete equipment maintenance records			
		5.4	Explain the use and importance of volume and flow verification for static and dynamic lung volumes			
		5.5	Explain the use of physiological controls as part of the quality-assurance procedures for static and dynamic lung volumes in children			
		5.6	Perform vital capacity measurements using a calibration syringe			
		5.7	Perform forced vital capacity, forced expiratory volume in one second (FEV1) and peak expiratory flow measurements on a physiological control			
		5.8	Perform functional residual capacity/total gas volume, total lung capacity and vital capacity measurements on a physiological control			
		5.9	Explain the purpose of calibration logs			
		5.10	Explain the purpose of volume calibration verification at differing flow rates on one piece of equipment			
		5.11	Discuss the purpose of quality assurance in respiratory physiology			
		5.12	Explain the procedure to be followed in the event of identifying an issue of quality assurance			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 63: Scientific Basis of Neurosensory Science: Applied Physics and Measurement

Level:	**4**
Unit type:	**Mandatory**
Credit value:	**15**
Guided learning hours:	**120**

Unit summary

In this unit, you will develop an understanding of the concepts of instrumentation used in the neurosensory sciences together with an appreciation of the physical and mathematical principles that underpin these concepts and measurements. The application of the knowledge gained in this unit will be applied and contextualised as you perform routine technical skills, and you will develop and build your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1–1.10 includes:

- atomic structure: the Bohr atom, charge, concept of free electrons, isotopes.

AC1.2 includes:

- electricity: current, potential difference, resistance, Ohm's law, resistivity, capacitors, rectification, circuits with resistors and capacitors, AC/DC, period, RMS values, static and dynamic instrument characteristics, measurement errors.

AC1.5 includes:

- how to calculate unknown from known quantities.

AC1.7 includes:

- electrical circuits, their components, terminology and symbols
- how voltage, current and resistance can be calculated for complex circuits.

AC2.2 includes:

- magnetism and electromagnetism: induction, electromagnetic radiation and their interactions with matter
- typical wavelength bands for infrared, the colour spectrum and ultraviolet.

AC2.3 includes:

- light and lasers: electromagnetic spectrum, wave and quantum theories, polarisation, lasers, refraction, reflection.

AC3.3 includes:

- sound and ultrasound: wave formation, simple harmonics, propagation, transmission through different media, diffraction/scatter, absorption, frequency, amplitude, velocity, acoustic interface and impedance, intensity, gain, decibel scale, measurement of sound
- what happens to velocity, frequency and wavelength as a sound wave travels through different media, and the reflection and refraction of sound.

AC3.6 includes:

- the attenuation, interference and diffraction of sound waves
- the Doppler effect and acoustic resonance.

AC3.7 includes:

- the frequencies used
- meaning of A- and B-mode.

AC4.1 includes:

- body mechanics: limb movement and lever
- Basal metabolic rate (BMR), energy power and work.

AC5.1 includes:

- units of measurement
- how pressure varies with depth in a fluid.

AC5.2 includes:

- the relationship between the flow rate of a fluid and its velocity.

AC5.3 includes:

- the difference between laminar and turbulent flow.

AC5.8 includes:

- fluid flow through tubes: Poiseuille's law, laminar and turbulent flow.

AC6.6 includes:

- percentages
- statistics: descriptive, sampling, distribution, parametric/non-parametric, errors, variance, logarithms, graphs: use of in clinical practice.

AC7.1 includes the wider clinical environment.

AC7.2 includes:

- dedicated versus non-dedicated environments, e.g. wards, intensive care, theatres, patient's home.

AC7.3 could include:

- the potential for artefacts/interference filters and amplifiers, e.g. gain, sensitivity, common-mode rejection ratio (CMRR), noise.

AC8.1 includes:

- electrical
- ionising radiation
- magnetic resonance imaging
- electromagnetic radiation.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles of electricity that underpin measurements in neurosensory sciences	1.1	Know the structure of the atom and atomic charges, electrostatic forces, potential difference and free electrons			
		1.2	Explain different methods of producing electricity, magnetism and electromagnetism and magnetic induction			
		1.3	Explain the properties of conductors, insulators and resistors			
		1.4	Explain the meaning of conventional and electron current flow			
		1.5	Know units of electrical measurement for voltage, current, resistance, power and capacitance			
		1.6	Compare how DC and AC current is generated and measured			
		1.7	Describe how transformers change the relationship between voltage and current in AC circuits			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the principles of electromagnetic radiation and light that underpin measurements in neurosensory sciences	2.1	Describe the fundamental properties and descriptive terminology for electromagnetic radiation			
		2.2	Describe the properties of the different wavelengths that comprise the electromagnetic spectrum			
		2.3	Explain the difference between wave (electromagnetic) and quantum theories of light			
		2.4	Describe the properties of diffraction, coherence, polarisation and phase and use this terminology to describe laser light			
		2.5	Describe the properties of reflection and refraction of light			
		2.6	Describe how light intensity is measured			
3	Understand the principles of wave motion and sound that underpin measurements in neurosensory sciences	3.1	Describe how mechanical waves are generated by vibrators and oscillators			
		3.2	Describe the characteristics of mechanical transverse and longitudinal waves			
		3.3	Explain the relationships between and units of measurement of velocity, frequency and wavelength of a sound wave			
		3.4	Explain the relationships between, and units of measurement of: loudness and amplitude; and frequency and pitch			
		3.5	Describe the sensitivity of the human ear to varying levels of loudness and pitch			
		3.6	Describe the basic principles of harmonics and standing waves			
		3.7	Describe the basic principles of diagnostic ultrasonography			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Understand the principles of mechanics and body mechanics that underpin measurements in neurosensory sciences	4.1	Describe different forms of energy and the law of conservation of energy			
		4.2	Define power and know how to calculate power from energy			
		4.3	Describe energy conversion in humans			
		4.4	Describe the meaning of basal metabolic rate in the context of work, energy and power			
		4.5	Explain how the principles of force and torques are applied to the study of human biomechanics			
5	Understand the principles of fluids and fluid dynamics that underpin measurements in neurosensory sciences	5.1	Describe the concepts of density and pressure as applied to fluids			
		5.2	Explain how the velocity changes as fluid passes through tubes of different diameters			
		5.3	Explain the relationship between laminar flow and the viscosity of a fluid			
		5.4	Explain the relationship between resistance to laminar flow and viscosity, length and radius of a tube as expressed in Poiseuille's law			
		5.5	Describe factors that may be responsible for turbulent flow			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Understand the principles of mathematics and statistics that underpin measurements in neurosensory sciences	6.1	Differentiate between basic, supplementary and derived International System of Units (SI)			
		6.2	Know how to use appropriate metric units, prefixes and exponential notation when describing data			
		6.3	Calculate the mean and standard deviation from data relevant to own area of work			
		6.4	Explain the use and calculation of statistics in neurosensory sciences			
		6.5	Explain the purpose and limitations of the use of paired and unpaired t-testing			
7	Understand how different environments can affect neurosensory measurement systems	7.1	Explain the importance of physics and measurement in neurosensory sciences			
		7.2	Describe the range of settings in which neurosensory science investigations are undertaken			
		7.3	Explain the potential effect of the environment on measurement systems used in own area of work			
		7.4	Discuss how the physical characteristics affect the quality of measured data			
		7.5	Evaluate strategies to minimise the effect of the environment on neurosensory measurements			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
8	Understand the health and safety systems that underpin neurosensory physiological measurements	8.1	Explain the health and safety policies, legislation and regulatory framework in own area of work			
		8.2	Explain the incident reporting structure in own area of work			
		8.3	Explain the roles and responsibilities of staff for health and safety systems in own area of work			
		8.4	Explain personal responsibilities regarding health and safety systems within own area of work			
9	Understand the quality-assurance processes in own department which underpin safety and good practice	9.1	Explain the key components of the quality-management processes within own area of work			
		9.2	Explain the process of service accreditation for own area of work			
		9.3	Explain how quality management contributes to safe and effective high-quality care			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 64: Scientific Basis of Neurosensory Sciences: Applied Anatomy, Physiology and Pathophysiology: The Nervous System

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will develop your knowledge of the anatomy, physiology and pathophysiology of the nervous system with respect to neurosensory sciences. This unit covers the structure, function and organisation of the nervous system. You will be expected to apply and contextualise your knowledge and skills, performing routine technical procedures and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1 includes:

- central nervous system, peripheral nervous system
- somatic nervous system and autonomic nervous system
- sensory, integrative and motor functions.

AC1.2 includes:

- sensory function
- integrative function
- motor function.

AC4.1 includes:

- protective coverings of the brain:
  - cranial meninges
  - dura mater
  - arachnoid mater
  - pia mater.

AC4.2 includes:

- brainstem:
  - medulla
  - pons
  - mid brain
- cerebellum:
  - diencephalon (thalamus and hypothalamus)
- cerebrum:
  - limbic system
  - basal ganglia
  - cerebral hemispheres
  - lobes
  - cerebral white matter
- cranial nerves
- formation and circulation of cerebrospinal fluid
- blood – cerebrospinal fluid circulation barrier.

AC5.2 includes the major sensory and motor tracts.

AC6.1 includes:

- structure and functions of sympathetic and parasympathetic systems, and neurotransmitters.

AC6.2 includes:

- somatic motor and sensory pathways
- common peripheral nerves.

AC6.5 includes:

- receptor types:
  - mechanoreceptor
  - thermoreceptors
  - nociceptors
  - chemoreceptors
  - photoreceptors
- stimuli:
  - mechanical displacement
  - temperature change
  - pain
  - chemicals
  - light
  - sound.

AC7.1 includes examples from each specialism within neurosensory sciences:

- carpal tunnel syndrome
- epilepsy
- hydrocephalus
- meningitis
- multiple sclerosis
- neuralgia
- paraesthesia
- audiological hearing loss (presbycusis)
- stroke
- tinnitus
- transient ischaemic attacks
- raised intracranial pressure
- shingles
- Raynaud's phenomenon.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the main structures and functions of the nervous system	1.1	Explain the main subdivisions of the nervous system			
		1.2	Explain the subdivisions of the peripheral nervous system			
		1.3	Explain the main functions of the nervous system			
2	Understand the general histology of the nervous system	2.1	Explain the histological characteristics and functions of neurons and neuroglia in central and peripheral nervous systems			
		2.2	Explain the function of myelination in the nervous system			
		2.3	Explain the structure of grey and white matter in the central nervous system			
		2.4	Explain the structure of nerves and ganglia in the peripheral nervous system			
		2.5	Explain the maturation of neurosensory systems			
		2.6	Explain the differences in response to trauma between central and peripheral nervous systems			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the cellular properties of neurons and how they communicate with one another	3.1	Explain the terms: • membrane potential • resting membrane potential • current • ion channels • action potential • synapses • neurotransmitters			
		3.2	Explain the cellular properties that permit communications among neurons and effectors			
		3.3	Explain the factors that maintain a resting membrane potential			
		3.4	Analyse how action potentials are generated and propagated			
		3.5	Explain the classes and functions of neurotransmitters			
4	Understand the anatomy of the brain	4.1	Explain the protective structures of the brain			
		4.2	Explain the anatomical components of the brain and their function			
		4.3	Describe the blood supply to the brain and the blood-brain barrier			
		4.4	Explain the protective effect of the blood-brain barrier			
5	Understand the anatomical components and functions of the spinal cord	5.1	Describe the protective structures of the spinal cord			
		5.2	Describe the spinal nerves and the internal structure of the spinal cord and their functions			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Understand the structure and function of the autonomic and somatic nervous systems and motor functions	6.1	Explain and compare the structure and functions of the autonomic and somatic nervous systems			
		6.2	Describe the location and function of the receptors for tactile, thermal and pain sensations			
		6.3	Explain the histology and function of skeletal, smooth and cardiac muscle			
		6.4	Explain excitation-contraction coupling of skeletal, smooth and cardiac muscle			
		6.5	Explain the role of motor units and receptors			
		6.6	Compare smooth and skeletal muscle contraction			
7	Understand the pathophysiology of common neurological diseases and how these diseases impact on patients and their families	7.1	Explain how common neurological diseases may affect the nervous system			
		7.2	Discuss the impact of common neurological diseases on the patient and their families			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 65: Scientific Basis of Neurosensory Sciences: Applied Anatomy, Physiology and Pathophysiology: The Ear

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

In this unit, you will build on and extend your knowledge of the anatomy, physiology and pathophysiology of the ear and hearing. This unit extends the learning covered by the Level 2 – *Unit 23: Anatomy and Physiology: The Nervous System*. You will be expected to apply and contextualise your knowledge of and skills in performing routine technical procedures, and you will develop and build your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1 includes:

- anatomy of the ear, including:
  - outer
  - middle
  - inner ear (osseous labyrinth and membranous labyrinth).

AC1.2 includes:

- afferent and efferent auditory pathways
- cranial nerves with specific emphasis on the vestibular-cochlear nerve
- neural coding, including the generation of action potentials and synaptic transmission
- hair-cell and cochlear nerve physiology and sound transduction
- semi-circular canal physiology, otolith function and balance pathways.

AC2.1 includes:

- overview of pathophysiology, clinical and practical aspects of central, peripheral and vestibular disorders, for example:
    - cochlear disease
    - conductive hearing loss
    - Ménière's disease
    - neuritis
    - sensorineural hearing loss
    - tumours
    - tinnitus
    - vertigo.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the anatomy and physiology of the auditory and vestibular system	1.1	Explain the anatomy of the auditory and vestibular systems, at both the peripheral and central levels			
		1.2	Explain the physiology of the auditory and vestibular systems, at both the peripheral and central levels			
		1.3	Explain the purpose of the pinna			
		1.4	Explain the purpose of ear wax and how it is produced			
2	Understand the pathophysiology of the auditory and vestibular system	2.1	Evaluate how basic pathologies of the auditory system interfere with the efficient working of the peripheral and central mechanisms			
		2.2	Evaluate how basic pathologies of the peripheral vestibular system interfere with the efficient working of the balance system			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 66: Adult Hearing Screening and Assessment

Level: 4

Unit type: Optional

Credit value: 25

Guided learning hours: 200

Unit summary

In this unit, you will build on and extend your knowledge of the anatomy, physiology and pathophysiology of the ear and hearing. You will be expected to apply and contextualise your knowledge of and skills in performing routine audiological procedures, and develop and build your professional practice in accordance with Good Scientific Practice.

Additional information

It is suggested that learners will have completed the Level 2 – *Unit 84: Performing Basic Otoscopic Examinations* and Level 2 – *Unit 87: Communicating with People with a Hearing Loss*, or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) in own area of work.

AC1.4 includes:

- age
- gender
- socio-economic status
- ethnic background.

Learning outcome 5 includes:

- minimise risks and hazards, including the control of infection in accordance with health and safety policies
- ensure that all the required equipment is working correctly and safely, including any daily calibration requirements
- use effective communication skills within the healthcare environment, adapting communication style and language to meet the needs of the listener
- as appropriate, retrieve the patient's records, referral, file, or medical notes; obtain and review a suitably completed request form; identify and greet the patient; check patient ID

- as appropriate, prepare the environment, set up and calibrate equipment ready for use for each type of investigation and select equipment settings appropriate to the audiological test requirements
- evaluate the technical quality of recordings/measurements, identify suboptimal recordings/measurements and re-record/measure where necessary, knowing when to refer to senior colleagues.

AC5.1 includes:

- selection of starting point for the test based on the patient history
- current published recommended procedure for threshold testing. Appropriate patient instructions and understanding check
- correct placement of transducers, including supra-aural headphones, inserts and bone conductors
- reasons why variation in technique may be necessary.

AC5.4 should include **one** common disorder of hearing.

AC5.5 should include **one** common disorder of balance.

AC5.6 includes:

- challenges of ageing, learning difficulties, dementia, culture and language.

AC6.9 includes:

- modifying their technique according to patient performance or ability
- utilising the results of the not-masked PTA to select the initial masking level.

AC7.3 includes:

- restocking of consumables.

Learning outcome 8:

- national standards refer to ISO and BSI calibration procedures performed by an external specialist once a year
- national refers to BSA guidelines.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the impact of hearing loss on the health of individuals and the role of screening and prevention	1.1	Explain the term hearing impairment in the context of the World Health Organization International Classification of Functioning, Disability and Health (WHO ICF)			
		1.2	Explain the public health problems associated with hearing impairment related to demography			
		1.3	Explain the terms incidence and prevalence			
		1.4	Explain the prevalence of hearing/balance disorders and tinnitus in relation to demographic characteristics			
		1.5	Explain the purpose of screening for health conditions			
		1.6	Assess the criteria for appraising the viability, effectiveness and appropriateness of a screening programme			
		1.7	Discuss the role of healthcare science audiology services in adult hearing screening and the newborn hearing screening programme			
		1.8	Explain how common disorders of hearing, balance and tinnitus can be prevented			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the healthcare science services provided by audiology	2.1	Explain the range of healthcare science services provided by audiology in different settings			
		2.2	Discuss the common reasons for referring people to healthcare science audiology services			
3	Understand the role of the healthcare science associate in audiology	3.1	Explain the legislation, policy, quality management systems and good practice underpinning the practice of audiology			
		3.2	Explain the regulatory framework underpinning the delivery of healthcare science audiology services			
		3.3	Explain the process of incident reporting			
		3.4	Discuss own personal responsibilities regarding processes and procedures as described in Good Scientific Practice			
		3.5	Explain the limits of own authority and to whom to report any problems encountered fall outside limits of own authority			
4	Be able to communicate effectively with a range of people with hearing disabilities	4.1	Explain the principles of corrective communication with people who have hearing impairment			
		4.2	Explain the types of hearing loss and the potential impact on the patient and their ability to communicate			
		4.3	Explain how people with a hearing loss can adapt their ways of communication			
		4.4	Communicate effectively with people with a variety of hearing disabilities, adapting communication to meet the needs of the listener			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Understand the common reasons for referral to a healthcare science audiology service	5.1	Explain the purpose of investigations undertaken in people with hearing/balance disorders and tinnitus			
		5.2	Discuss the range of common procedures to investigate hearing/balance disorders and tinnitus			
		5.3	Explain the effect of common disorders of hearing on the patient and their quality of life			
		5.4	Explain the effect of common disorders of balance on the patient and their quality of life			
		5.5	Explain the effect of tinnitus on the patient and their quality of life			
		5.6	Evaluate the hearing assessment and management needs of particular specialist populations in audiology			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to perform pure tone audiometry (PTA)	6.1	Evaluate the Standard Operating Procedures for not-masked and masked pure tone audiometry			
		6.2	Prepare the environment and equipment for PTA according to standard operating procedures			
		6.3	Explain the procedure to the patient using effective communication skills			
		6.4	Gain and document informed consent for the procedure			
		6.5	Perform not-masked PTA in adult patients (including AC and BC), modifying technique according to patient performance or ability			
		6.6	Plot the results of not-masked PTA according to BSA guidelines, identifying any potential errors or factors that might affect the results			
		6.7	Record the results of not-masked PTA according to BSA guidelines			
		6.8	Perform masked PTA (including AC and BC), modifying technique according to patient performance or ability			
		6.9	Plot the results of masked PTA according to BSA guidelines, identifying any potential errors or factors that might affect the results			
		6.10	Record the results of masked PTA according to BSA guidelines			
		6.11	Provide person-centred care at all times, working within your appropriate scope of practice			
		6.12	Explain the procedure for giving the results to the patient			
		6.13	Seek advice and appropriate supervision to ensure safe and appropriate practice			
		6.14	Follow procedures for referral for identified referable conditions			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Be able to clean equipment, and leave the room in a suitable condition for reuse	7.1	Justify the protocols for cleaning equipment used for PTA			
		7.2	Clean equipment as per protocols			
		7.3	Arrange the room in a suitable condition for reuse			
8	Be able to calibrate and maintain auditory test equipment following national standards	8.1	Explain the purpose of routine equipment calibration in audiology			
		8.2	Perform daily calibration checks of audiometers and tympanometers			
		8.3	Record calibration status according to local policies/departmental protocols			
		8.4	Escalate errors in calibration checks according to departmental protocols			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 67: Hearing Aid Repair and Maintenance

Level: 4

Unit type: Optional

Credit value: 15

Guided learning hours: 120

Unit summary

In this unit, you will develop the knowledge, understanding and skills needed to be able to perform hearing aid repairs and maintenance. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedure and Good Manufacturing Practice.

AC1.1 – communication needs of people with a hearing impairment includes:

- lip-reading
- communication skills training
- assertiveness training
- hearing tactics
- involvement of significant others.

AC2.3 includes:

- greeting the patient – 'hello my name is'
- explain own role
- communicating with patients in a way that respects their dignity, rights, privacy and confidentiality.

AC2.6 includes:

- adherence to quality-control procedures
- adherence to health and safety procedures
- adherence to infection control procedures.

AC3.2 includes routine and specialist aids.

AC6.2 includes like-for-like hearing aid replacement.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the psychosocial aspects of hearing loss	1.1	Evaluate the communication needs of people with hearing impairment			
		1.2	Explain the impact of hearing impairment on the relationships with significant others			
		1.3	Discuss the implications of hearing impairment on mental health			
		1.4	Discuss different models of disability in relation to employment and equality			
		1.5	Explain own strategies for communicating with people who have hearing impairment			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to take ear mould impressions and modify ear moulds	2.1	Compare the type of ear moulds and open ear fittings available			
		2.2	Explain how the acoustical properties of an ear mould and open ear fitting can impact on a hearing aid's potential to deliver sound to the ear			
		2.3	Explain the impression taking procedure to the patient using effective communication skills			
		2.4	Treat patients in a way that respects their dignity, rights, privacy and confidentiality			
		2.5	Gain and document informed consent for the procedure			
		2.6	Take and process impressions of ears for customised ear moulds following recommended procedures			
		2.7	Order the appropriate ear mould type and additional modifications according to existing specifications			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the role of hearing aid provision within a patient management plan	3.1	Explain the role of hearing aid provision within a patient management plan			
		3.2	Evaluate the different types of hearing aids available for people with hearing impairment			
		3.3	Explain how current hearing aid technology and performance supports people with hearing impairment			
		3.4	Explain how the sound modification features of hearing aids maximise benefit for people with hearing impairment			
		3.5	Explain the process of assessing hearing aid candidacy for people with hearing impairment			
		3.6	Explain the process of hearing aid selection for people with hearing impairment			
4	Be able to use a hearing aid test box according to Standard Operating Procedures	4.1	Explain the Standard Operating Procedure for the use of a hearing aid test box			
		4.2	Assess the hearing aid performance against a range of agreed parameters			
		4.3	Document the results of the hearing aid test box procedure			
		4.4	Interpret the results of hearing aid performance measures			
		4.5	Compare the hearing aid test box results to the manufacturer's published specifications for the specific digital hearing aid			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to undertake like-for-like replacement of hearing aids in the repair clinic	5.1	Discuss the reasons a patient may require like-for-like replacement of hearing aids			
		5.2	Undertake like-for-like replacement of hearing aids in the repair clinic following standard operation procedures			
		5.3	Complete the required documentation in line with standard operation procedures			
6	Be able to perform routine hearing aid maintenance and checks	6.1	Perform listening checks of hearing aids as part of routine maintenance			
		6.2	Perform hearing aid repairs as part of routine maintenance			
		6.3	Replace life tubes and domes, adjusting length to fit the ear			
		6.4	Re-tube an ear mould, adjusting length to fit the ear			
		6.5	Use specialist ear mould modification machinery to finish and polish ear moulds for patient comfort			
		6.6	Follow procedures for referral for identified referable conditions			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 68: Assisting with Electroencephalography

Level: 4

Unit type: Optional

Credit value: 15

Guided learning hours: 120

Unit summary

In this unit, you will develop the knowledge, understanding and skills needed to be able to assist and support the healthcare science practitioner/clinical scientist in performing quality-assured, safe, electroencephalography in adults and children. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own work practice.

AC1.1 includes knowledge of a range of procedures undertaken in neurophysiology, which could include:

- electroencephalography
- electromyograms
- nerve conduction studies
- evoked potentials
- visual evoked potentials
- visual electrophysiology
- brainstem auditory evoked potentials
- somatosensory evoked potentials
- intraoperative monitoring.

AC1.2 could include:

- carpal tunnel syndrome
- diabetic neuropathy
- disorders of the optic nerve
- disorders of the retina
- disorders of sleep
- dementia
- encephalitis
- entrapment neuropathies
- epilepsy
- head injury
- meningitis
- multiple sclerosis
- myopathy
- stroke.

AC1.3 includes:

- greeting the patient – 'hello my name is'
- explain own role
- communicating with patients in a way that respects their dignity, rights, privacy and confidentiality.

AC1.6 includes:

- recognising that you are personally responsible for and must be able to justify your decisions.

AC2.4 includes:

- informed consent procedures in adults and children.

AC3.1 includes:

- minimising risks and hazards in compliance with health and safety policies
- controlling infection risks
- washing hands
- identification of potential risks of using defective equipment and measures to resolve common problems
- chaperoning.

AC3.5 includes:

- requirements for the investigation environment to ensure privacy, dignity and comfort of the patient.

AC3.7 includes:

- checking calibrating and preparing the equipment
- identification of common faults and taking remedial action.

AC3.8 includes:

- correct positioning
- how to respond when faced with an uncooperative patient.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the range of procedures undertaken in a neurophysiology department and the importance of patient-centred practice	1.1	Explain the range of procedures undertaken in neurophysiology departments			
		1.2	Explain the common reasons for referring patients to neurophysiology departments			
		1.3	Explain how to embed the principles of patient-centred care in own area of practice			
		1.4	Explain the principles, guidance and law for gaining informed consent, including the limits of consent			
		1.5	Evaluate safeguarding procedures and the process for reporting safeguarding issue			
		1.6	Discuss the limits of your practice and when to seek advice or refer to another professional			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the principles and practice of electroencephal-ography (EEG)	2.1	Explain the pathophysiological changes associated with epilepsy			
		2.2	Explain the routine clinical indications and contraindications for EEG			
		2.3	Explain the measurements that may be required pre and post investigation			
		2.4	Discuss the potential risks of using defective equipment in clinical practice and the implications of use			
		2.5	Evaluate the requirements for quality-assured investigations			
		2.6	Explain the procedure to be followed in the event of identifying an issue of quality assurance			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to assist with recording of electroencephal-ograms (EEG) in accordance with Standard Operating Procedures	3.1	Evaluate the Standard Operating Procedure underpinning the recording of EEGs			
		3.2	Explain the factors influencing the choice of equipment for the investigation			
		3.3	Select suitable equipment in accordance with the requirements of the test			
		3.4	Explain the principles of measurement for the range of equipment used			
		3.5	Assist in preparing the environment and equipment for EEG			
		3.6	Assist in preparing the patient with respect and compassion			
		3.7	Perform all procedures in accordance with the Standard Operating Procedures			
		3.8	Explain the potential special needs of patients referred for investigation and the relevant action required			
		3.9	Act on any special patient requirements, discussing with senior staff and carers if necessary			
4	Be able to assist following completion of the recording	4.1	Explain how to remove electrodes and clean the site with minimum discomfort to the patient			
		4.2	Remove electrodes and clean the site minimising discomfort to the patient			
		4.3	Provide information to the patient with respect to how they will be informed of results of the investigation			
		4.4	Ensure that all the required arrangements are in place for the patient/carer following completion of the electroencephalogram			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to clean and decontaminate equipment used to record an EEG	5.1	Evaluate the protocols for cleaning and decontaminating equipment used to record an EEG			
		5.2	Decontaminate equipment following protocols			
		5.3	Ensure equipment is left in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 69: Performing Machine Function Tests

Level:	**4**
Unit type:	**Optional**
Credit value:	**7**
Guided learning hours:	**58**

Unit summary

In this unit, you will develop the knowledge, understanding and skills needed to be able to perform machine function tests on neurophysiological recording equipment. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own work practice.

AC2.2 includes:

- safety of the machine, including all cables and connectors
- importance of the safety rating and ensuring regular safety checks.

AC2.3 includes:

- checking the condition of all cables and connectors
- ensuring there is an adequate storage medium for the test to be carried out
- confirming the correct date and time is displayed
- identifying the number of enabled channels and sampling
- reporting faults and rectifying (if possible).

AC2.4 includes:

- default settings (filters, sensitivity, time base and montage/montages)
- the function of the high- and low-frequency filter and default sensitivity setting, and use of a square wave signal
- the time base, time marker, range of different time bases, cursors
- the function of the stimulator and correct use of the stimulus parameters (stimulation rate and where appropriate stimulus duration).

AC2.6 includes:

- permanent records, which could be a printout or information could be stored on the hard drive.

AC3.1 includes:

- selection and connection of external devices to measure frequency response
- selection of the correct input signal voltage, frequency/frequencies and type of wave (square/sine) on a signal generator for the measurement of frequency response curves
- selection of the correct display parameters for the measurement of frequency response curves
- the range of test frequencies and number of different bandwidths (both low- and high-frequency filters), including 50 Hz notch filter.

AC3.4 includes:

- an appropriate set of graphs showing the response from a number of filter bandwidths, including the 50 Hz notch filter
- calculation of the machine's turnover frequency -3db for appropriate filter settings and show on the graph.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and application of machine function tests on neurophysiological recording equipment	1.1	Explain the principles and application of machine function tests			
		1.2	Explain the process to be followed if errors in machine function are detected			
2	Be able to perform internal calibration procedures on neurophysiological recording equipment in accordance with Standard Operating Procedures	2.1	Evaluate the Standard Operating Procedure for performing internal calibration procedures			
		2.2	Explain the importance of electrical safety for neurophysiology investigations			
		2.3	Perform internal calibration procedures on the recording equipment used following standard operating procedures			
		2.4	Explain the principles of internal calibration procedures for neurophysiological recording equipment			
		2.5	Perform internal calibration procedures on neurophysiological recording			
		2.6	Record the machine function tests in a permanent format			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to perform external calibration procedures on neurophysiological recording equipment in accordance with the Standard Operating Procedures	3.1	Evaluate the Standard Operating Procedure for performing internal calibration procedures			
		3.2	Perform external calibration procedures on the recording equipment used following standard operating procedures			
		3.3	Test the machine over a range of frequencies using a number of different bandwidths			
		3.4	Assess the external calibration procedures, identifying and explaining any issues with the procedure			
4	Be able to measure common mode rejection ratio using a signal generator for a number of recorder channels	4.1	Explain how correct external devices are selected			
		4.2	Record common mode rejection ratio using a signal generator for a number of recorder channels			
		4.3	Calculate the common mode rejection ratio in decibels, identifying and explaining any issues with the procedure			
5	Be able to measure internal noise of a number of the recorder's channels	5.1	Explain how correct external devices/transducers are selected			
		5.2	Explain how to select the correct input signal voltage, frequency/frequencies and type of wave (square/sine)			
		5.3	Measure internal noise of a number of the recorder's channels			
		5.4	Assess the measurements, identifying and explaining any issues with the procedure			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Understand how machine function tests contribute to the provision of quality-assured investigations	6.1	Evaluate the requirements for quality-assured investigations			
		6.2	Explain how machine function tests contribute to the provision of quality-assured investigations			
		6.3	Explain the procedure in the event of identifying an issue of quality assurance (fault log)			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 70: Assist in the Recording of Visual Evoked Potentials

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 52

Unit summary

In this unit, you will develop the knowledge, understanding and skills needed to be able to assist in the recording of visual evoked potentials. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own work practice.

AC1.2 includes:

- visual acuity:
  - cataract
  - maculopathy
  - optic nerve disease
- colour vision:
  - optic nerve disease
  - congenital colour vision defects.

AC1.3 includes:

- underlying health conditions such as:
  - diabetes
  - glaucoma
  - age-related macular degeneration
  - multiple sclerosis
- a side effect of medications such as:
  - digoxin
  - ethambutol
  - chloroquine
  - hydroxychloroquine
  - phenytoin
  - sildenafil.

AC2.1 includes:

- how to mark the electrode sites accurately, in accordance with a recommended placement system and the planned investigation
- how to correctly and securely site the electrodes and correctly position the leads
- how to ensure that the contact impedances are appropriate for the electrode type
- the importance of correctly and accurately positioning the stimulators.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and application of the measurement of visual evoked potentials (VEP) and the importance of patient-centred practice	1.1	Explain the anatomy and physiology of the eye and visual pathway in relation to VEPs			
		1.2	Explain the recording principles of VEPs			
		1.3	Explain how visual acuity and colour vision are affected by clinical conditions			
		1.4	Explain the routine clinical indications and contraindications for VEPS			
		1.5	Explain the principles, guidance and law for gaining informed consent, including the limits of consent			
		1.6	Evaluate ways to ensure and promote patient-centred care in own area of practice			
2	Be able to assist with the planning, preparation and delivery for recording visual evoked potentials (VEPs)	2.1	Evaluate the Standard Operating Procedure for measuring VEPs			
		2.2	Prepare the environment for the measurement			
		2.3	Assist with the planning and preparation for recording			
		2.4	Assess the visual acuity, ensuring the patient is comfortable and positioned to optimise the recording quality			
		2.5	Assist, as directed, in the procedure			
		2.6	Treat every person with compassion, dignity and respect to meet standards of patient-centred care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to assist following completion of the recording	3.1	Explain how to remove electrodes and clean the site with minimum discomfort to the patient			
		3.2	Remove electrodes and clean the site minimising discomfort to the patient			
		3.3	Provide information to the patient with respect to how they will be informed of results of the investigation			
4	Be able to decontaminate equipment, and leave in a suitable condition for reuse	4.1	Evaluate the protocols for cleaning and decontaminating equipment			
		4.2	Decontaminate equipment following standard operating procedures			
		4.3	Ensure equipment is left in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 71: Assist in the Recording of Visual Electrophysiological Investigations

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 52

Unit summary

In this unit, you will develop the knowledge, understanding and skills needed to be able to assist in the recording of visual electrophysiological investigations spanning electroretinograms (ERG), pattern electroretinograms (PREG) and electro-occulograms (EOG). You will also be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own work practice.

AC1.2 includes:

- visual acuity:
  - cataract
  - maculopathy
  - optic nerve disease
- colour vision:
  - optic nerve disease
  - congenital colour vision defects.

AC2.1 includes:

- how to mark the electrode sites accurately, in accordance with a recommended placement system and the planned investigation
- how to correctly and securely site the electrodes and correctly position the leads
- how to ensure that the contact impedances are appropriate for the electrode type
- the importance of correctly and accurately positioning the stimulators.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and application of the measurement of visual electrophysiological investigations and the importance of patient-centred practice	1.1	Explain the anatomy and physiology of the eye and visual pathway in relation to the visual electrophysiological investigations (ERG, PREG and EOG)			
		1.2	Discuss the recording principles of visual electrophysiological investigations			
		1.3	Explain the routine clinical indications and contraindications for visual electrophysiological investigations			
		1.4	Explain the principles, guidance and law for gaining informed consent, including the limits of consent			
		1.5	Evaluate ways to ensure and promote patient-centred care in own area of practice			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to assist with the planning, preparation and delivery for recording visual electrophysiological investigations	2.1	Evaluate the Standard Operating Procedure for measuring visual electrophysiological investigations			
		2.2	Prepare the environment for the recording of recording visual electrophysiological investigations			
		2.3	Assist with the planning and preparation for recording			
		2.4	Assess the visual acuity, ensuring the patient is comfortable and positioned to optimise the recording quality			
		2.5	Assist, as directed, in the procedure			
		2.6	Treat every person with compassion, dignity and respect to meet standards of patient-centred care			
3	Be able to assist following completion of the recording	3.1	Explain how to remove electrodes and clean the site with minimum discomfort to the patient			
		3.2	Remove electrodes and clean the site minimising discomfort to the patient			
		3.3	Provide information to the patient with respect to how they will be informed of results of the investigation			
4	Be able to decontaminate equipment, and leave in a suitable condition for reuse	4.1	Evaluate the protocols for cleaning and decontaminating equipment			
		4.2	Decontaminate equipment following Standard Operating Procedures			
		4.3	Ensure the equipment is left in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 72: Assist during Nerve Conduction Studies and Electromyography

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 52

Unit summary

In this unit, you will develop the knowledge, understanding and skills needed to be able to assisting in the preparation of patients for nerve conduction studies and electromyography (EMG). You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own work practice.

AC1.2 – indications for nerve conduction studies and EMG:

supporting the diagnosis, monitoring and management of peripheral nerve and muscle problems:

- peripheral neuropathies:
  - diabetic
- entrapment neuropathies, e.g. carpal tunnel syndrome
- radiculopathies:
  - cervical
- muscle disorders:
  - motor neurone disease

contraindications to EMG and nerve conduction studies include:

- significant coagulopathies
- blood dyscrasia
- implanted cardiac defibrillator.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and application of nerve conduction studies and electromyography (EMG) and the importance of patient-centred practice	1.1	Explain the anatomy and physiology of the peripheral nervous system relevant to nerve conductions studies and EMG			
		1.2	Discuss the recording principles of nerve conduction studies and electromyography (EMG)			
		1.3	Describe the routine clinical indications and contraindications for nerve conductions studies and EMG			
		1.4	Explain the principles, guidance and law for gaining informed consent, including the limits of consent			
		1.5	Evaluate ways to ensure and promote patient-centred care in own area of practice			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to assist with the planning, preparation and delivery for recording nerve conduction studies and electromyography (EMG)	2.1	Evaluate the Standard Operating Procedure for measuring nerve conduction studies and EMG			
		2.2	Prepare the environment for the measurement of nerve conduction studies and EMG			
		2.3	Assist with the planning and preparation for recording nerve conduction and EMG			
		2.4	Assist in the procedure, giving the patient clear instructions			
		2.5	Treat every person with compassion, dignity and respect to meet standards of patient-centred care			
		2.6	Assist in the annotation of the recording			
3	Be able to assist following completion of the recording	3.1	Explain how to remove electrodes and clean the site with minimum discomfort to the patient			
		3.2	Remove electrodes and clean the site, minimising discomfort to the patient			
		3.3	Provide information to the patient with respect to how they will be informed of results of the investigation			
4	Be able to decontaminate equipment, and leave in a suitable condition for reuse	4.1	Evaluate the protocols for cleaning and decontaminating equipment			
		4.2	Decontaminate equipment following standard operating procedures			
		4.3	Ensure the equipment is left in a suitable condition for reuse			
		4.4	Dispose of sharps safely in accordance with health and safety procedures			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 73: Ophthalmic and Vision Science: Applied Microbiology

Level:	**4**
Unit type:	**Optional**
Credit value:	**6**
Guided learning hours:	**52**

Unit summary

In this unit, you will gain an understanding of the practical application of microbiology principles and practice within an ophthalmic and vision science setting. You are required to understand the causes, routes of transmission and procedures to reduce and prevent healthcare-associated infections across healthcare and within your own area of practice.

Additional information

AC1.1 includes:

- bacteria
- fungi
- protozoa
- viruses.

AC1.2 includes:

- bacteria
- fungi
- protozoa
- viruses.

AC1.3 includes:

- mutualism
- commensalism
- parasitism.

AC2.2 includes:

- bacteria
- chlamydiae
- viruses
- fungi
- acanthamoeba.

AC2.3 should involve **one** type of microbe relevant to own area of work.

AC3.1 examples of hospital-acquired infections include:

- adenovirus in ophthalmic settings.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the different categories of microbes and their classification	1.1	Describe the classification of different types of microbes			
		1.2	Explain the distinguishing features of different types of microbes			
		1.3	Explain the symbiotic relationships between humans and microbes			
		1.4	Explain the concepts of pathogen, infection and contagion, normal flora and opportunistic infections			
2	Understand how specimens are collected and transported, and how microbes are identified in the laboratory	2.1	Explain procedures for microscopy and culture of microorganisms in the laboratory			
		2.2	Discuss procedures for specimen collection from the eye and how they are transported to the laboratory			
		2.3	Explain the laboratory identification of a type of microbe relevant to own area of practice			
		2.4	Explain local protocols and procedures for sight-threatening corneal ulcers and endophthalmitis			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the causes and routes of transmission of healthcare-associated infection (HAI) and procedures to reduce and prevent healthcare-associated infections	3.1	Explain procedures for containing outbreaks of HAI			
		3.2	Explain the sources and routes of transmission of healthcare-associated infections			
		3.3	Evaluate the principles and methods of antisepsis and disinfection in healthcare			
		3.4	Discuss the additional procedures that may be undertaken when a patient with a known or suspected eye infection is examined in an eye clinic			
4	Understand the relevant workplace policies and procedures in an ophthalmic setting	4.1	Evaluate the standard precautions for infection control in own area of practice			
		4.2	Explain how maintaining a sterile field reduces the risk of transmission of infection			
		4.3	Explain the procedures for laying out and clearing away instruments for a minor surgical procedure or intravitreal injection			
		4.4	Evaluate the protocols and procedures undertaken prior to, during and following intraocular surgery that reduce the risk of endophthalmitis			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 74: Ophthalmic Pharmacology

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 48

Unit summary

In this unit, you will gain an understanding of ophthalmic pharmacology, beginning with the general principles and the principles and methods of ophthalmic drug formulation and delivery to the eye. You will be expected to know the major categories of ophthalmic diagnostic and therapeutic drugs, their indications, mode of action and adverse effects and the operational policies in your own area of practice.

Additional information

Learning outcome 1 spans:

- pharmaceutics
- pharmacokinetics
- pharmacodynamics
- therapeutics.

AC1.2 includes:

- chemical name
- generic name
- proprietary name.

AC1.3 should include drugs used for diagnostic purposes, rather than for treatment:

- topical
- local
- systemic
- enteral
- parenteral.

AC1.4 includes:

- barriers to their distribution.

AC1.5 could include:

- how they can interact with receptors or interfere with enzyme function
- how the effect of drugs is related to their concentration.

AC2.1 includes:

- measures to reduce the risk of microbial contamination in eye medication containers.

AC3.1 to 3.3 include for:

- local anaesthetics
- dyes and stains
- mydriatics and cycloplegics
- anti-infective drugs
- anti-inflammatory drugs
- drugs for treating glaucoma
- ocular lubricants and decongestants.

AC4.1 includes:

- prescription
- administration
- supply and dispensing of drugs
- application of ophthalmic drugs in practice
- concordance
- compliance
- adherence.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the general principles of pharmacology	1.1	Explain the terms pharmaceutics, pharmacokinetics, pharmacodynamics and therapeutics			
		1.2	Explain drug nomenclature and the difference between generic and proprietary names for drugs			
		1.3	Explain the routes by which drugs are administered			
		1.4	Explain how drugs are absorbed into the body across cell membranes and distributed within the body			
		1.5	Explain how drugs can affect the body			
		1.6	Explain how drugs can be biologically transformed, detoxified, and excreted			
2	Understand the principles and methods of ophthalmic drug formulation and delivery to the eye	2.1	Explain the different formulations and packaging of topical ophthalmic drugs			
		2.2	Explain how topical, periocular and intraocular ophthalmic drugs penetrate ocular tissues and are eliminated from the eye			
		2.3	Explain the blood-eye barriers and how systemic drugs penetrate ocular tissues			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the major categories of ophthalmic diagnostic and therapeutic drugs, their indications, mode of action and adverse effects	3.1	Explain the major categories of ophthalmic diagnostic and therapeutic drugs			
		3.2	Explain the mode of action of the major categories of ophthalmic diagnostic and therapeutic drugs			
		3.3	Discuss the adverse effects of the major categories of ophthalmic diagnostic and therapeutic drugs			
4	Understand the operational drug policies in own area of practice	4.1	Explain what is meant by prescription, administration, supply and dispensing of drugs			
		4.2	Evaluate how adherence to treatment can be improved with patient communication and education			
		4.3	Explain the regulatory requirements for the storage and disposal of medicines in own area of practice			
		4.4	Discuss different kinds of adverse drug reactions, their management, and procedures for documentation and reporting			
		4.5	Explain the tests, procedures and treatments that are performed in own area of practice that require the administration of drugs			

Learner name: _____

Learner signature: _____

Assessor signature:_____

Internal verifier signature: _____
(*if sampled*)

Unit 75: Instil Eye Medication for Purpose of Investigation or Treatment

Level:	**3**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

In this unit, you will apply and extend your knowledge, understanding and skills in the use of drugs in ophthalmic practice, applying your learning from the ophthalmic pharmacology unit, while developing your skills with respect to patient-centred compassionate care. You will be expected to build your patient-centred professional practice to enable you to undertake this skill safely in the workplace.

Additional information

AC1.5 includes:

- explaining the procedure to the patient
- maintain patient confidentiality:
  - auditory
  - written
  - electronic
- the purpose, effect, duration of drug action
- actions to take or avoid following drug administration.

Learning outcome 2 includes:

- communicating effectively with the patient and carers, confirming patient identification, explaining personal role and nature and purpose of procedure at a level appropriate to the patient/carer's understanding, and ensuring patient has the opportunity to explain any problems or difficulties
- identifying any special needs, e.g. age, sensory impairment, physical disability, learning disability, cognitive dysfunction, and adapting communication style and testing methods to meet these needs
- obtaining verbal consent from patient/carer
- maintain patient confidentiality: auditory, written and electronic
- demonstrating effective infection control practices according to local protocols.

AC2.6 – if a learner does not encounter an adverse drug reaction during training this should be assessed by simulation.

AC2.7 includes:

- instillation of topical anaesthetic
- requirement not to drive or work with machinery until effects of dilating drops have worn off.

AC2.9 – if a learner does not encounter an adverse drug reaction during training this should be assessed by simulation.

AC2.9 includes:

- date
- name
- signature
- professional role
- noting any patient concerns or difficulties with drug administration, or other relevant information.
- reporting any concerns to a more senior member of the team.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to establish professional relationships with patients	1.1	Communicate effectively with the patient, parent or carers			
		1.2	Confirm patient identification, identify and respond to any special needs			
		1.3	Explain personal role and nature and purpose of procedure at a level appropriate to the patient/carer's understanding			
		1.4	Ensure patient has opportunity to explain any problems or difficulties			
		1.5	Gain informed consent			
		1.6	Identify any cautions or contraindications for use of prescribed medication			
		1.7	Ensure patient confidentiality is maintained at all times			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to instil eye medication for purpose of investigation or treatment	2.1	Explain the principles and methods for administration of ophthalmic drugs in own area of practice			
		2.2	Interpret instruction of prescription or direction for drug administration			
		2.3	Select the correct drug for the procedure			
		2.4	Check with patient and patient's record for history of adverse reaction to drug			
		2.5	Check drug name, dose and expiry date			
		2.6	Demonstrate the correct technique and patient/parent/carer instruction for drug administration			
		2.7	Document drug administration in patient's paper or electronic record			
		2.8	Monitor the effects of drugs, and repeat instillation as required, according to role and local protocols			
		2.9	Respond to adverse drug reactions, reporting this following local policies			
		2.10	Provide information to patients/parent/carer, including actions to take or avoid following administration of drugs			
		2.11	Maintain the highest standards of person-centred care, treating every person with compassion, dignity and respect			
		2.12	Adhere to infection control practices according to local protocols			
		2.13	Store and dispose of drugs according to local policies			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to advise and support patients with regard to management and administration of prescribed drugs	3.1	Document the use of prescribed medications by the patient and any adverse effects and difficulties with compliance			
		3.2	Explain the aids available to assist patients with self-administration of prescribed medications			
		3.3	Demonstrate the procedure to the patient			
		3.4	Teach the patient to self-administer the prescribed medications, providing aids as indicated to assist patients			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 76: Anatomy, Physiology and Pathophysiology of the Visual System

Level:	**4**
Unit type:	**Optional**
Credit value:	**6**
Guided learning hours:	**48**

Unit summary

This unit enables you to build and extend your knowledge of the anatomy, physiology and pathophysiology of the eye, and how the brain processes information to provide a visual perception of the world around us. You will be expected to apply and contextualise their knowledge and skills by performing routine technical skills, and developing and building your professional practice in accordance with good scientific practice.

Additional information

AC1.1 includes:

- epithelial, connective, muscular and nervous tissue.

AC1.2 includes:

- common anatomical terms and nasal, temporal, visual axis, clock hours.

AC8.1 includes:

- inflammatory; infectious; allergic and autoimmune; ischaemic; metabolic; congenital, including genetic; developmental; degenerative; neoplastic; traumatic.

AC8.2 includes:

- orbital fracture
- dry eye.

AC8.3 includes:

- conjunctivitis
- eyelid tumours
- cataract.

AC8.4 includes:

- glaucoma
- macular degeneration
- diabetic retinopathy.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Know the general principles of anatomy and physiology as they are applied to the eye and ocular adnexae	1.1	Explain different types of body tissue that form the eye and ocular adnexae			
		1.2	Explain the relationships between the various structures of the eye and ocular adnexae, using directional terms and anatomical planes and sections			
2	Know the structures of the ocular adnexae and their function	2.1	Explain the components and structure of the ocular adnexae and explain their purpose			
		2.2	Explain the role of the ocular adnexae in maintaining the health of the ocular surface			
		2.3	Describe the nerve supply of the extraocular muscles and describe their actions			
		2.4	Describe the relationship of the bony orbit to surrounding structures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Know the structures of the anterior segment of the eye and their functions	3.1	Describe the three layers and three chambers of the eye			
		3.2	Describe the anatomy and functions of the cornea and explain why the cornea is transparent			
		3.3	Describe the anatomy of the iris, lens and ciliary muscle and explain their functions			
		3.4	Describe the structure of the ciliary body and anterior chamber angle, and their role in the production and drainage of aqueous			
4	Know the structures of the posterior segment of the eye and their functions	4.1	Describe the retinal pigment epithelium and the layers of the neuroretina, and their cellular components and functions			
		4.2	Describe transduction and how neural impulses are transmitted through the retina			
		4.3	Describe the structure of the ganglion cell layer and optic nerve, and normal variations in the appearance of the optic nerve on ophthalmoscopy			
		4.4	Explain the blood supply to the retina and choroid, and the differences in the circulation of blood to the choroid and retina			
5	Understand the structure and function of the visual pathway, the pupillary light reflex, and cranial nerves that have a role in the visual system	5.1	Explain the distribution and functions of the cranial nerves that have a role in the visual system			
		5.2	Explain the structure and function of the visual pathway			
		5.3	Explain how light impulses are transmitted from retina to visual cortex			
		5.4	Explain the pathway for the pupillary light reflex			
		5.5	Explain why light shone into one eye causes both pupils to constrict			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Understand different aspects of visual perception	6.1	Discuss visual acuity and contrast sensitivity, relating this to the structure and function of the visual system			
		6.2	Discuss visual field, relating this to the structure and function of the visual system			
		6.3	Explain binocular vision and stereopsis			
		6.4	Explain colour vision and common abnormalities of colour perception			
7	Understand the role of the autonomic nervous system and the eye	7.1	Explain the sympathetic and parasympathetic innervation of the eye			
		7.2	Describe cholinergic (muscarinic and nicotinic) and adrenergic (α and β) receptors and effects of agonist and antagonist drugs when administered to the eye			
		7.3	Explain the process of neurotransmission and the modes of action and effects of agonist and antagonist drugs when administered to the eye			
8	Understand the pathophysiological mechanisms, clinical and practical aspects of disorders affecting the visual system	8.1	Explain the pathophysiological mechanisms of diseases of the eye			
		8.2	Discuss common conditions affecting the ocular adnexae			
		8.3	Discuss common conditions affecting the anterior segment of the eye			
		8.4	Discuss common conditions affecting the posterior segment of the eye and optic nerve			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 77: Imaging the eye with fundus camera and optical coherence tomography

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 48

Unit summary

The aim of this unit is to ensure that you are able to apply your knowledge, understanding and skills to perform imaging of the eye. You will also develop your skills with respect to patient-centred compassionate care. You will be expected to build your patient-centred professional practice to enable you to undertake this skill safely in the workplace.

Additional information

AC3.1 includes:

- communicating effectively with the patient, parent or carers
- confirming patient identification, identifying and responding to any special needs
- explaining own role and nature and purpose of the procedure at a level appropriate to the patient/carer's understanding
- ensuring patient has the opportunity to explain any problems or difficulties
- gaining informed consent
- identifying any cautions or contraindications for the procedure
- maintaining patient confidentiality.

AC3.2 includes:

- demonstrating correct method for instillation
- monitoring for effects.

AC3.4 includes:

- ensuring equipment is calibrated and maintained according to manufacturer instructions and workplace protocol; demonstrating, as required, procedures for calibration and maintenance of equipment
- ensuring equipment is working correctly and safely
- ensuring appropriate environmental conditions for obtaining results; appropriate room illumination, but could also include issues such as maintaining a comfortable room temperature, auditory privacy
- identifying hazards and risks and take appropriate action; hazards/risks of trailing leads and cables, inappropriate patient seating.

AC3.6 includes demonstrating effective infection control practices according to local protocols:

- ensuring effective hand decontamination before each patient contact
- ensuring effective decontamination of equipment and devices
- ensuring the safe disposal of clinical waste
- maintaining a clean and tidy clinical environment.

AC 3.8 includes:

- incorrect use of equipment (e.g. not setting equipment for the patient's refractive error)
- patient conditions that can cause poor-quality images (e.g. media opacities, small pupil, patients' physical or mental disabilities).

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the normal appearance of ocular structures and how ocular pathology can be identified and documented	1.1	Explain how the different structures of the eye can be imaged with different imaging modalities and techniques			
		1.2	Explain the process of digitising, processing and storing images			
2	Understand the different equipment that can be used for imaging the eye	2.1	Explain the components and function of a fundus camera, and the applications and limitations when obtaining images of the fundus			
		2.2	Explain the basic components of optical coherence tomography (OCT), and the applications and limitations when obtaining images of the eye			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to perform imaging of the eye	3.1	Establish professional relationships with patients			
		3.2	Instil dilating drops as required for procedure			
		3.3	Provide clear and concise instructions to the patient			
		3.4	Adhere to safe working practices in own area of work			
		3.5	Monitor the patient throughout to obtain required fixation and concentration throughout testing			
		3.6	Control infection risks in accordance with workplace protocols			
		3.7	Obtain images of suitable clarity and type and in sufficient quantity to respond to clinical question			
		3.8	Minimise artefacts and poor-quality images due to ocular conditions, operator error and patient compliance			
4	Record and report test results	4.1	Document results in patient record, noting patient responses and any difficulties with compliance			
		4.2	Record information in line with national and local policy and protocol			
		4.3	Evaluate results and report any issues of concern to the appropriate person			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 78: Measuring Visual Acuity

Level: 3

Unit type: Optional

Credit value: 3

Guided learning hours: 17

Unit summary

In this unit, you will develop the understanding and skills needed to prepare for and measure visual acuity, minimising risks and hazards and ensuring all equipment is working correctly, recording the outcomes accurately.

Additional information

There are no specific assessment requirements for this unit. Please refer to the assessment strategy in *Annexe A*.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the purpose and importance of accurate measurement of visual acuity	1.1	Explain what is meant by visual acuity, the importance of visual acuity as part of patient assessment, and describe ocular structures and function essential for normal visual acuity			
		1.2	Explain how visual acuity is measured, the relationship between letter size and distance from patient, and possible errors in visual acuity testing			
		1.3	Describe errors of refraction and how they are corrected			
		1.4	Describe common types of spectacles and contact lenses used to correct errors of refraction			
		1.5	Describe common conditions that can reduce visual acuity			
2	Know different equipment used for assessment of visual acuity for distance and near in adults and children	2.1	Describe charts used for assessing visual acuity for distance and near			
		2.2	Describe charts and methods used for testing people who are non-literate, or who have communication, learning or cognitive difficulties			
		2.3	Describe charts and methods used for testing children of different ages			
		2.4	Describe charts and methods used for testing people with vision impairment			
		2.5	Describe indications for use of pinhole			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to establish professional relationship with patient, identifying and addressing any special needs, and maintaining patient confidentiality	3.1	Communicate effectively with the patient and carer/s, confirming patient identification, explaining personal role and nature and purpose of procedure at a level appropriate to the patient/carer's understanding, and ensuring patient has opportunity to explain any problems or difficulties			
		3.2	Identify any special needs, e.g. age, sensory impairment, physical disability, learning disability, cognitive dysfunction, and adapt communication style and testing methods to meet these needs			
		3.3	Obtain verbal consent from patient/carer			
		3.4	Maintain patient confidentiality: auditory, written and electronic			
4	Be able to minimise risks and hazards when measuring visual acuity	4.1	Demonstrate effective infection control practices according to local protocols			
		4.2	Demonstrate or describe safe manual handling practices			
		4.3	Explain how to reduce risks for patients with vision impairment, e.g. signage, contrast, lighting			
5	Be able to ensure that all the required equipment is working correctly and safely and test environment is appropriate for the procedure	5.1	Describe procedures for calibration and maintenance of equipment			
		5.2	Demonstrate procedures for calibration and maintenance of equipment			
		5.3	Ensure chart is illuminated correctly			
		5.4	Ensure room lighting is appropriate for test			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to measure visual acuity for distance and near	6.1	Obtain relevant history and documentation from patient and patient's record			
		6.2	Obtain relevant history and documentation from patient and patient's record			
		6.3	Confirm patient's existing use of optical correction			
		6.4	Select appropriate test according to patient's age, co-operation, ability and any cultural and special needs			
		6.5	Position patient at the correct distance from the test chart			
		6.6	Measure visual acuity for distance and near, with and/or without optical correction, according to local protocols, encouraging the patient to read to the smallest letters they can identify			
		6.7	Ensure occluder is completely covering the non-tested eye			
		6.8	Measure visual acuity for distance with pinhole as indicated, according to local protocols			
7	Be able to accurately record results and patient responses	7.1	Accurately document results in patient's paper or electronic record, including date, name, signature and professional role			
		7.2	Note any patient concerns, difficulties with performing the test, or other relevant information			
		7.3	Report any concerns to a more senior member of the team			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 79: Visual Field Assessment

Level: 3

Unit type: Optional

Credit value: 5

Guided learning hours: 40

Unit summary

The aim of this unit is to ensure that you apply knowledge, understanding and skills to perform a visual field assessment. You will develop your skills with respect to patient-centred compassionate care. You will be expected to build your patient-centred professional practice to enable you to safely undertake this skill in the workplace.

Additional information

AC2.5 includes:

- operator error
- ocular conditions
- patient compliance.

Learning outcome 3 includes the following.

- Communicating effectively with the patient and carers, confirming patient identification, explaining personal role and the nature and purpose of the procedure at a level appropriate to the patient/carer's understanding, and ensuring patient has the opportunity to explain any problems or difficulties.
- Identifying any special needs, e.g. age, sensory impairment, physical disability, learning disability, cognitive dysfunction, and adapting communication style and testing methods to meet these needs.
- Adjusting equipment for the patient's refractive error as required and explain the consequences if this is not done.
- Obtaining verbal consent from patient/carer.
- Maintaining patient confidentiality: auditory, written and electronic.
- Demonstrating effective infection control practices according to local protocols.
- Demonstrating or describing safe manual handling practices.
- Reducing risks for patients with vision impairment, e.g. signage, contrast, lighting.
- Demonstrating, as required, procedures for calibration and maintenance of equipment.
- Ensuring equipment is working correctly.
- Ensuring room lighting is appropriate for test.

AC3.1 includes:

- the accurate recording of corrected visual acuity and current optical prescription.

AC3.2 includes:

- current optical prescription
- patient's age.

AC3.7 includes:

- selecting appropriate test parameters according to the patient's age, cooperation, ability and eye condition
- information in line with national and local policy and protocol, noting patient responses and any difficulties with compliance
- evaluating results and describing how to report any issues of concern to the appropriate person.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the structure and functioning of the visual system relevant to the assessment of visual field	1.1	Explain the extent of the normal uniocular and binocular visual field and the location of the blind spot			
		1.2	Explain retinal light sensitivity across the visual field with the concept of the 'island or 'hill' of vision			
		1.3	Explain the concept of scotoma, including relative and absolute scotoma			
		1.4	Discuss the types of scotoma that can occur with different conditions affecting the visual field			
2	Understand the principles and methods of visual field testing	2.1	Explain the principles of automated perimetry			
		2.2	Explain the term 'isopter' and the relationship between isopter, target size and brightness			
		2.3	Discuss different strategies and programmes used for threshold and screening automated static perimetry and their clinical indications			
		2.4	Describe reliability indices, their methods, purpose and limitations			
		2.5	Explain sources of error and artefact in visual field assessment and how to overcome them, including operator error, ocular conditions, and patient compliance			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to perform visual field assessments	3.1	Ensure all pre-test procedures for visual field assessment are completed			
		3.2	Enter relevant information, including current optical prescription and patient's age prior to commencement of test			
		3.3	Provide clear and concise instructions to the patient			
		3.4	Monitor the patient throughout to obtain required fixation and concentration throughout testing			
		3.5	Ensure appropriate test conditions, including illumination and test distance and occlusion of non-tested eye			
		3.6	Ensure that appropriate optical prescription is used and positioned correctly for test performance			
		3.7	Evaluate patient responses and alter testing strategies as indicated, selecting appropriate test parameters according to the patient's age, co-operation, ability and eye condition			
		3.8	Record and document test results			
		3.9	Evaluate results, reporting any issues of concern to the appropriate person			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 80: Measure Optical Prescriptions and Refractive Error

Level: 3

Unit type: Optional

Credit value: 5

Guided learning hours: 42

Unit summary

In this unit, you will apply knowledge, understanding and skills to perform a visual field assessment. You will also develop your skills with respect to patient-centred compassionate care. You will be expected to build your patient-centred professional practice to enable you to undertake this skill safely in the workplace.

Additional information

AC1.2 includes:

myopia:

- hypermetropia
- astigmatism.

Learning outcome 4 to include spectacles with a range of spherical and cylindrical corrections, and bifocal and varifocal additions.

Learning outcomes 4 and 5 include:

- communicating effectively with the patient and carers, confirming patient identification, explaining personal role and nature and purpose of procedure at a level appropriate to the patient/carer's understanding, and ensuring the patient has the opportunity to explain any problems or difficulties
- identifying any special needs, e.g. age, sensory impairment, physical disability, learning disability, cognitive dysfunction, and adapting communication style and testing methods to meet these needs
- obtaining verbal consent from patient/carer
- maintaining patient confidentiality: auditory, written and electronic
- demonstrating effective infection control practices according to local protocols
- demonstrating or describing safe manual handling practices
- reducing risks for patients with vision impairments, e.g. signage, contrast, lighting
- demonstrating, as required, procedures for calibration and maintenance of equipment
- ensuring equipment is working correctly.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the optical system of the eye, and optical defects (refractive errors)	1.1	Explain the optical system of the eye and how light is focused on the retina			
		1.2	Explain the optical defects of the eye, to include myopia			
		1.3	Explain the effects of myopia, hypermetropia and astigmatism on vision			
		1.4	Explain how the eye focuses for near, and how the eye loses focusing power with age			
2	Understand how optical defects of the eye are corrected and how to interpret optical prescriptions	2.1	Explain how optical defects of the eye are corrected with spectacle and contact lenses			
		2.2	Explain optical prescription notation and how to interpret an optical prescription			
		2.3	Explain single vision, bifocal and progressive power prescriptions			
		2.4	Explain how to transpose an optical prescription			
		2.5	Explain how to calculate spherical equivalence			
3	Understand the principles of focimetry and auto-refraction	3.1	Explain the principles of focimetry and the function of a focimeter			
		3.2	Explain the principles of auto-refraction and the function of an auto-refractor			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to determine the optical prescription of visual aids (focimetry)	4.1	Confirm patient's existing use of optical correction			
		4.2	Measure optical prescription of spectacles, including distance, intermediate and near corrections			
		4.3	Transpose optical prescription			
		4.4	Calculate spherical equivalent as required			
		4.5	Document optical prescription accurately, with correct notation, in patient record			
5	Be able to measure refractive error of the eye with an autorefractor	5.1	Confirm patient's existing use of optical correction			
		5.2	Confirm patient's understanding of procedure and requirements for compliance			
		5.3	Position and align patient correctly			
		5.4	Measure refractive error for distance with an autorefractor			
		5.5	Transpose the optical prescription as needed			
		5.6	Document refraction accurately, with correct notation in patient record			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 81: Introduction to Gastrointestinal Physiology

Level:	**4**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**42**

Unit summary

In this unit, you will gain the knowledge needed to be able to work as a healthcare science associate in gastrointestinal physiology. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

Learners completing any of the gastrointestinal physiology *Units 82–88* must complete this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP) in own area of practice.

AC1.1 includes:

- coeliac and non-coeliac gluten enteropathy
- detection of small intestinal bacterial overgrowth, fructose or lactose malabsorption
- dyspepsia
- dysphagia
- erosive and non-erosive gastro-oesophageal reflux disease
- faecal incontinence
- inflammatory bowel disease
- irritable bowel syndrome
- obstetric trauma
- pelvic floor dyssynergia
- rapid orocaecal transit
- sepsis
- slow transit constipation.

AC1.2 includes medication/non-surgical treatments used in the treatment of:

- fructose or lactose malabsorption (dietary advice, i.e. FODMAP diet)
- small intestinal bacterial overgrowth:
  - antibiotics, including rifaximin
- rapid orocaecal transit:
  - treatment of underlying conditions (thyrotoxicosis, loperamide)
- slow transit constipation:
  - prokinetics
  - diet
  - fluids
  - lifestyle modification
  - bulking agents
  - stool softeners
  - osmotic and stimulant laxatives
  - prucalopride
  - linaclotide
  - probiotics
- coeliac and non-coeliac gluten enteropathy
- gastro-oesophageal reflux disease:
  - antacids
  - H2 receptor antagonists
  - proton pump inhibitors
  - prokinetics
- dysphagia; specific motility disorders – Botox and dilatation
- faecal incontinence:
  - loperamide
  - codeine phosphate
- pelvic floor dyssynergia:
  - diet and lifestyle modification
  - Botox
  - rectal self-irrigation

upper GI:

- H2 receptor antagonists, e.g.:
  - ranitidine
  - cimetidine
- antacids
- proton pump inhibitors, e.g.:
  - Omeprazole
  - Lansoprazole
  - Pantoprazole

- motility disorders:
    - amitriptyline
    - prokinetcs
    - Botox
- small bowel overgrowth:
    - antibiotics, including Rifaximin
- H.pylori eradication
- triple therapy regimen, e.g.:
    - proton pump inhibitor plus clarithromycin and amoxicillin or metronidazole

lower GI:

- constipation:
    - prokinetics
    - prucalopride
    - linaclotide
    - domperidone
- laxatives:
    - bulk forming
    - dietary fibre
    - lubricatin
    - stimulant
    - osmolitic
    - stool softeners
- antidiarrhoeals:
    - loperamide
    - codeine phosphate.

AC1.3 includes medication and surgical treatment used in the treatment of:

- fructose or lactose malabsorption (dietary advice, i.e. FODMAP diet)
- slow transit constipation:
    - pelvic floor retraining/biofeedback
    - sacral nerve stimulation
    - antegrade continence enema (ACE) procedure
    - stoma
- gastro-oesophageal reflux disease:
    - lifestyle measures:
        - weight loss
        - cessation of smoking
        - moderation of alcohol, caffeine and spicy foods
    - antireflux surgery
- dysphagia:
    - balloon dilatation
    - cricopharyngeal and Heller's myotomy
    - Botox

- faecal incontinence:
    - pelvic floor retraining/biofeedback
    - percutaneous tibial nerve stimulation (PTNS)
    - sacral nerve stimulation (SNS)
    - fenix – continence restoration system
    - injectable sphincter bulking agents
- proctalgia (anal pain):
    - sphincterotomy
    - fissurectomy

upper GI:

- reflux disease:
    - lifestyle measures
    - weight loss
    - moderation of:
        - fatty foods
        - alcohol
        - spicy food
        - caffeine
        - exercise
    - smoking cessation
    - raising the bed head
    - smaller meals
    - antireflux surgery
    - oesophageal dilation.

lower GI:

- low FODMAP diet
- biofeedback/pelvic floor retraining
- moderation of dietary fibre
- percutaneous tibial nerve stimulation (neuromodulation).

AC2.4 includes:

- patient first
- respect
- privacy
- dignity
- rights to have or not to have a chaperone present
- risks
- documentation of patient's request
- children and transitional adult consent for chaperone
- confidentiality
- safe lone worker practice.

AC4.1 includes:

- audit aim
- objectives and standards
- developing standards using SMART (Specific, Measurable, Achievable, Realistic, Timely)
- target setting
- patient, public and staff involvement
- sample size
- literature review
- audit cycle
- dissemination of results
- identify and promote good practice
- improve patient care
- provide evidence about the effectiveness of a service
- highlight problems and help with solutions
- improve team working and communication
- aims and objectives
- setting standards
- audit cycle.

AC4.2 includes:

- Improving Quality In Physiological Services (IQIPS) programme
- Infection Control Accreditation Programme (ICAP).

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the common disorders of the gastrointestinal tract and the underlying physiology	1.1	Know the common disorders of the gastrointestinal tract			
		1.2	Know the common medications prescribed for common disorders of the gastrointestinal tract			
		1.3	Explain the non-pharmacological measures that are recommended for common disorders of the gastrointestinal tract			
		1.4	Explain the underpinning physiology for **one** disorder of the gastrointestinal tract			
		1.5	Discuss the potential impact of **one** disorder of the gastrointestinal tract on the patient and their family			
2	Understand the range of procedures available to investigate common disorders of the gastrointestinal tract	2.1	Explain the purpose of investigations undertaken in people with disorders of the gastrointestinal tract			
		2.2	Know a range of common disorders of the gastrointestinal tract and the procedures used to investigate them			
		2.3	Explain what is meant by the term intimate examination in the context of gastrointestinal physiology			
		2.4	Evaluate the role and requirements of the chaperone in the context of gastrointestinal physiology			
		2.5	Explain the Datix system and how to access and report an incident			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to work within policy guidelines to support a patient during intimate examination	3.1	Explain the policy guidelines for supporting a patient during intimate examination			
		3.2	Demonstrate the ability to support a patient during intimate examination			
		3.3	Demonstrate the ability to record accounts of presence of chaperone			
4	Be able to assist senior staff to undertake departmental audits and accreditation programmes	4.1	Demonstrate the ability to assist in the departmental audit programme			
		4.2	Demonstrate the ability to assist in departmental accreditation programmes			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 82: Performing a Breath Test for Carbohydrate Malabsorption

Level: 4

Unit type: Optional

Credit value: 8

Guided learning hours: 64

Unit summary

In this unit, you will gain the understanding and skills needed to prepare for and perform safe and quality-assured hydrogen and methane tests for carbohydrate malabsorption (including lactose, fructose, and sorbitol malabsorption) in adults, transitional adults and children, if appropriate to the service, generating test results and performing quality-control checks. In addition, you will be able to undertake routine maintenance, calibration and quality-assurance procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to your scope of practice.

Additional information

Learners completing this unit must also complete *Unit 81: Introduction to Gastrointestinal Physiology*.

AC1.1 includes:

- principles of the breakdown of carbohydrates in the bowel
- risk factors for, and causes of carbohydrate malabsorption
- effect of carbohydrate malabsorption on the gastrointestinal system and the patient
- symptoms experienced by patients (including their potential impact on quality of life) that may lead to referral for the test:
    - abdominal bloating and pain
    - cramps
    - flatulence
    - diarrhoea
    - weight loss
    - malnutrition.

AC1.3 includes:

- when hydrogen and methane breath tests will not be accurate in patients taking some medications, e.g. following a course of antibiotics, within four weeks following a colonoscopy, i.e. due to bowel preparation
- antibiotics
- not adhering to pre-test dietary fibre restrictions
- following colonoscopy (due to bowel preparation)
- smoking.

AC2.1 includes:

- the pre-test preparations a patient should make
- what to do in the event that the pre-test preparation has not been followed
- prepare the equipment and environment for the test
- adhere to the appropriate standards of professional practice as defined in Good Scientific Practice
- the requirements for the investigation and the environment
- checking, calibrating and preparing the equipment
- the principles of measurement for the range of equipment used
- identifying common faults and take remedial action
- the potential special needs of patients referred for investigation and the relevant action required.

AC2.2 includes:

- consent process for adults and children
- limits of consent
- greeting the patient and checking patient identification
- communicating with patients in a way that respects their dignity, rights, privacy and confidentiality
- introducing self and own role
- reviewing the request form
- explaining the investigation to the patient in appropriate language, addressing any investigation-related questions
- providing information on how the patient will be informed of the results
- evaluating the risks and benefits of undertaking the investigation
- gaining informed consent
- documenting informed consent
- explaining the principles, guidance and law for gaining informed consent, including the limits of consent
- obtaining and reviewing relevant patient information
- explaining potential special requirements of patients referred for investigations
- identifying and acting on any special patient requirements and, if necessary, discussing with senior staff and carers.

AC2.3 includes:

- the potential risks of using defective equipment and measures to resolve problems
- the factors influencing the choice of equipment for the investigation
- selecting the correct equipment and consumables.

AC2.4 includes:

- treating the patient with respect and compassion
- introducing self and own role
- gaining informed consent
- complying with the procedures defined in the Standard Operating Procedure, including:
    - calibration
    - infection control
    - performing hydrogen and methane breath tests in a range of patient age conditions, and comorbidities
    - explaining how the test results will be communicated to the patient, their carer and their consultant
    - demonstrating good infection control techniques appropriate for the investigation

the range of patients could include those with:

- lactose intolerance
- fructose intolerance
- small bowel overgrowth

also in a range of ages and comorbidities, including:

- adults
- transitional adults and, if appropriate to the service, children.

AC2.5 includes:

- uploading breath test results onto the patient data system (e.g. InfoFlex) for checking and sign off by supervisor
- understanding the need for accuracy, information governance and safe management of patient data to maintain confidentiality
- following checks, sending to appropriate referrer
- booking follow-up appointments.

AC2.6 includes:

- recording the results accurately in an appropriate format
- discussing the relevance of investigations to referral request and differential diagnosis
- documenting any technical comments that may influence the test outcome
- seeking advice as required.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the processes of carbohydrate metabolism and the use of hydrogen and methane breath tests	1.1	Explain the process of carbohydrate metabolism and the effect of carbohydrate malabsorption on the gastrointestinal system and the patient			
		1.2	Explain the use of hydrogen and methane breath tests and how the results produced contribute to the management of patients with carbohydrate malabsorption			
		1.3	Explain the indications and contraindications for a hydrogen and methane breath test			
		1.4	Describe the other investigations that support the diagnosis and treatment of carbohydrate malabsorption			
		1.5	Evaluate and explain the Standard Operating Procedure (SOP) for the hydrogen and methane breath test			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform hydrogen and methane breath tests in accordance with the Standard Operating Procedure (SOP)	2.1	Prepare the environment and equipment for hydrogen and methane breath tests			
		2.2	Communicate effectively with the patient, explaining the test and gaining informed consent			
		2.3	Select suitable equipment for the investigation in accordance with the requirements of the test			
		2.4	Perform hydrogen and methane breath tests for carbohydrate malabsorption in a range of patients			
		2.5	Demonstrate the ability to upload breath test results onto the patient data system			
		2.6	Produce the technical results for a range of patients and conditions			
3	Be able to clean equipment, and leave the room in a suitable condition for reuse	3.1	Demonstrate the ability to decontaminate all non-single use only equipment, dispose of any single-use items appropriately, restock consumables and leave room in a suitable condition			
4	Be able to perform quality-control checks referring to senior staff as required	4.1	Evaluate the requirements that underpin the provision of quality-assured investigations			
		4.2	Perform routine calibration checks			
		4.3	Perform routine maintenance, including replacing filters and complete the required records			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 83: Performing Percutaneous Tibial Nerve Stimulation (PTNS) in Patients with Faecal and Urinary Incontinence Over Active Bladder (OAB)

Level: 4

Unit type: Optional

Credit value: 12

Guided learning hours: 96

Unit summary

In this unit, you will gain the understanding and skills needed to prepare for and perform safe and quality-assured percutaneous tibial nerve stimulation (PTNS) in adults, transitional adults and, where appropriate, children with faecal/urinary incontinence or over active bladder (OAB), generating test results and performing quality-control checks. In addition, you will be able to undertake routine maintenance and quality-assurance procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to your scope of practice.

Additional information

Learners completing this unit must also complete *Unit 81: Introduction to Gastrointestinal Physiology*.

AC1.1 includes:

- action of sphincters
- peristalsis
- segmenting and mixing waves
- voluntary and involuntary movement and striated muscle within the GI and urinary tract
- detrusor activity
- storage and voiding
- bladder stretch reflex
- the autonomic and somatic nervous arms of the nervous system.

AC1.3 includes:

- faecal and urinary urgency
- functional diarrhoea
- detrusor sphincter and pelvic floor dyssynergia
- voiding postponement
- stress and giggle incontinence
- dysfunctional voiding in children.

AC1.4 common pharmacological treatments for faecal incontinence and OAB could include:

- faecal incontinence:
    - ioperamide
    - codeine phosphate
- over active bladder (OAB):
    - antimuscarinics:
        - oxybutinin
        - tolteradine
        - solifenacin
        - trospium
        - beta-3 adrenergic
- receptor agonists, e.g. mirabegron, Botox
- other non-pharmacological treatments for faecal incontinence and over active bladder:
    - lifestyle modification
    - weight loss
    - caffeine restriction
    - biofeedback.

AC1.5 includes:

- faecal incontinence:
    - pelvic floor retraining and biofeedback
    - lifestyle changes
    - rectal irrigation
    - percutaneous tibial nerve stimulation (PTNS)
    - sacral nerve stimulation (SNS)
    - sphincter repair
    - stoma
- urinary incontinence:
    - pelvic floor retraining and biofeedback
    - lifestyle changes
    - self-catheterisation
- causes of faecal incontinence and OAB in adults, transitional adults and children
- the non-surgical management of patients with bowel and bladder dysfunction
- how neuromodulation is used to manage faecal incontinence and OAB.

AC1.6 – the potential impact of faecal and urinary incontinence on patients includes:

- shame
- embarrassment
- isolation
- social and sexual dysfunction
- skin infections and reactions.

AC2.1 includes the:

- Standard Operating Procedure for PTNS
- preparations a patient should make, the exclusion criteria and what to do in the event that these have not been followed
- preparation of the area and ensuring equipment and sharps bin are in close proximity.

AC2.2 includes:

- explaining the consent procedures for adults and minors
- greeting the patient and, if appropriate the responsible adult with the child, and check patient identification
- using effective communicate skills and working with children and their parents/carers/responsible adult in a way that respects their dignity, rights, privacy and confidentiality
- communicating with patients in a way that respects their dignity, rights, privacy and confidentiality
- introducing self and own role
- reviewing the request form
- explaining the investigation to the patient in appropriate language, addressing any investigation-related questions
- evaluating the risks and benefits of undertaking the investigation
- gaining informed consent
- documenting informed consent
- explaining the principles, guidance and law for gaining informed consent, including the limits of consent
- providing information on how the patient will be informed of the results
- explaining potential special requirements of patients referred for investigations
- identifying and acting on any special patient requirements and, if necessary, discussing with senior staff and carers
- referring to colleagues appropriately.

AC3.2 includes:

- disposing of any consumables safely and appropriately
- cleaning and disinfecting equipment appropriately.

AC2.3 includes:

- identifying the potential risks of using defective equipment and measures to resolve problems
- describing the factors influencing the choice of equipment for the investigation
- selecting the correct equipment.

AC2.4 includes:

- treating the patient with respect and compassion
- completing standardised audit forms or clinical questionnaires to help demonstrate the baseline incontinence frequency and any associated symptoms
- complying with the procedures and infection control methods that are defined in the Standard Operating Procedures
- complying with the Standard Operating Procedures to safely perform this treatment
- describing the set-up procedure of this equipment
- explaining how the needle will be inserted
- describing the sensations the patient may experience to confirm correct positioning of the needle and stimulation of the tibial nerve
- completing audit forms or clinical questionnaires to assess baseline symptoms
- undertaking 30 minutes of stimulation to complete the sessional treatment
- removing the needle and disposing of it immediately and safely
- removing the lead set and disposing of it according to infection control guidance and appropriate waste management
- documenting stimulation levels, if the right or left foot is used, sensations felt, any untoward events and any improvement in symptoms at each visit
- performing baseline and 12-week post-treatment PTNS
- repeating the standardised audit forms or clinical questionnaires to help demonstrate improvement in baseline symptoms and any associated symptom improvement

a range of patients could include:

- gender
- adult, transitional adult (age <18 years) or child
- a range of conditions, i.e. faecal incontinence, faecal urgency, urinary incontinence, over active bladder
- a range of comorbidities.

AC2.6 includes:

- indications and the contraindications for PTNS
- evidence base to determine the risks of undergoing this treatment
- stimulator functions and the settings used
- using the stimulator safely in conjunction with other equipment in the vicinity.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the anatomy, physiology and pathology in relation to percutaneous tibial nerve stimulation (PTNS), faecal incontinence, faecal urgency, over active bladder (OAB) and urinary incontinence	1.1	Explain the structure and function of the GI and urinary tract			
		1.2	Discuss the neurophysiology of the GI tract in relation to PTNS and faecal incontinence and OAB			
		1.3	Describe the pathology of some functional intestinal and bladder disorders			
		1.4	Discuss common pharmacological and other non-pharmacological treatments for faecal incontinence and OAB			
		1.5	Discuss the causes of faecal incontinence and OAB and the non-interventional treatment options available			
		1.6	Discuss the potential impact of faecal and urinary incontinence on patients			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform percutaneous tibial nerve stimulation (PTNS) in accordance with the Standard Operating Procedure (SOP)	2.1	Prepare the environment and equipment for PTNS			
		2.2	Communicate effectively with the patient, explaining the test and gaining informed consent			
		2.3	Select suitable equipment for the investigation in accordance with the requirements of the test			
		2.4	Perform baseline PTNS and, where appropriate, 12-week post-treatment PTNS in a range of patients			
		2.5	Assist in the generation of a report to the referring consultant with the outcome of the treatment, and archive safely			
		2.6	Discuss the precautions to be adhered to, to safely perform PTNS			
3	Be able to clean equipment, and leave the room in a suitable condition for reuse	3.1	Demonstrate the ability to decontaminate all non-single use only equipment, dispose of any single-use items appropriately, restock consumables and leave room in a suitable condition			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 84: 24 Hour Upper Gastrointestinal Physiology Studies: Post-Recording Management Studies

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will develop the understanding and skills needed to manage patients returning from 24-hour studies, including oesophageal manometry and pH monitoring, and perform extubation. In addition, you will be able to undertake routine maintenance, calibration and quality-assurance procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to your scope of practice.

Additional information

Learners completing this unit must also complete *Unit 81: Introduction to Gastrointestinal Physiology.*

AC1.1 includes:

- the structure the nose, throat, oesophagus and stomach
- the function of the nose, throat, oesophagus and stomach
- the pathology of the common conditions affecting the upper GI tract.

AC1.3 includes:

- the indications and contraindications for:
    - 24-hour oesophageal manometry
    - 24-hour oesophageal pH monitoring
    - 24-hour combined oesophageal pH and impedance
- the risks, benefits and side effects of undergoing these tests and of extubating the patient following their test
- the medications that should be stopped before the test and the time period they should be stopped for.

AC2.2 includes:

- explaining the requirements for the optimum investigation environment
- checking, calibrating and preparing the equipment according to Standard Operating Procedures (SOPs) and manufacturers' guidance.

AC2.3 includes:

- checking patient identification
- introducing self and own role
- communicating with patients in a way that respects privacy and confidentiality
- obtaining and reviewing relevant patient information, including the diary, and editing any data in the software
- providing information on how the patient will be informed of the results
- explaining and performing extubation
- undertaking post-test calibration checks as required
- disposing of single-use equipment appropriately
- understanding the data upload techniques in a range of equipment
- explaining the principles of measurement for the range of equipment used
- identifying common faults and taking remedial action
- explaining the impact of incorrect positioning or non-cooperation on the patient, the investigation and the results.

AC2.4 – safely extubate patients following the completion of gastrointestinal physiology procedures including:

- an understanding of intubation and extubation procedures
- safe disposal of single-use items
- good infection control methods
- when to check calibration post recording.

AC3.1 includes:

- referring to and using local SOPs and manufacturers' guidance on safe decontamination of ambulatory equipment
- explaining how to safely dispose of single-use items
- maintaining a safe and clean patient environment.

AC3.2 includes:

- disposing of any consumables safely and appropriately
- cleaning and disinfecting equipment appropriately.

AC4.1 includes:

- manometry
- standard pH
- combined pH and impedance
- telemetric pH.

AC4.2 and 4.3 include:

- governance and ethical requirements for audit
- the role of internal audit
- the audit cycle
- planning an audit
- performing an audit:
    - designing the data collection form
    - collecting the data
    - data verification
    - data analysis
    - data interpretation
    - writing an audit report
    - presenting the audit outcome
    - agreeing audit actions
    - re-auditing.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the practice and principles underpinning upper gastrointestinal tract (GI) investigations	1.1	Explain the anatomy, physiology and pathology of the upper gastrointestinal tract			
		1.2	Describe the range of equipment used to record ambulatory signals from the GI tract			
		1.3	Explain the reasons for undertaking oesphogeal manometry, 24-hour pH and impedance monitoring			
2	Be able to perform gastrointestinal physiology post-measurement procedures	2.1	Select suitable equipment for the investigation in accordance with the requirements of the test			
		2.2	Prepare the environment for removal of implantable devices, e.g. pH or impedance catheters			
		2.3	Demonstrate the ability to upload post-measurement data			
		2.4	Demonstrate the ability to safely extubate patients following the completion of gastrointestinal physiology procedures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to clean equipment, and leave the room in a suitable condition for reuse	3.1	Demonstrate the ability to decontaminate all non-single use only equipment, dispose of any single-use items appropriately, restock consumables and leave room in a suitable condition			
4	Be able to perform routine calibration and quality-assurance procedures	4.1	Demonstrate the ability to calibrate a range of ambulatory equipment			
		4.2	Perform a patient safety audit			
		4.3	Perform a quality audit			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 85: Assist in Post Sacral Nerve Stimulation Implantation Follow-up Clinics

Level:	**5**
Unit type:	**Optional**
Credit value:	**6**
Guided learning hours:	**52**

Unit summary

In this unit, you will develop the understanding and skills needed to assist senior colleagues in follow-up clinics that patients attend following sacral nerve stimulator implantation.

Additional information

Learners completing this unit must also complete *Unit 81: Introduction to Gastrointestinal Physiology.*

AC1.1 includes:

- the indications and the contraindications for sacral nerve stimulation
- the evidence base to determine the risks of undergoing this treatment
- the stimulator functions and the settings used
- how to use this equipment safely in conjunction with other equipment in the vicinity.

AC1.2 includes:

- the Standard Operating Procedure for sacral nerve stimulation implantation follow-up clinics.

AC1.3 includes:

- checking that the patient has completed a validated pre-SNS assessment questionnaire
- confirming that the temporary paper identification card has been completed with relevant patient details, and confirming that they will receive a permanent identification card
- checking that patients have been advised against any exercise for the next four weeks (swimming six to eight weeks)
- checking that patients are aware of how to switch off the implant, for example in airport security, during medical and dental procedures
- checking that patients have been informed that MRI is not allowed with the implant.

AC2.2 includes:

- putting batteries into patient handset
- syncing up the programmer, patient handset and implant
- bonding the patient handset with the implant using the following details:
  - Lead Model
  - lead location – use operation notes to choose correct side and site of lead (i.e. left/right, S2/S3 etc.)
- entering the patient's details when prompted.

AC2.4 includes the ability to:

- use appropriate hand-washing and infection control methods
- explain the preparations a patient should make, the exclusion criteria and what to do in the event that these have not been followed
- deal with patients in an appropriate manner and maintain dignity and privacy at all times
- ensure programming equipment is available
- ensure batteries are replaced if necessary to ensure the session can be completed appropriately
- collect patient from waiting area and introduce yourself in accordance with patient safety zone policy
- check two forms of identity of the patient
- understand that each session will be individual to the patient depending on their requirements
- accurately document any concerns in patient notes
- assist in positioning the telemetry head and instruct the patient in how to hold it over their implant
- assist with connecting the programming equipment to the implant and then to the patient handset as prompted
- help ensure that the patient implant is switched on (and switch on if implant has been inadvertently switched off)
- assist in battery and lead impedance check at each appointment
- assist and document when patients with implants that are nearing end of service will require referring to a consultant to be listed for a replacement
- help to support the patient if they report untoward symptoms during the reprogramming control or inappropriate sensation (i.e. vagina, foot, leg etc.)
- document response and amplitude of each electrode combination on reprogramming log
- document any adjustments to other parameters such as pulse width, rate etc. where appropriate
- when it is not possible to obtain an appropriate setting, assist with lead/device location and check or manage the administration of referral to a consultant
- assist in instructing patients in how to use an icon handset if required
- agree and help with the administration of appropriate follow-up appointments.

AC2.5 includes:

- assisting with the documentation of any parameter change
- helping to show patients how to use their personal programmer and giving patients information leaflets describing how to use the handset
- giving patients the Medtronic helpline telephone number for any implant-related questions
- helping arrange appropriate follow-up period for patient (usually three months for first follow up).

AC3.2 includes:

- disposing of any consumables safely and appropriately
- cleaning and disinfecting equipment appropriately.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the underpinning principles of sacral nerve stimulation	1.1	Explain how direct neuromodulation of the bowel and bladder is used to control incontinence			
		1.2	Explain how and where the sacral nerve stimulation electrodes are implanted and configured to achieve optimum symptom management			
		1.3	Describe how impedance and battery checks are undertaken			
		1.4	Explain the programmes employed to achieve optimum stimulation			
2	Be able to assist in the management of patients with a permanent implant	2.1	Prepare the area and ensure equipment is in close proximity			
		2.2	Confirm the patient's understanding why they have a sacral nerve stimulator implant, how it works and how to reprogramme			
		2.3	Demonstrate the ability to set up the sacral nerve stimulator			
		2.4	Assist with the follow-up procedures			
		2.5	Assist with documentation and patient support and advice			
3	Be able to clean equipment, and leave the room in a suitable condition for reuse	3.1	Demonstrate the ability to decontaminate all non-single use only equipment, dispose of any single-use items appropriately, restock consumables and leave room in a suitable condition			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 86: Preparing Equipment for Ambulatory 24 Hour Monitoring, including pH and Combined pH/Impedance Studies

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 52

Unit summary

In this unit, you will develop the understanding and skills needed to prepare equipment for ambulatory pH and impedance tests. In addition, you will be able to undertake routine maintenance and calibration procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to your scope of practice.

Additional information

Learners completing this unit must also complete *Unit 81: Introduction to Gastrointestinal Physiology*.

AC1.1 includes:

- standard pH
- combined pH/impedance
- telemetric pH bile reflux monitoring.

AC1.2 includes:

- the impact of incorrect calibration on the patient, the investigation and the results
- identification of common faults and remedial action required
- safety testing
- routine maintenance in accordance with the manufacturer's recommendations.

AC1.4 includes:

- typical gastro-oesophageal symptoms:
  - heartburn
  - regurgitation
  - chest discomfort
  - cough
- atypical:
  - hoarseness
  - tooth wear
  - dysphonia
  - aerophagia.

AC2.1 includes the:

- potential risks of using defective equipment and measures to resolve problems
- factors influencing the choice of equipment for the investigation.

AC2.2 includes:

- the requirements for the investigation environment
- ensuring that all consumables are available
- the principles of measurement for the range of equipment used
- identifying common faults and taking remedial action
- explaining the measurements that are required pre-investigation
- explaining the impact of incorrect calibration on the patient, the investigation and the results.

AC2.3 includes:

- the Standard Operating Procedure for the equipment used
- checking that equipment complies with all current safety standards, e.g. biomedical engineering/clinical engineering (BME) commissioning number
- checking that equipment is safety-tested and regularly maintained in accordance with the manufacturer's recommendations
- withdrawing externally-damaged recorders from patient use and completing required documentation
- selecting the correct catheter
- using appropriate infection control and hand-washing methods
- checking use-by dates and the pH of the buffer solutions
- using single-use catheters according to the manufacturer's guidance.

AC3.2 includes:

- disposing of catheters appropriately
- cleaning and disinfecting equipment appropriately.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the underpinning principles of ambulatory 24-hour pH monitoring and impedance studies	1.1	Explain the principles of measurement for the range of equipment used			
		1.2	Explain the purpose of equipment calibration			
		1.3	Explain the factors influencing the choice of equipment for each investigation			
		1.4	Know the indications and contraindications for each investigation			
2	Be able to prepare equipment and environment for ambulatory 24-hour pH monitoring and impedance studies	2.1	Demonstrate the ability to select suitable equipment for the investigation in accordance with the requirements of the test			
		2.2	Prepare the environment and equipment for investigations			
		2.3	Perform the calibration of equipment at the beginning of every test according to the manufacturer's instructions			
3	Be able to clean equipment, and leave the room in a suitable condition for reuse	3.1	Demonstrate the ability to decontaminate all non-single use only equipment, dispose of any single-use items appropriately, restock consumables and leave room in a suitable condition			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 87: Preparing Lower GI Equipment: High Resolution Anorectal Manometry

Level:	**4**
Unit type:	**Optional**
Credit value:	**6**
Guided learning hours:	**46**

Unit summary

In this unit, you will develop the understanding and skills needed to prepare equipment to investigate the lower gastrointestinal tract using high resolution anorectal manometry. You will also be able to undertake routine maintenance and calibration procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to your scope of practice.

Additional information

Learners completing this unit must also complete *Unit 81: Introduction to Gastrointestinal Physiology.*

AC1.2 includes:

- the impact of incorrect calibration on the patient, the investigation and the results
- identification of common faults and remedial action required
- safety testing
- routine maintenance in accordance with the manufacturer's recommendations.

AC1.4 includes:

- pelvic floor dysfunction
- faecal incontinence
- obstructive defaecation
- anal pain
- surgical or obstetric trauma.

AC2.1 includes the:

- potential risks of using defective equipment and measures to resolve problems
- factors influencing the choice of equipment for the investigation.

AC2.2 includes:

- the requirements for the investigation environment
- ensuring that all consumables are available
- the principles of measurement for the range of equipment used
- identifying common faults and taking remedial action
- explaining the measurements that are required pre-investigation
- explaining the impact of incorrect calibration on the patient, the investigation and the results
- cleaning and disinfecting faulty catheters and documenting a manufacturer's fault report.

AC2.3 includes:

- the Standard Operating Procedure for the equipment used
- checking that equipment complies with all current safety standards, e.g. BME commissioning number
- checking that equipment is safety-tested and regularly maintained in accordance with the manufacturer's recommendations
- withdrawing externally damaged recorders from patient use and completing required documented
- selecting the correct catheter
- using appropriate infection control and hand-washing methods
- checking use-by dates and the pH of the buffer solutions
- using single-use catheters according to the manufacturer's guidance.

AC3.2 includes:

- disposing of catheters appropriately
- cleaning and disinfecting equipment appropriately.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the underpinning principles of high resolution anorectal manometry	1.1	Explain the principles of measurement for the range of equipment used			
		1.2	Explain the purpose of equipment calibration and maintenance			
		1.3	Explain the factors influencing the choice of equipment for the investigation			
		1.4	Know the indications and contraindications for the investigation			
2	Be able to prepare equipment and environment for high resolution anorectal manometry	2.1	Demonstrate the ability to select suitable equipment for the investigation in accordance with the requirements of the test			
		2.2	Prepare the environment and equipment for investigations			
		2.3	Perform the calibration of equipment at the beginning of every test according to the manufacturer's instructions			
3	Be able to clean equipment, and leave the room in a suitable condition for reuse	3.1	Demonstrate the ability to decontaminate all non-single use only equipment, dispose of any single-use items appropriately, restock consumables and leave room in a suitable condition			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 88: Preparing Lower GI Equipment: Endoanal Ultrasound

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 46

Unit summary

In this unit, you will develop the understanding and skills needed to prepare equipment to investigate the lower gastrointestinal tract using endoanal ultrasound. You will also be able to undertake routine maintenance and calibration procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to your scope of practice.

Additional information

Learners completing this unit must also *complete Unit 81: Introduction to Gastrointestinal Physiology.*

AC1.2 includes:

- the impact of incorrect calibration on the patient, the investigation and the results
- identification of common faults and remedial action required
- safety testing
- routine maintenance in accordance with the manufacturer's recommendations.

AC1.4 includes:

- faecal incontinence
- sepsis
- tumour identification
- sphincter dysfunction.

AC2.1 includes the:

- potential risks of using defective equipment and measures to resolve problems
- factors influencing the choice of equipment for the investigation.

AC2.2 includes:

- the requirements for the investigation environment
- ensuring that all consumables are available
- the principles of measurement for the range of equipment used
- identifying common faults and taking remedial action
- explaining the measurements that are required pre-investigation
- explaining the impact of incorrect calibration on the patient, the investigation and the results
- cleaning and disinfecting faulty catheters and documenting a manufacturer's fault report.

AC2.3 includes:

- the standard operating procedure for the equipment used
- ensuring that all consumables are available
- lubricating gel
- sheaths
- checking the patient notes for latex allergy
- checking that equipment complies with all current safety standards, e.g. BME commissioning number
- checking that equipment is safety-tested and regularly maintained in accordance with the manufacturer's recommendations
- withdrawing externally-damaged transducers from patient use and completing required documentation
- using appropriate infection control and hand-washing methods
- disinfecting equipment before (and after) use according to equipment manufacturers' instructions
- applying the appropriate sheath for the purpose.

AC3.2 includes:

- disposing of any consumables safely and appropriately
- cleaning and disinfecting equipment appropriately.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the underpinning principles of endoanal ultrasound	1.1	Explain the principles of measurement for the range of equipment used			
		1.2	Explain the purpose of equipment calibration and maintenance			
		1.3	Explain the factors influencing the choice of equipment for the investigation			
		1.4	Know the indications and contraindications for the investigation			
2	Be able to prepare equipment and environment for endoanal ultrasound	2.1	Demonstrate the ability to select suitable equipment for the investigation in accordance with the requirements of the test			
		2.2	Prepare the environment and equipment for investigations			
		2.3	Perform the calibration of equipment at the beginning of every test according to the manufacturer's instructions			
3	Be able to clean equipment, and leave the room in a suitable condition for reuse	3.1	Demonstrate the ability to decontaminate all non-single use only equipment, and leave equipment and environment in a suitable condition for reuse, including restocking consumables			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 89: The Urinary System

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 48

Unit summary

In this unit, you will gain an understanding of the anatomy and physiology of the urinary system and build on your learning from the Level 2 Diploma in Healthcare Science.

Additional information

It is suggested that learners will have completed the following units:

- **Level 2 –*Unit 26: Anatomy and Physiology: Urogenital System***
- **Level 2 – *Unit 93: Performing a Urine Flow Test***
- **Level 4 – *Unit 11: Scientific Basis of Healthcare Science: Clinical Science***

or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.1 includes:

- kidneys
- ureters
- urinary bladder
- urethra
- sphincters
- prostate
- pelvic floor.

AC2.1 includes:

- regulating blood ionic composition
- regulating blood pH
- regulating blood volume
- regulating blood pressure
- maintaining blood osmolarity
- producing hormones
- regulating blood glucose level
- excreting waste products.

AC4.1 includes:

- volume
- colour
- turbidity
- odour
- pH
- specific gravity.

AC5.1 – terms include:

- dysuria (painful urination)
- enuresis (repeated inability to control urination)
- frequency
- haematuria (blood in the urine)
- nocturia (the need to wake and pass urine at night)
- nocturnal enuresis (repeated inability to control urination while sleeping)
- polyuria (frequent urination)
- urinary incontinence (the unintentional passing of urine)
- urinary retention
- urgency.

AC5.2 – signs and symptoms include:

- abdominal, pelvic, or lower back pain or discomfort
- changes in the urine
- dysuria
- fever and chills
- haematuria
- hesitancy
- intermittency
- leaking of urine
- nocturia
- polyuria
- poor flow
- post-micturition dribbling
- terminal dribbling
- urgent need to urinate.

AC5.3 should include **two** disorders, which could include:

- bladder outlet obstruction
- detrusor failure
- detrusor overactivity
- detrusor sphincter dyssynergia
- detrusor underactivity
- Fowler's syndrome
- painful bladder syndrome
- polycystic kidney disease
- prostate cancer
- renal failure
- stress urinary incontinence
- urethral stricture
- urge urinary incontinence
- urinary bladder cancer
- urinary tract infection (UTI).

AC5.5 should include **two** routine blood tests.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the urinary system	1.1	Explain the structures that comprise the urinary system			
		1.2	Explain the function of the urinary system			
		1.3	Explain the effect of ageing on the urinary system			
2	Understand the anatomy, histology and physiology of the kidneys	2.1	Describe the structure and function of the kidneys and nephron			
		2.2	Explain the blood and nerve supply to the kidneys			
		2.3	Explain the process of glomerular filtration			
		2.4	Explain the term osmolarity			
3	Understand the anatomy and physiology of the ureters, urinary bladder, urethra and pelvic floor	3.1	Describe the structure of the ureters, urethra and urinary bladder			
		3.2	Compare the urinary systems in males and females			
		3.3	Explain the structure and function of the pelvic floor			
4	Understand the formation and characteristics of urine	4.1	Explain the formation of urine and the characteristics of normal urine			
		4.2	Explain the micturition reflex			
		4.3	Describe the effects of ageing on the formation and characteristics of urine			
		4.4	Explain the potential impact of urinary incontinence on quality of life			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Understand routine tests undertaken to investigate disorders of the urinary system	5.1	Explain common terms related to urinary disorders			
		5.2	Explain the common symptoms of urinary disorders			
		5.3	Discuss how urological disorders affect the urinary system			
		5.4	Explain the indications of urinalysis for patients with urinary symptoms/disorders			
		5.5	Explain the indications for routine blood tests that provide information about kidney function, including the reference ranges			
		5.6	Explain the role of uroflowmetry and urodynamics in investigating disorders of the urinary system			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 90: Performing Urine Dip Stick Analysis

Level:	**4**
Unit type:	**Optional**
Credit value:	**7**
Guided learning hours:	**54**

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to perform urine dip stick analysis. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

It is suggested that learners will have completed the following units:

- **Level 2 – *Unit 26: Anatomy and Physiology: Urogenital System***
- **Level 2 – *Unit 93: Performing a Urine Flow Test***
- **Level 4 – *Unit 11: Scientific Basis of Healthcare Science: Clinical Science***
- **Level 4 – *Unit 90: The Urinary System***

or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC2.1 includes:

- introducing self by name and explaining role
- appropriate use of non-verbal communication
- providing information in a timely manner in appropriate language
- listening to the patient and addressing questions or seeking advice from senior colleagues
- communication during and after the test
- communicating in a way that:
    - respects the dignity, rights, privacy and confidentiality of the patient/carer
    - considers and addresses potential cultural differences (undressing etc.), determines when it may be necessary to invite a family member to be present.

AC2.3 includes:

- following the correct procedures in relation to health and safety:
    - wearing appropriate personal protective equipment (PPE) before performing the urine test
- collecting the correct equipment for urine testing
- checking the reagent strips are in date
- correctly identifying the person requiring urine testing
- advising the patient which type of sample is required and how to obtain a sample without contamination
- washing hands before performing the urine test
- obtaining a fresh urine sample in an appropriate container.

AC2.4 includes:

- using the correct technique to accurately test the person's urine sample, following manufacturers' instructions and national guidance, including:
    - fully dips the reagent strip in the urine
    - removes strip immediately and excess urine is removed
    - holds strip at an angle to avoid mixing
    - records the result for each test pad on the strip after the correct time interval.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles underpinning urine dip stick analysis	1.1	Explain the indications and limitations of urine dip stick analysis			
		1.2	Explain the importance of obtaining a midstream specimen			
		1.3	Explain the need to use a clean sterile container			
		1.4	Explain the process for collecting a specimen from a catheter			
		1.5	Compare the characteristics of normal urine to common abnormal findings from urine dip stick analysis			
		1.6	Explain the difference between qualitative and semi-quantitative strips			
		1.7	Describe the use of urine microscopy			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform urine dip stick analysis	2.1	Explain the procedure to the patient using effective communication skills			
		2.2	Gain and document informed consent			
		2.3	Obtain a urine specimen from the patient in accordance with standard operating procedures			
		2.4	Use the correct technique to accurately test the urine sample, following manufacturers' instructions and national guidance			
		2.5	Read the test results with an awareness of the indicators and possible causes of abnormal results			
		2.6	Complete appropriate documentation for the analysis			
		2.7	Clean all testing equipment in accordance with Standard Operating Procedures			
		2.8	Dispose of the personal and protective equipment in accordance with Standard Operating Procedures			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 91: Ultrasound Measurement of Post-Void Residual Urine

Level:	**4**
Unit type:	**Optional**
Credit value:	**12**
Guided learning hours:	**96**

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to perform the measurement of post-void residual urine. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

It is suggested that learners will have completed the following units:

- **Level 2 – *Unit 26: Anatomy and Physiology: Urogenital System***
- **Level 2 – *Unit 93: Performing a Urine Flow Test***
- **Level 4 – *Unit 11: Scientific Basis of Healthcare Science: Clinical Science***
- **Level 4 – *Unit 90: The Urinary System***
- **Level 4 – *Unit 52: Principles of Ultrasound***

or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.3 – Level 4 learners will be expected to identify **two** common factors that may affect normal bladder filling and emptying typical of patients referred to their own department, which could include:

- non-pharmacological, e.g. age, lifestyle (i.e. diet and fluid intake)
- pharmacological, including intravenous fluids, anti-hypertensive medication, recreational or illicit drugs
- disorders of the kidney
- some neurological diseases, e.g. multiple sclerosis
- neurological injury
- postoperative urinary retention (surgery, anaesthesia and analgesia), e.g. following spinal surgery
- sleep apnoea.

AC1.4 – common symptoms that patients referred for urodynamic science investigations may experience:

- a strong, persistent urge to urinate
- a burning sensation when urinating
- passing frequent, small amounts of urine
- urine that appears cloudy
- blood in the urine.

AC1.5 should be assessed in relation to the typical referrals to the learner's own area of work, and could include to:

- confirm urinary retention
- identify incomplete bladder emptying
- determine whether early removal of a catheter has been appropriate
- assess bladder volume if a catheter is not draining
- identify whether an indwelling catheter is blocked
- determine bladder volume in a patient with decreased urine output
- provide information as part of the assessment continence.

AC1.6 should include:

- equipment safety
- patient safety
- staff safety
- accuracy
- potential errors and how to minimise/correct errors.

AC1.8 should include false positives or negative results.

When measuring post-void residual urine, caution should be exercised in the presence of a known pelvic cystic lesion such as an ovarian cyst, as this can give a false positive.

AC2.2 includes:

- introducing self by name and explaining role
- appropriate use of non-verbal communication
- providing information in a timely manner in appropriate language
- listening to the patient and addressing questions or seeking advice from senior colleagues
- communication during and after the test
- communicating in a way that:
    - respects the dignity, rights, privacy and confidentiality of the patient/carer
    - considers and addresses potential cultural differences (undressing etc.), determines when it may be necessary to invite a family member to be present.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice underpinning the measurement of post-void residual urine	1.1	Explain the anatomy and physiology of the bladder and the process of micturition			
		1.2	Define urinary retention			
		1.3	Discuss factors affecting normal bladder filling and emptying			
		1.4	Explain the common symptoms that patients referred for urodynamic science investigations in own area of work may experience			
		1.5	Explain the common indications for the measurement of post-void residual urine			
		1.6	Evaluate the standard operating procedure for the measurement of post-void residual urine using ultrasound			
		1.7	Discuss the method of measurement of post-void residual urine using a catheter			
		1.8	Evaluate the potential errors associated with the measurement of post-void residual urine			
		1.9	Explain the care pathway for patients presenting with symptoms of chronic urinary retention, including the use of the measurement of post-void residual urine			
		1.10	Explain the application of two-dimensional and three-dimensional ultrasound to measure post-void residual urine			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform the measurement of pre- and post-void residual urine	2.1	Prepare the environment for the procedure			
		2.2	Explain the procedure to the patient using effective communication skills			
		2.3	Gain and document informed consent			
		2.4	Select suitable equipment in accordance with the requirements of the test			
		2.5	Prepare the patient for the measurement of post-void residual urine			
		2.6	Treat the patient with respect and compassion			
		2.7	Support the patient during each phase of the study as required			
		2.8	Measure the pre-void and post-void bladder volume using ultrasound			
		2.9	Explain the potential special needs of patients referred for this investigation and the relevant action required			
		2.10	Respond to any special patient requirements, discussing with senior staff and carers as required			
		2.11	Record information as required			
		2.12	Prepare a report of the results			
3	Be able to assist following completion of the investigation	3.1	Evaluate the protocols for cleaning and decontaminating equipment			
		3.2	Decontaminate equipment, leaving it in a suitable condition for reuse			
		3.3	Clean the room, leaving it in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 92: Assisting with Standard Urodynamic Studies

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to assist and support the healthcare science practitioner/clinical scientist in performing quality-assured, safe, standard urodynamic studies in adults. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

It is suggested that learners will have completed the following units:

- **Level 2 – *Unit 26: Anatomy and Physiology: Urogenital System***
- **Level 2 – *Unit 93: Performing a Urine Flow Test***
- **Level 4 – *Unit 11: Scientific Basis of Healthcare Science: Clinical Science***
- **Level 4 – *Unit 90: The Urinary System***

or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.1 could include:

- ambulatory urodynamics
- filling cystometry
- flowmetry
- frequency-volume chart/bladder diary
- residual urine assessment by ultrasound
- sphincter electromyogram (EMG)
- urethral pressure profile (UPP)
- urinalysis
- voiding cystometry
- video urodynamics.

AC.1.4 includes personal responsibilities for decisions.

AC2.1 includes:

- legal requirements for informed consent
- limits of consent
- own role in the consent process
- importance of documenting informed consent.

AC2.4 could include the following indications:

- abnormal renal function thought to be secondary to lower urinary tract dysfunction
- assessment of pain
- enuresis
- feelings of incomplete emptying
- hesitancy
- nocturia
- increased daytime frequency
- intermittency
- pre/post-surgical evaluation
- retention
- slow stream
- straining
- terminal dribble
- urgency
- urinary incontinence (stress, urge or mixed).

and contraindications:

- recent lower urinary tract surgery
- active urine infection
- poor patient tolerance
- treatment with anticholinergics.

AC2.5 includes:

- the procedure to be followed in the event of identifying an issue of quality assurance.

AC 2.6 includes the following equipment safety measures:

- equipment should be regularly safety tested and regularly maintained in accordance with the manufacturer's recommendations
- an externally damaged equipment should be withdrawn from patient use
- calibration checks should be undertaken at the beginning of every month
- faults should be documented on the relevant sheet
- single-use consumables should be replaced every test.

AC2.7 includes the following infection control measures:

- check if patient is particularly at risk, e.g. implant, immune-compromised; investigation may be contraindicated, or require prophylactic antibiotics
- wash hands prior to setting up, before the test and once the test has finished
- use plastic apron and non-latex gloves for protection when undertaking test
- all sterile equipment should be opened using aseptic technique onto a sterile surface
- all single-use consumables should be disposed of after use
- should a catheter fall out during the test, it should be disposed of and a new one used
- all non-disposable equipment should be cleaned in accordance with departmental procedures.

AC3.1 includes:

- setting up the computer
- setting up the trolley
- setting up the pressure measurement system, including transducers.

AC3.4 includes:

- introducing self by name and explaining role
- appropriate use of non-verbal communication
- providing information in a timely manner in appropriate language
- listening to the patient and addressing questions or seeking advice from senior colleagues
- communication during and after the test
- communicating in a way that:
    - respects the dignity, rights, privacy and confidentiality of the patient/carer
    - considers and addresses potential cultural differences (undressing etc.), determines when it may be necessary to invite a family member to be present.

AC3.5 should include:

- an explanation of how learners would respond to any special patient requirements, discussing with senior staff and carers.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the services provided by urodynamic science services and own role in relation to these services	1.1	Describe the range of procedures undertaken by urodynamic science services			
		1.2	Explain the common reasons for referring patients to urodynamic science services			
		1.3	Evaluate safeguarding procedures and the process for reporting safeguarding issues			
		1.4	Discuss the limits of your practice and when to seek advice or refer to another professional			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the principles and practice of standard urodynamic studies	2.1	Explain the principles, guidance and law for gaining informed consent, including the limits of consent			
		2.2	Evaluate the Standard Operating Procedure for standard urodynamic studies in own area of practice			
		2.3	Explain the measurement principles underpinning the measurement of pressure and flow as part of urodynamic studies			
		2.4	Explain the indications and contraindications for standard urodynamic studies			
		2.5	Evaluate the requirements for quality-assured standard urodynamic studies			
		2.6	Explain the equipment safety standards applicable to the equipment used			
		2.7	Evaluate the infection control procedures required for standard urodynamic studies			
		2.8	Explain the factors influencing the choice of equipment for the investigation			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to assist during standard urodynamic studies	3.1	Prepare the equipment in accordance with the requirements of the test			
		3.2	Assist in preparing the environment for standard urodynamic studies			
		3.3	Assist in preparing the patient, treating the patient with respect and compassion			
		3.4	Support the patient during each phase of the study as required, communicating effectively			
		3.5	Explain the potential special needs of patients referred for investigation and the relevant action required			
		3.6	Record information as required			
4	Be able to assist following completion of the study	4.1	Evaluate the protocols for cleaning and decontaminating equipment			
		4.2	Decontaminate equipment, leaving it in a suitable condition for reuse			
		4.3	Clean the room, leaving it in a suitable condition for reuse			
5	Be able to perform required calibration procedures	5.1	Explain the calibration procedures required for each item of equipment used			
		5.2	Carry out calibration procedures for equipment used in standard urodynamic studies			
		5.3	Document calibration procedures			
		5.4	Report all errors in calibration according to local procedures			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 93: Assisting with Flowmetry Studies

Level: 4

Unit type: Optional

Credit value: 10

Guided learning hours: 80

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to assist and support the healthcare science practitioner/clinical scientist in performing quality-assured, safe, flowmetry studies. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

It is suggested that learners will have completed the following units:

- **Level 2:** ***Unit 26: Anatomy and Physiology: Urogenital System***
- **Level 2:** ***Unit 93: Performing a Urine Flow Test***
- **Level 4:** ***Unit 11: Scientific Basis of Healthcare Science: Clinical Science***
- **Level 4:** ***Unit 90: The Urinary System***

or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP).

AC1.4 includes personal responsibility for decisions.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand key aspects of professional practice applied to investigations in urodynamic science services	1.1	Explain how to embed the principles of patient-centred care in own area of practice			
		1.2	Explain the principles, guidance and law for gaining informed consent, including the limits of consent			
		1.3	Evaluate safeguarding procedures and the process for reporting a safeguarding issue			
		1.4	Discuss the limits of your practice and when to seek advice or refer to another professional			
		1.5	Explain the impact of culture, equality and diversity on practice			
		1.6	Explain the importance of maintaining confidentiality			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the principles and practice underpinning flowmetry studies	2.1	Evaluate the Standard Operating Procedure for flowmetry studies in own area of practice			
		2.2	Explain the measurement principles underpinning flowmetry studies, including recognition of common artefacts and how to avoid them			
		2.3	Explain the indications and contraindications for standard flowmetry studies			
		2.4	Evaluate the requirements for quality-assured flowmetry studies			
		2.5	Explain the procedure to be followed in the event of identifying an issue of quality assurance			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to assist during flowmetry studies	3.1	Explain the equipment safety standards applicable to the equipment used			
		3.2	Evaluate the infection control procedures required for flowmetry studies			
		3.3	Explain the factors influencing the choice of equipment for the investigation			
		3.4	Select suitable equipment in accordance with the requirements of the test			
		3.5	Compare the differences in the procedure for male and female patients			
		3.6	Prepare the environment for flowmetry studies in accordance with the Standard Operating Procedure			
		3.7	Assist in preparing the patient in accordance with the Standard Operating Procedures, treating the patient with respect and compassion			
		3.8	Support the patient during each phase of the study as required			
		3.9	Explain the potential special needs of patients referred for investigation and the relevant action required			
		3.10	Respond to any special patient requirements, discussing with senior staff and carers			
		3.11	Analyse a simple uroflowmetry accounting for artefacts			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to assist following completion of the study	4.1	Evaluate the protocols for cleaning and decontaminating equipment			
		4.2	Decontaminate equipment, leaving it in a suitable condition for reuse			
		4.3	Clean the room, leaving it in a suitable condition for reuse			
5	Be able to perform required calibration procedures	5.1	Explain the calibration procedures required for each item of equipment used			
		5.2	Carry out calibration procedures for equipment used in standard urodynamic studies			
		5.3	Document calibration procedures			
		5.4	Report all errors in calibration according to local procedures			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 94: Introduction to Autonomic Science

Level: 4

Unit type: Optional

Credit value: 8

Guided learning hours: 64

Unit summary

In this unit, you will gain the knowledge needed to be able to assist and support the healthcare science practitioner/clinical scientist in performing quality-assured, safe, autonomic science investigations. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of practice.

AC1.2 includes:

- sensory input
- control of motor output
- motor neuron pathway
- neurotransmitters and hormones
- effectors and responses.

AC1.4 includes:

- cholinergic and adrenergic neurons and receptors
- receptor agonists and antagonists.

AC1.8 includes:

- role of autonomic reflex
- structure of autonomic reflex arc
- role of hypothalamus.

AC2.1 includes:

- cardiovascular
- sudomotor
- alimentary
- urogenital
- eye.

AC2.2 includes:

- cardiovascular, e.g.
    - postural hypotension
    - supine hypertension
    - lability of blood pressure
    - paroxysmal hypertension
    - tachycardia
    - bradycardia
- sudomotor, e.g.
    - hypohidrosis or anhidrosis
    - hyperhidrosis
    - gustatory sweating
    - hypothermia
    - hyperpyrexia
    - heat intolerance
- alimentary:
    - xerostomia
    - dysphagia
    - gastric stasis
    - dumping syndromes
    - constipation
    - diarrhoea
- urogenital:
    - nocturia
    - frequency
    - urgency
    - retention
    - incontinence
    - erectile failure
    - ejaculatory failure
    - retrograde ejaculation
    - priapism
- eye:
    - pupillary abnormalities
    - ptosis
    - alachryma
    - abnormal lacrimation with food ingestion.

AC 2.3 includes:

- vasovagal syncope
- autoimmune autonomic ganglionopathy
- orthostatic hypotension
- postural tachycardia
- carotid sinus supersensitivity
- multiple system atrophy.

AC2.4 includes:

- palmar and plantar hyperhidrosis
- anhidrosis
- hyperhidrosis.

AC3.1 includes:

- autonomically-mediated syncope (vasovagal and carotid sinus super-sensitivity)
- postural tachycardia syndrome
- hyperhidrosis
- hypohidrosis and anhidrosis.

AC4.1 includes to:

- determine if autonomic function is normal or abnormal
- evaluate, if an abnormality has been observed, the degree of autonomic dysfunction
- determine if autonomic dysfunction is of the primary or secondary variety.

AC4.2 includes:

- head-up tilt (60°); standing; Valsalva manoeuvre
- pressor stimuli (isometric exercise, cutaneous cold, mental arithmetic)
- heart rate responses – deep breathing, hyperventilation, standing, head-up tilt, liquid meal challenge
- modified exercise testing
- carotid sinus massage
- assessment of plasma catecholamine and biochemical levels.

AC4.3 should include **one** common disorder of cardiovascular autonomic function.

AC5.1 includes:

- developing an awareness of situations likely to cause symptoms, e.g. standing in hot weather or exercising after a large meal
- taking action at the onset of symptoms by sitting, crouching or lying down, drinking water and returning to normal activity slowly
- head-up tilt on the bed overnight ideally by putting additional support under the mattress or raising the legs of the bed
- maintaining a good fluid intake, drinking 500 ml immediately when getting out of bed and then sipping enough fluid to keep urine a pale-yellow colour
- avoiding postures likely to create symptoms such as standing still, bending over or raising arms above head, e.g. hanging washing on a line
- making the use of calf pump exercises (simple heel lifts) a habit before getting out of bed or before standing, or if standing still
- eating small meals, avoiding sugary foods and being cautious with alcohol
- finding ways to do as many daily activities as possible when sitting, including showering
- pacing daily activity to enable a brief rest and chance for circulation to recover from exertion.

AC5.2 includes:

- fludrocortisone
- midodrine
- ephedrine
- pyridostigmine
- clonidine
- propantheline also called pro-banthine
- beta-blockers
- ivabradine.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the normal anatomy and physiology of the somatic and autonomic nervous systems	1.1	Explain the anatomy of autonomic motor pathways			
		1.2	Explain the structural and functional differences between the somatic and autonomic parts of the nervous system			
		1.3	Explain the anatomical components of the sympathetic and parasympathetic divisions of the autonomic nervous system			
		1.4	Describe the neurotransmitters and receptors involved in autonomic responses			
		1.5	Explain the location and responses of adrenergic and cholinergic receptors			
		1.6	Explain the responses of the body to stimulation by the sympathetic and parasympathetic divisions of the autonomic nervous system			
		1.7	Explain the term autonomic reflex arc			
		1.8	Explain the integration and control of autonomic functions			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the common types of cardiovascular and sudomotor autonomic disorders and the underlying physiology	2.1	Discuss the body systems that can be affected by autonomic dysfunction			
		2.2	Know the common autonomic disorders			
		2.3	Explain the underpinning physiology for autonomic disorders of the cardiovascular system			
		2.4	Explain the underpinning physiology for autonomic disorders of the sudomotor system			
3	Understand the patterns of autonomic abnormalities seen with common cardiovascular and sudomotor autonomic disorders testing	3.1	Explain the patterns of autonomic abnormalities seen with cardiovascular autonomic failure			
		3.2	Explain the patterns of autonomic abnormalities seen with autonomically-mediated syncope			
		3.3	Explain the patterns of autonomic abnormalities seen with postural tachycardia syndrome			
		3.4	Explain the patterns of autonomic abnormalities seen with hyperhidrosis, hypo- and anhidrosis			
		3.5	Explain the symptoms patients may experience during autonomic science testing			
		3.6	Explain the factors that may confound autonomic testing			
		3.7	Discuss the potential impact of autonomic function disorders on patients			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Understand the range of procedures available to investigate autonomic function disorders	4.1	Explain the purpose of investigations undertaken in people with autonomic function disorders			
		4.2	Explain the range of common procedures to investigate cardiovascular autonomic disorders			
		4.3	Explain the range of common procedures to investigate sudomotor autonomic disorders			
		4.4	Discuss the effect of a common disorder of cardiovascular autonomic function on the patient and their quality of life			
5	Understand the common management options for autonomic disorders	5.1	Explain the non-pharmacological measures a patient may use to manage autonomic disorders			
		5.2	Discuss the common pharmacological treatment for autonomic disorders			
		5.3	Explain the mode of action of pharmacological treatment for an autonomic disorder			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 95: Assist in Performing Tilt Testing

Level:	**4**
Unit type:	**Optional**
Credit value:	**6**
Guided learning hours:	**48**

Unit summary

In this unit, you will develop the knowledge, understanding and skills needed to be able to assist the healthcare science practitioner/clinical scientist/medical staff in the performance of tilt testing. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

It is suggested that learners will have completed the following units:

- **Level 2 – *Unit 72: Measuring Blood Pressure using an Automatic Machine***
- **Level 2 – *Unit 75: Setting up a Cardiac Monitor***

or have appropriate experience before completing this unit.

The responsibility for the conduct of the test and gaining informed consent will lie with the Healthcare Science Practitioner/Clinical Scientist/Medical Staff.

AC2.2 includes:

- how essential it is to catch the transient, short-lived or rapid cardiovascular changes underlying these events.

AC2.4 includes:

- pre-test instructions in relation to stopping medication prior to testing
- only having water for four hours prior to the test
- seeking advice from a senior colleague, if needed, if the patient is an insulin-dependent diabetic.

AC2.5 includes:

- coughing
- micturition
- vomiting
- swallowing
- laughing
- hyperventilation
- Valsalva
- drug
- cervical and head movements.

AC3.3 includes:

- ensuring all of the equipment is available in the room and working, spanning:
    - data measurement/capture system to record beat-to-beat blood pressure and heart rate, 3-lead ECG and derived continuous heart rate and respiration
    - ECG electrodes
    - respiratory monitor
    - automated sphygmomanometer
    - tilt table
    - stop clock.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles of tilt testing in the assessment of autonomic disorders and the importance of patient-centred practice	1.1	Explain the physiological changes that occur in response to tilting			
		1.2	Explain the indications and contraindications for undertaking tilt testing to assess autonomic disorders			
		1.3	Evaluate ways to ensure and promote patient-centred care in own area of practice			
2	Be able to assist with the planning, preparation and performance of tilt testing	2.1	Evaluate the Standard Operating Procedure for tilt testing			
		2.2	Explain the rationale for continuous blood pressure and heart rate monitoring during tilt testing			
		2.3	Prepare the environment for tilt testing			
		2.4	Assist with the patient's preparation for tilt testing			
		2.5	Measure the height and weight of the patient			
		2.6	Gather information on current medication			
		2.7	Assist in correct positioning of the patient			
		2.8	Set up all monitoring equipment			
		2.9	Maintain the highest standards of person-centred care, treating every person with compassion, dignity and respect			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to assist in monitoring the patient during and post tilt testing	3.1	Monitor the patient's blood pressure, heart rate and cardiac output			
		3.2	Alert senior staff to marked falls or rises in blood pressure or heart rate			
		3.3	Alert senior staff to any discolouration of the feet or hands when upright is documented			
		3.4	Keep accurate records following local policies			
4	Be able to clean equipment, and leave the room in a suitable condition for reuse	4.1	Discuss the protocols for cleaning equipment used			
		4.2	Clean equipment as per protocol			
		4.3	Arrange the room in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 96: Withdrawal of Blood from an Indwelling Peripheral Cannula

Level: 4

Unit type: Optional

Credit value: 2

Guided learning hours: 15

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to assist and support the healthcare science practitioner/clinical scientist in performing quality-assured, safe, autonomic science investigations. Specifically, this unit ensures that you will be able to withdraw blood from an indwelling cannula. This skill will be typically utilised during investigations such as the measurement of plasma catecholamines supine and tilted.

You will be expected to build your patient-centred professional practice to enable you to safely undertake this skill in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP) in own area of practice.

The lead investigator will gain informed consent for the withdrawal of blood from an indwelling cannula.

AC1.3 includes:

- patients who lack mental capacity
- the legal action that can be taken if you fail to obtain consent.

AC1.5 includes:

- policy of own organisation for sharps and other occupational exposure to blood and bodily fluids
- actions that must be taken following an occupational exposure
- the importance of risk assessment for possible exposure to blood and body fluids
- the importance of wearing personal protective equipment (PPE)
- strategies for reducing sharps incidents.

AC1.6 includes:

- how cannulae can become infected
- actions that can be taken to reduce the risk of infection
- hand hygiene
- aseptic technique
- personal protective equipment (PPE)
- the four main principles involved in Aseptic Non Touch Technique (ANTT®):
    - Always wash hands effectively
    - Never contaminate key parts
    - Touch non-key parts with confidence
    - Take appropriate infective precautions

AC2.2 includes:

- wearing eye protection if there is a clear chance of splash or spray.

AC2.3 includes:

- introducing self by name and explaining role
- appropriate use of non-verbal communication
- providing information in a timely manner in appropriate language
- listening to the patient and addressing questions or seeking advice from senior colleagues
- communication during and after the test
- communicating in a way that:
    - respects the dignity, rights, privacy and confidentiality of the patient/carer
    - considers and addresses potential cultural differences (undressing etc.), determines when it may be necessary to invite a family member to be present.

AC2.4 includes:

- labelling of blood and plasma storage tubes (patient's name, test date, assay to be performed and nature of sample, e.g. supine)

  Note: plasma storage tubes can also be labelled during the head-up tilt
- adding preservatives to the blood-collection tubes as per protocol.

AC2.8 includes:

- mixing blood as per protocol.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of obtaining venous samples from an indwelling peripheral cannula	1.1	Explain the purpose of an indwelling peripheral cannula for autonomic science investigations			
		1.2	Explain own scope of practice in the context of obtaining venous samples from an indwelling peripheral cannula			
		1.3	Explain the process of gaining informed consent			
		1.4	Explain own responsibilities for recording the cannulation process			
		1.5	Explain safe working practices when obtaining venous samples from an indwelling peripheral cannula			
		1.6	Explain the importance of infection control when obtaining venous samples from an indwelling peripheral cannula			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to withdraw venous blood during autonomic science investigations in accordance with the standard operating procedure	2.1	Evaluate the Standard Operating Procedure for withdrawing venous blood from an indwelling cannula			
		2.2	Risk assess all tasks for possible exposure to blood and body fluids			
		2.3	Communicate effectively with the patient throughout the procedure			
		2.4	Prepare the blood-collecting and plasma-storage tubes			
		2.5	Prepare for the procedure using an aseptic technique			
		2.6	Check the cannula site for swelling or redness and escalate any concerns to senior staff			
		2.7	Perform the flushing procedure for the cannula			
		2.8	Collect supine and tilted blood samples and flush cannula as per protocol			
		2.9	Remove the cannula when and if appropriate			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 97: Assist with the Assessment of Plasma Catecholamine and Biochemical Levels

Level:	**4**
Unit type:	**Optional**
Credit value:	**7**
Guided learning hours:	**56**

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to assist and support the Healthcare Science Practitioner/Clinical Scientist in performing quality-assured, safe, autonomic science investigations. Specifically, you will be able to assist in the assessment of plasma catecholamines and biochemical levels. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of practice.

AC1.1 includes:

- underlying physiology of hormonal and nervous systems that affect blood pressure
- timescales on which the levels change in the circulation
- role of the cardiovascular system
- short-term neural control
- short-term chemical control
- long-term renal regulation.

AC1.6 should include **three** commonly prescribed medications.

AC1.8 should include **one** non-pharmacological measure.

AC2.1 includes:

- nerve tissue
- the brain
- the adrenal glands.

AC2.2 includes:

- three catecholamines (dopamine, noradrenaline and adrenaline)
- break down into vanillylmandelic acid (VMA), metanephrine, and normetanephrine. Metanephrine and normetanephrine also may be measured during a catecholamine test.

AC2.3 includes:

- increasing heart rate, blood pressure, breathing rate, muscle strength, and mental alertness
- increasing blood going to the major organs, such as the brain, heart, and kidneys
- lowering the amount of blood going to the skin and intestines.

AC2.4 includes:

- high blood pressure
- excessive sweating
- headaches
- fast heartbeats (palpitations)
- tremors.

AC2.6 should include **one** disorder that results in an unexpected rise or fall in catecholamines, which could include:

- phaeochromocytoma
- hyperadrenergic postural tachycardia syndrome
- peripheral and central autonomic failure
- AAG (autoimmune autonomic ganglionopathy).

AC4.3 includes:

- preparing the environment
- introducing self and own role
- measuring the height and weight of the patient
- gathering information on current medication
- assisting in correct positioning of the patient
- documenting information
- labelling and storage of collected blood.

AC4.8 includes:

- treating every person with compassion, dignity and respect.

AC4.12 includes:

- relevant protocols for assay immediately or at a future date
- forwarding it to specialist departments as necessary.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the normal physiological regulation of heart rate and blood pressure	1.1	Explain the physiological mechanism that regulates heart rate			
		1.2	Explain the physiological mechanism that regulates blood pressure			
		1.3	Explain the effect of moving from supine to standing on heart rate and blood pressure			
		1.4	Know the normal range of heart rate			
		1.5	Explain the definition of normal blood pressure, borderline hypertension and hypertension			
		1.6	Explain how commonly prescribed medications lower blood pressure			
		1.7	Explain common risk factors for cardiovascular disease			
		1.8	Explain how a non-pharmacological measure may reduce blood pressure			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the production and function of catecholamines	2.1	Explain where catecholamines are produced			
		2.2	Explain the mode of action and breakdown of the main types of catecholamines			
		2.3	Explain the effects of normal levels of catecholamines in the blood			
		2.4	Explain the effects of an increased amount of catecholamines in the blood			
		2.5	Discuss how urinary catecholamines can be measured as part of the investigation of a patient with suspected disorders of autonomic function			
		2.6	Explain how a disorder that results in an unexpected rise or fall in catecholamines, at rest or with postural challenge, can be diagnosed and treated			
3	Understand the principles and practice of the assessment of plasma catecholamine levels	3.1	Explain the short- and long-term physiological control of blood pressure			
		3.2	Explain the indications and contraindications for the assessment of plasma catecholamines levels			
		3.3	Explain the reasons cannulation is used rather than venepuncture for the assessment of plasma catecholamine levels			
		3.4	Discuss the rationale behind the timing of the cannulation and the sampling			
		3.5	Explain why samples for catecholamine assay are frozen			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to assist with the planning, preparation and taking blood for the assessment of plasma catecholamine levels	4.1	Evaluate the Standard Operating Procedure to assess plasma catecholamine levels			
		4.2	Explain the reason for the timing of the blood sampling			
		4.3	Set up all monitoring equipment for the assessment being carried out			
		4.4	Monitor the patient's blood pressure and heart rate			
		4.5	Maintain the highest standards of person-centred care			
		4.6	Alert senior staff to marked changes in blood pressure and/or heart rate			
		4.7	Withdraw blood from the indwelling cannula			
		4.8	Process blood in the appropriate manner using relevant safety and infection control protocols			
5	Be able to clean equipment, and leave the room in a suitable condition for reuse	5.1	Discuss the protocol for cleaning equipment used			
		5.2	Clean equipment as per protocol			
		5.3	Arrange the room in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 98: Assist in Performing Situational Provocation Testing

Level:	**4**
Unit type:	**Optional**
Credit value:	**7**
Guided learning hours:	**56**

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to assist the healthcare science practitioner/clinical scientist/medical staff in the performance of situational provocation testing. You will be expected to build your patient-centred professional practice and practise safely in the workplace.

Additional information

It is suggested that learners will have completed the following units:

- **Level 2 – *Unit 72: Measuring Blood Pressure Using an Automatic Machine***
- **Level 2 – *Unit 75: Setting up a Cardiac Monitor***

or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of practice.

The responsibility for the conduct of the test and gaining informed consent will lie with the healthcare science practitioner/clinical scientist/medical staff.

AC2.5 includes:

- coughing
- micturition
- vomiting
- swallowing
- laughing
- hyperventilation
- Valsalva manoeuvre
- drug
- cervical and head movements.

AC2.6 should include **two** methods used for provocation.

AC3.2 includes:

- how it is essential to catch the transient, short-lived or rapid cardiovascular changes underlying these events.

AC3.3 includes:

- ensuring all of the equipment is available in the room and working, spanning:
    - data measurement/capture system to record beat-to-beat blood pressure and heart rate, 3-lead ECG and derived continuous heart rate and respiration
    - ECG electrodes
    - breath monitor
    - automated sphygmomanometer
    - tilt table
    - stop clock.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the physiological changes that occur in response to situational provocation	1.1	Explain the term vasovagal syncope			
		1.2	Explain the physiological changes that occur during an episode of vasovagal syncope			
		1.3	Explain the physiological effect of the Valsalva manoeuvre			
		1.4	Explain the physiological effect of carotid sinus super sensitivity			
2	Understand the principles of situational provocation testing and the importance of patient-centred practice	2.1	Explain the indications and contraindications for undertaking situational provocation testing			
		2.2	Discuss the possible symptoms experienced by a patient experiencing episodes of vasovagal syncope			
		2.3	Explain how vasovagal syncope can impact on quality of life			
		2.4	Explain the purpose of head-up tilt and head-down tilt			
		2.5	Explain the types of provocation that may be used			
		2.6	Evaluate ways to ensure and promote patient-centred care in own area of practice			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to assist with the planning and preparation for situational provocation testing in accordance with the Standard Operating Procedure	3.1	Evaluate the Standard Operating Procedure for situational provocation testing			
		3.2	Explain the rationale for continuous blood pressure and heart rate monitoring during situational provocation testing			
		3.3	Prepare the environment for situational provocation testing			
		3.4	Measure the height and weight of the patient			
		3.5	Gather information on current medication			
		3.6	Assist in correct positioning of the patient			
		3.7	Set up all monitoring equipment			
		3.8	Maintain the highest standards of person-centred care, treating every person with compassion, dignity and respect			
4	Be able to assist in monitoring the patient during and post situational provocation testing	4.1	Monitor the patient's blood pressure, heart rate and cardiac output			
		4.2	Alert senior staff to marked falls or rises in blood pressure or heart rate as part of a syncopal event			
		4.3	Keep accurate records			
5	Be able to clean equipment, and leave the room in a suitable condition for reuse	5.1	Discuss the protocols for cleaning equipment used situational provocation testing			
		5.2	Clean equipment as per protocol			
		5.3	Arrange the room in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 99: Peripheral Intravenous Cannulation as Part of Autonomic Testing

Level:	**5**
Unit type:	**Optional**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to assist and support the healthcare science practitioner/clinical scientist in performing quality-assured, safe, autonomic science investigations by being able to insert peripheral intravenous cannulae. This is an invasive procedure, with associated risks. Complications can cause considerable pain and discomfort to the patient; correct technique, high standards of hygiene and the use of good-quality equipment can significantly minimise the occurrence and severity of these complications. You will be expected to build your patient-centred professional practice to undertake this skill safely in the workplace.

You may have to attend a training course in your own organisation that will provide the underpinning learning for this unit. The policy of your own trust must be adhered to when performing cannulation.

Additional information

It is suggested that learners will have completed the following units:

- **Level 3 – *Unit 63: Obtain Venous Blood Samples***

or have appropriate experience before completing this unit.

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of practice.

AC1.1 includes:

- administration of intravenous drugs
- blood sampling to aid diagnosis and treatment.

AC2.3 includes:

- consent when a patient lacks mental capacity
- legal action that can be taken if you fail to obtain consent.

AC3.1 includes:

- occupational exposure to blood or body fluids incident is defined as: inoculation with an instrument such as a needle or scalpel blade that has been contaminated with blood or other body fluid, or blood or body fluid splashed into the eye or onto a mucous membrane or (onto) skin surface that has an open cut or abrasion.

AC3.7 includes:

- eliminating or substituting sharps (eliminates unnecessary injections)
- using engineering controls (auto-disable syringes, safer needle devices)
- training in the use of safety engineered devices
- adopting administrative and work practice controls (standard precautions; no recapping provision and placement of sharps containers)
- wearing personal protective equipment (PPE) (e.g. gloves, goggles).

AC4.1 includes patients who:

- are immunocompromised
- are critically ill
- are very young
- have a haematological malignancy
- are receiving chemotherapy.

AC4.2 includes:

- hand hygiene
- aseptic technique
- personal protective equipment (PPE)
- skin preparation
- dressing and secure device
- correct disposal of sharps and waste
- documentation.

AC4.3 includes:

- coagulase negative staphylococci (35%)
- Staphylococcus aureus (25%) (DTB 2001)
- methicillin-resistant Staphylococcus aureus (MRSA) accounted for 40–45% of Staphylococcus aureus (Smyth 2006)
- less commonly isolated organisms are:
  - gram-negative rods
  - Candida albicans.

AC4.4 includes:

- always
- never
- touch
- take.

AC4.5 includes:

- vasovagal
- anxiety
- pain
- haematoma
- thromboembolism
- air embolism
- thrombophlebitis
- blood spurt on entry
- no flashback seen
- mobile veins
- mechanical irritation
- infection
- dressings.

AC5.3 includes:

- the patient
- veins
- site and indication
- local Standard Operating Procedure.

AC6.1 includes:

- wearing of eye protection if there is a clear chance of splash or spray.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of peripheral intravenous cannulation as part of autonomic testing	1.1	Explain the indications for peripheral intravenous cannulation as part of autonomic testing			
		1.2	Explain the local guidelines for peripheral intravenous cannulation			
2	Understand own professional responsibilities when performing peripheral intravenous cannulation	2.1	Explain own scope of practice in the context of performing peripheral intravenous cannulation			
		2.2	Explain the risks and benefits of peripheral intravenous cannulation			
		2.3	Explain the process of gaining informed consent			
		2.4	Explain own responsibilities for recording for the cannulation process			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand safe working practices when performing peripheral intravenous cannulation	3.1	Explain the term occupational exposure to blood or body fluids			
		3.2	Explain policy of own organisation for dealing with sharps and other occupational exposure to blood and bodily fluids			
		3.3	Explain the actions that must be taken following an occupational exposure			
		3.4	Explain the role of senior colleagues for subsequent actions			
		3.5	Explain the importance of risk assessment for possible exposure to blood and body fluids			
		3.6	Explain the importance of wearing personal and protective equipment			
		3.7	Explain strategies for reducing sharps incidents			
4	Understand the importance of infection control when performing peripheral intravenous cannulation	4.1	Explain how cannulae can become infected			
		4.2	Describe patients who are most at risk of bacteraemia			
		4.3	Explain the actions that can be taken to reduce the risk of infection			
		4.4	Discuss the most commonly isolated organisms from all types of intravenous cannulae			
		4.5	Explain the four main principles involved in aseptic non-touch technique			
		4.6	Explain the potential complications of intravenous cannulation			
5	Be able to select the cannula and site of cannulation	5.1	Name the veins of the hand			
		5.2	Name the veins and nerves of the arm			
		5.3	Explain how to select the right size of cannula for the withdrawal of blood			
		5.4	Select the cannula and site of cannulation for the withdrawal of blood			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to perform cannulation for withdrawal of blood during autonomic science investigations in accordance with the Standard Operating Procedure	6.1	Risk assess all tasks for possible exposure to blood and body fluids			
		6.2	Explain the procedure to the patient			
		6.3	Gain and document informed consent			
		6.4	Prepare for the procedure using an aseptic technique			
		6.5	Select the cannulation site			
		6.6	Insert the cannula and flush			
		6.7	Stabilise the cannula			
		6.8	Dispose of sharps safely at the point of use			
		6.9	Complete documentation, including cannula insertion record			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 100: Introduction to Vascular Science

Level:	**4**
Unit type:	**Optional**
Credit value:	**3**
Guided learning hours:	**20**

Unit summary

In this unit, you will gain an overview of the services provided by vascular science, the regulatory framework within which these services operate and the quality-assurance processes that underpin the high-quality, safe investigations undertaken in this specialism of healthcare science.

Additional information

AC1.1 should include:

- primary care
- vascular surgical clinics
- one-stop transient ischaemic attack (TIA) clinics
- one-stop deep vein thrombosis (DVT) clinics
- hospital wards
- theatre and recovery.

AC1.2 should include:

- carotid duplex
- venous duplex for DVT and venous insufficiency
- lower limb arterial duplex
- aneurysmal duplex for aorta and popliteal aneurysms
- non-imaging investigations:
  - ankle brachial indices (ABPI)
  - pre- and post-exercise ABPI.

AC1.4 includes how the key principles of the NHS constitution apply to patient-centred care and own role.

AC2.1 includes: the process of incident reporting.

AC2.2 includes the role of:

- Health and Care Professions Council
- Academy for Healthcare Science.

AC3.1 includes:

- the importance of immediately reporting any issues that are outside own scope of competence to the relevant member of staff.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the range of healthcare science services provided by vascular science	1.1	Explain the range of settings in which vascular science investigations are undertaken			
		1.2	Explain the range of key vascular science diagnostic techniques to diagnose and monitor vascular diseases in different settings			
		1.3	Evaluate strategies to embed patient-centred care in healthcare			
		1.4	Explain how the principles of patient-centred care are embedded in own work and the services provided by vascular science			
2	Understand the regulatory framework within which vascular science operates, appropriate to own job role	2.1	Explain the legislation, policy and good practice underpinning the practice of vascular science			
		2.2	Explain the regulatory framework underpinning the delivery of vascular science services			
		2.3	Explain personal responsibilities for processes and procedures as described in Good Scientific Practice			
		2.4	Explain the role of the healthcare science associate in vascular science			
		2.5	Explain the limits of own authority and who to report any problems that they cannot resolve			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the quality-assurance processes in own department which underpin safety and good practice	3.1	Explain the key components of the quality-management processes within vascular science			
		3.2	Explain the process of service accreditation for vascular science services			
		3.3	Explain how quality management contributes to safe and effective high-quality care			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 101: Measuring Ankle Brachial Pressure Index

Level: 3

Unit type: Optional

Credit value: 2

Guided learning hours: 14

Unit summary

This unit aims to give you the understanding and skills you need to be able to prepare for and carry out the measurement of ankle brachial pressure, and to document the results.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPS)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the blood supply to the lower limbs and diseases that can lead to vascular disease of the lower limbs	1.1	Describe the structure and function of the arterial and venous blood vessels supplying the lower limbs			
		1.2	State the normal systolic pressures in the lower limbs			
		1.3	Describe the structure and function of the lymphatic system in the lower limbs			
		1.4	Describe a range of common vascular diseases affecting the lower limbs, e.g. lower limb arterial bypass graft, angioplasty, stent, leg ulcers			
		1.5	Describe one venous and one arterial disease that affects the lower limb			
		1.6	Outline the potential impact of vascular disease of the lower limb on patients and their lifestyle			
		1.7	Explain the common risk factors for developing vascular disease of the lower limbs			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the basic principles and indications for measuring ankle brachial pressure index (ABPI)	2.1	Explain the term ABPI			
		2.2	Identify the normal values for ABPI			
		2.3	Describe the basic principles of a continuous wave hand-held ultrasound unit and sphygmomanometer			
		2.4	Explain how to choose the appropriate probe, including frequency			
		2.5	State the clinical indications for measuring ABPI			
		2.6	State the contraindications for measuring ABPI			
		2.7	Describe the standard operating procedure for measuring ABPI			
3	Be able to prepare for measuring ABPI	3.1	Select the appropriate equipment			
		3.2	Explain the reasons for the choice of equipment			
		3.3	State the requirements to only use equipment that has been validated, maintained and calibrated correctly			
		3.4	State the environmental conditions required for accurate ABPI measurement			
		3.5	Consider cultural differences (undressing etc.) when it may be necessary to invite a family member to be present			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to communicate relevant information effectively to patients	4.1	Greet the patient, introduce yourself and your role			
		4.2	Confirm the patient's identity and explain the activity to be undertaken			
		4.3	Obtain verbal consent			
		4.4	Outline the purpose of informed consent, types of consent and the importance of always obtaining consent			
		4.5	Gather information from the patient; maintain the individual's privacy and dignity at all times			
		4.6	Treat the individual with compassion and respect			
		4.7	Apply standard safety precautions, including infection prevention and control			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to perform the measurement of ankle and brachial pressures at rest	5.1	Adhere to all infection control procedures			
		5.2	Explain the correct position for patients when measuring ABPI			
		5.3	State how long a patient should be resting for prior to measurement and the reasons for this			
		5.4	State how to choose the correct size of cuff required and the impact of using an incorrectly-sized cuff or placing the cuff incorrectly			
		5.5	Measure the brachial pressure in each arm			
		5.6	Explain the importance of palpation			
		5.7	Position the cuff on the ankle immediately above the malleoli			
		5.8	Describe the location of the posterior tibial artery (PTA) and dorsalis pedis artery (DPA)			
		5.9	Locate the site of the PTA and DPA			
		5.10	Make appropriate adjustments for patients with leg ulcers or open wounds			
		5.11	Angle the Doppler probe appropriately and measure the ankle pressures and record the highest ankle pressure measured			
		5.12	Calculate the ABPI in both legs			
		5.13	Evaluate the technical quality of the ABPI measurements			
		5.14	Record the results in accordance with local procedures			
		5.15	Refer to or seek advice from colleagues appropriately			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to document relevant information	6.1	Document the results with respect to ABPI in accordance with local procedures			
		6.2	State the normal values for ABPI and the situations where ABPI may be significantly high, e.g. diabetes, renal disease			
7	Be able to maintain equipment according to manufacturer's instructions	7.1	Outline the local guidelines and protocols for cleaning and maintaining continuous wave hand-held ultrasound units and sphygmomanometers			
		7.2	Clean and maintain continuous wave hand-held ultrasound units			
		7.3	Clean and maintain sphygmomanometers, including cuffs			
8	Be able to perform and document quality-assurance procedures, including calibration in accordance with the Standard Operating Procedure (SOP)	8.1	Describe the quality-control procedures required for continuous wave hand-held ultrasound units and sphygmomanometers			
		8.2	Perform quality-control procedures on continuous wave hand-held ultrasound units and sphygmomanometers			
		8.3	Document the results of quality-control procedures in accordance with the Standard Operating Procedure (SOP)			
		8.4	Refer/report issues of quality in accordance with the Standard Operating Procedure (SOP)			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 102: Measurement of Post-Exercise Ankle Brachial Pressure Index

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 48

Unit summary

In this unit, you will gain the understanding and skills needed to perform safe and quality-assured measurements of post-exercise ankle brachial pressure index, generating test results and performing quality-control checks. In addition, you will be able to undertake routine maintenance, calibration and quality-assurance procedures on the equipment used. You will be expected to build your patient-centred professional practice and practise safely in the workplace, seeking advice and referring as appropriate to the scope of their own practice.

Additional information

It is suggested that learners will have completed the following units:

- **Level 3 – *Unit 101: Measuring Ankle Brachial Pressure Index (ABPI)***

or have appropriate experience before completing this unit.

AC1.3 includes:

- the normal effect of exercise on lower limb blood flow
- the physiological effect of exercise on the:
  - cardiovascular system
  - respiratory system
  - musculoskeletal system.

AC2.5 includes:

- intermittent claudication
- diabetes
- atherosclerosis
- arterial thrombus
- aneurysmal disease.

AC2.10 includes the effect of exercise on patients with peripheral arterial disease.

AC3.2 includes:

- patient's resting ABPI is calcified
- patient unable to perform exercise test adequately
- test may not pick up short proximal stenosis
- unable to do exercise using toe pressures.

AC4.1 includes:

- treadmill
- timed walk
- dorsal flexion device attached to couch.

AC4.2 includes:

- the reasons for stopping the exercise test
- importance of stopping the test when the patient indicates
- stopping immediately if the patient complains of:
    - chest pain
    - dizziness
    - unsteadiness.

AC4.3 includes:

- provocation of angina and/or arrhythmia.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the normal anatomy and physiology of the blood supply to the lower limbs	1.1	Explain the structure and function of the arterial and venous blood vessels supplying the lower limbs			
		1.2	Explain the structure and function of the lymphatic system in the lower limbs			
		1.3	Explain the physiological changes that occur on exercise and the effect on lower limb blood flow and ankle-brachial pressure index			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the pathological changes associated with peripheral arterial disease	2.1	Explain the term peripheral arterial disease			
		2.2	Explain the pathological changes associated with peripheral arterial disease in patients with and without diabetes			
		2.3	Explain the terms sensitivity and specificity of investigations			
		2.4	Explain the conditions that may reduce the diagnostic accuracy of the ankle-brachial pressure			
		2.5	Discuss the common conditions that may result in an ankle-brachial pressure index below normal values			
		2.6	Know conditions that may increase the ankle-brachial pressure index above normal values			
		2.7	Explain the common risk factors for developing peripheral arterial disease			
		2.8	Explain how the ankle-brachial pressure index contributes to the assessment of cardiovascular risk			
		2.9	Explain the non-pharmacological measures that can be taken to reduce the risk of peripheral arterial disease			
		2.10	Discuss how peripheral arterial disease can impact on quality of life			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the principles, indications and contraindications for measuring ankle-brachial pressure index at pre and post exercise	3.1	Explain the indications and contraindications for measuring ankle brachial pressure index pre and post exercise			
		3.2	Explain the limitations of the measurement of ankle-brachial pressure index on exercise			
		3.3	Explain the derivation of the normal values for ankle-brachial pressure index and the effect of exercise in normal subjects			
		3.4	Explain the principles of a continuous wave hand-held ultrasound unit			
		3.5	Explain the principles of systolic blood pressure measurement as part of the measurement of ankle-brachial pressure index			
		3.6	Evaluate the potential errors when measuring ankle-brachial pressure index and the impact on the outcome of the investigation			
		3.7	Explain how to choose the appropriate probe for each patient			
		3.8	Evaluate the Standard Operating Procedure for measuring ankle-brachial pressure index at rest and on exercise			
4	Be able to perform post-exercise measurements of ankle-brachial pressure index	4.1	Explain the range of exercise methods available and the protocol used in own area of work			
		4.2	Support the patient performing the exercise protocol stopping the test according to the protocol			
		4.3	Explain the potential complications of exercise on the patient			
		4.4	Measure the ankle-brachial pressure index following a period of exercise			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to clean and decontaminate equipment, and leave in a suitable condition for reuse	5.1	Evaluate the protocols for cleaning and decontaminating equipment used to record ABPI at rest and post exercise			
		5.2	Decontaminate equipment, leaving it in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 103: Scientific Basis of Physical Sciences: Mathematics, Statistics and Informatics

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will gain the understanding of mathematics, statistics and informatics needed to work within physical sciences. You will be expected to apply and contextualise your knowledge and skills by performing routine technical skills and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1 must include an explanation of each of the three topics (mathematics, statistics and informatics):

- data sharing and the role of the patient in informed consent
- legal and ethical issues associated with:
  - information security and governance
  - safeguarding personal data
  - confidentiality
  - privacy.

AC1.4 includes:

- networking of medical devices
- effective system management
- patient safety and confidentiality
- patient consent for use of data.

AC2.1 to 2.2 – learners should be able to select the most appropriate technique to analyse data and information and use spreadsheets, databases and presentation software. The range of mathematical and statistical techniques used in physical sciences that should be covered include:

- numerical representation and scientific calculator use: standard form, negative numbers, percentages, accuracy and precision, conversion of units of measure
- algebra: review of basic concepts
- graphs: linear and non-linear graphs in the x-y plane, plotting a graph of the function, solving equations using graphs, solving simultaneous equations graphically
- logarithmic expressions: indices, laws of indices, laws of logs, combinations of logs, natural logs and base 10 logs, solving equations with logarithms, properties and graph of ln and log function
- angles and trigonometry: degrees, radians, trigonometry ratios (sine, cosine, tangent), solving trigonometric equations, maxima and minima, graphs and waves generated by trigonometry
- exponential functions: exponential expressions, exponential function and its graph, solving equations involving exponential terms using a graphical method
- determinants, matrices and vectors
- differentiation: gradient function, rules for differentiation, higher derivatives, maximums, minimums, points of inflection, differentiation of sums, differentiation of differences
- advanced differentiation: products, quotients, exponential functions, logarithmic functions, function of a function
- indefinite integration: indefinite integration, some rules for indefinite integration, constant of integration
- definite integration: areas under curves, areas bounded by lines and curves, finding areas where some or all lie below the x-axis
- types of data: discrete and continuous data
- summarising data graphically: dot plot, stem and leaf, box and whisker, grouped frequency distribution, histogram, cumulative frequency distribution, cumulative frequency polygon, bar chart, one and two
- summarising data numerically: mean, median, mode, samples, when to use various averages, standard deviation, error, interquartile range, box and whisker plots, variance, range, measures of skewness
- normal distribution: mean, standard deviation, areas under the curve, standard normal transformation, solution of problems
- simple probability
- samples and population distributions: reasons for sampling sample size, random sampling, biased sampling, quota sampling, systematic sampling and stratified sampling, relationship to normal distribution, primary and secondary data

- basic set theory for database application of one-to-one and one-to-many application:
    - the basic principles of databases
    - the basic principles of spreadsheets
    - creating a database
    - interrogating a database and producing reports
    - evaluating and amending a database
    - interpreting data using spreadsheet software
    - present data using spreadsheet software
    - using data securely, respecting confidentiality and maintaining consent in the use of data
    - identifying potential errors in data analysis and how these can be minimised
    - identifying potential errors in data interpretation and how these can be minimised.

AC2.3 includes applying the knowledge and skills gained in 2.1 and 2.2:

- the principles of data presentation, effective choice and use of data presentation methods
- selection and use of presentation software
- creation of a short presentation applying appropriate techniques
- effective use of visual aids
- delivering the presentation
- obtaining feedback from peers
- critical reflection.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the application of mathematics, statistics and informatics in physical science	1.1	Explain how mathematics, statistics and informatics are applied in own area of practice within physical sciences			
		1.2	Evaluate processes to maintain data security and confidentiality in own area of work			
		1.3	Analyse the reporting process for breaches in data security and confidentiality			
		1.4	Discuss the essential issues associated with computing technologies and their management in physical sciences			
2	Be able to manipulate, analyse and present technical and clinical information	2.1	Analyse technical and clinical data within a work-based context			
		2.2	Present technical and clinical information appropriately, using spreadsheets, databases and presentation software			
		2.3	Solve problems by applying appropriate mathematical and statistical techniques			
		2.4	Use data securely, respecting confidentiality and maintaining consent in the use of data			
		2.5	Present data appropriately and communicate effectively			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 104: Scientific Basis of Engineering: Electrical and Basic Electronics

Level:	**4**
Unit type:	**Optional**
Credit value:	**15**
Guided learning hours:	**120**

Unit summary

In this unit, you will gain a working knowledge of essential engineering electronics as applied to the field of clinical engineering. You will be expected to apply and contextualise your knowledge and skills by performing routine technical skills and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1 includes:

- concepts of electricity and magnetism, structures of matter and its properties
- SI units and laws associated with electrical and electronic engineering
- conductors and insulators
- semiconductor theory.

AC1.2 includes:

- power supply systems and the principles that underpin them
- earth bonding and electrical safety and the principles that underpin them
- the risks to the human body from external energy sources associated with the equipment being serviced.

AC1.3 includes:

- analogue and digital electronic components
- circuits and systems
- typical transducers used in medical equipment
- amplifier circuits for linear applications
- amplifier circuits for non-linear applications
- circuit components and associated symbols

- elementary analogue circuits:
    - resistive
    - capacitive and inductive
    - oscillators
    - amplifiers, including op amps
    - power amplifiers
    - power circuits, including transformers
- basic transducer theory
- thermocouple, bridges, etc.

AC1.4 includes:

- noise
- bandwidth
- impedance.

AC1.6 includes signal processing and manipulation:

- signal conditioning:
    - amplification
    - filtering
    - clipping
    - modulation
- signal sampling:
    - simple sample-and-hold/track-and-hold devices
- analogue-to-digital and digital-to-analogue converters
- voltage-to-frequency and frequency-to-voltage converters
- signal isolation principles
- analogue line drivers and receivers.

AC1.5 includes elementary digital systems:

- logic theory
- digital circuits, functions
- programmable devices
- microprocessor/microcontroller
- interfacing with microprocessor/microcontroller
- programming of microprocessor/microcontroller
- application to simple control problems
- communication principles:
    - serial
    - parallel
    - Bluetooth®
    - Wi-Fi.

AC1.7 includes:

- signal processing
- signal manipulation
- the basic principles of interfacing a device to a microprocessor or programmable device.

AC2.2 includes:

- planning a simple device programme
- writing a very simple microprocessor/programmable device programme
- testing the programme
- completing the required documentation.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the scientific basis of electrical and basic electronics underpinning clinical engineering	1.1	Explain the basic laws that underpin electricity and magnetism			
		1.2	Explain the principles of power supply systems, earth bonding and electrical safety			
		1.3	Explain the principles of analogue and digital electronic components, circuits and systems			
		1.4	Evaluate how a range of factors can influence signal quality			
		1.5	Explain the principles of signal processing and signal manipulation			
		1.6	Explain the basic principles of interfacing a device to a microprocessor or programmable device			
		1.7	Describe the architecture of microprocessors and programmable devices			
2	Be able to write a basic microprocessor/ programmable device programme	2.1	Explain the steps that have to be taken to ensure compliance with security, governance and ethics			
		2.2	Write a basic microprocessor/programmable device programme for a clinical engineering purpose			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to interpret basic circuit diagrams, recognising some common configurations	3.1	Interpret basic circuit diagrams			
		3.2	Explain some common circuit configurations			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 105: Scientific Basis of Engineering: Basic Mechanics

Level:	**4**
Unit type:	**Optional**
Credit value:	**15**
Guided learning hours:	**120**

Unit summary

In this unit, you will gain a working knowledge of essential engineering mechanics as applied to the field of clinical engineering. You will be expected to apply and contextualise your knowledge and skills, performing routine technical procedures and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1 includes:

- fundamental concepts; units of measurements; International System of Units (SI); numerical calculations
- force, mass and acceleration
- work, energy and power.

AC1.2 includes:

- effects of force on materials
- moments:
    - equilibrium of a particle
    - free body diagram
    - force system resultants
    - principle of moments
    - moment of a force
    - moment of a couple
    - resultant forces and couples
    - equilibrium of planar system of forces
    - graphical and analytical method

- internal forces:
    - shear and moments
    - relation between distributed load
    - shear and moment
    - stress and strain
    - tensile and compressive stress and strain
    - factor of safety
- Hooke's law and elastic constants
- friction:
    - dry friction
    - frictional forces on screws, belts and bearing
    - rolling resistance
    - lubrication
- moment of area:
    - first and second moments
    - polar second moment of area
    - centroids
    - theorem of perpendicular axis
- bending of beams:
    - stresses due to bending
    - neutral axis
    - radius of curvature
    - moment of resistance
    - general bending formula
    - principles of finite element analysis
- torsion of shafts:
    - stresses due to top twisting, angle of twist, general torsion formula, power and work.

AC1.3 includes:

- explanation of the term simple harmonic motion
- identification of examples of the application of simple harmonic motion in clinical engineering.

AC1.4 includes:

- safe working practice applied to basic mechanical processes
- quality standards
- quality management
- quality assurance
- Standard Operating Procedures (SOPs)
- audit
- service accreditation.

AC1.5 includes:

- areas where clinical engineering could be developed to enhance the care offered to patients
- how effective patient-healthcare staff operate in clinical engineering

AC2.2 should include the criteria for selecting tools to perform basic mechanical tasks.

AC5.2 could include volume flow rate, mass flow rate, input and output flow velocities, input and output diameters, continuity of volume and mass for incompressible fluid flow.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the scientific basis of mechanics underpinning clinical engineering	1.1	Explain the fundamental principles of applied mechanics			
		1.2	Explain how a range of simple machines use a single applied force to do work against a single load force			
		1.3	Evaluate the mechanisms that underpin the delivery of a safe, quality-assured clinical engineering service			
		1.4	Evaluate the impact of Clinical Engineering services on patients and patient care pathways			
		1.5	Analyse critical incidents that impact on patient care and where actions have resulted in safer care			
2	Be able to perform basic mechanical tasks	2.1	Solve basic mechanical problems using the application of force			
		2.2	Select appropriate tools to perform basic mechanical tasks			
3	Be able to determine the operating characteristics of lifting machines	3.1	Explain various types of lifting machines and their characteristics			
		3.2	Explain parameters of lifting machines like kinetic parameters, dynamic parameters			
		3.3	Identify types of lifting machines used in a healthcare environment and discuss their characteristics			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Understand how to determine the stress in structural members and joints	4.1	Explain structural members and joints in relation to medical equipment			
		4.2	Explain single and double shear joints, fastening and joint parameters			
5	Understand how to determine the parameters of fluid systems	5.1	Explain various types of fluid systems used in healthcare			
		5.2	Explain flow characteristics of a gradually tapering pipe			
		5.3	Discuss effects of fluid dynamics and fluid characteristics on medical devices like infusion pumps, dialysis equipment etc.			
6	Understand how to determine the characteristics of simple harmonic motion in engineering systems	6.1	Explain simple harmonic motion in terms of the action of forces			
		6.2	Explain vibrating mechanical systems and use medical devices as examples			
		6.3	Explain the generation of simple harmonic motion and application to mechanical systems			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 106: Scientific Basis of Medical Physics

Level: 4

Unit type: Optional

Credit value: 30

Guided learning hours: 240

Unit summary

In this unit, you will gain the understanding of the breadth of the application of science within medical physics technology, the underpinning radiation physics and you will be able to work safely within the medical physics environment in a hospital. You will be expected to apply and contextualise your knowledge and skills by performing routine technical skills and developing and building your professional practice in accordance with Good Scientific Practice.

Additional information

AC1.1 includes:

- the basic laws that underpin electricity and magnetism
- sources of radiation and their physical properties
- physical properties of radiation.

AC1.2 includes:

- interactions of radiation with matter
- radiation quality – half-value layer (HVL) and tenth-value layer (TVL), quality index
- attenuation, absorption and scatter (photo-electric, Compton scatter and pair production)
- exponential attenuation of monoenergetic photons
- electron scattering and bremsstrahlung
- ionisation and excitation
- electron range and energy
- inverse square law
- filters and filtration
- effects of electron and photon energy, absorber density and atomic number tissue equivalent materials.

AC1.3 includes:

- basic ionising radiation protection
- international and national legislation, guidance, standards and recommendations
- hospital organisation of radiological protection: radiation safety policy, local rules
- designation of areas
- classification of persons
- roles and responsibilities of staff, including duty holders
- as low as reasonably practicable (ALARP)
- basic principles of dose limitation: time, distance, shielding
- radiation protection of public and staff
- radiation protection of patients
- transportation of radioactive materials
- administration of radionuclides
- high-activity materials
- disposal of radioactive materials
- personnel and environmental dose monitoring.

Learning outcome 2 includes:

- the sources of radiation and their physical properties
- the physical properties of radiation
- atomic structure and radioactive decay
- atomic and nuclear structure, mass number, atomic number, isotopes
- mechanisms of radioactive decay
- alpha, beta and gamma radiation
- half-life, mean life, physical half-life
- decay schemes and energy level diagrams
- the units of activity
- specific activity, radioactive concentration.

AC2.1 includes:

- the types of radiation
- the basic equipment and clinical applications of each type of radiation, to include diagnosis and therapy
- introduction to ionising radiation equipment in medical physics
- radiation detectors
- gamma camera and single-photon emission computed tomography (SPECT)
- basic diagnostic x-ray equipment
- computed tomography (CT)
- SPECT-CT

- positron emission tomography (PET) and PET/CT
- accelerator
- orthovoltage (kV) radiotherapy unit
- radiotherapy treatment planning system (TPS)
- brachytherapy after-loaders
- cyclotron
- production of x-rays
- general principles
- electromagnetic spectrum
- production of x-rays (low to megavoltage)
- x-ray tubes
- linear accelerators.

AC4.1 includes:

- diagnostics
- therapeutics
- the equipment life cycle
- innovation and service development.

AC4.2 includes the role of a medical physics healthcare science associate in radiotherapy:

- mould room
- treatment planning
- quality assurance
- quality control

the role of a medical physics healthcare science associate in nuclear medicine:

- radiopharmacy
- scanning
- radionuclide therapy

the role of a medical physics healthcare science associate in radiation protection:

- room surveys
- quality assurance
- quality control
- environmental monitoring
- personnel monitoring
- sealed sources
- unsealed sources.

AC4.3 includes:

- the patient pathway and within the wider context of healthcare.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand core principles of medical physics	1.1	Explain, using the correct scientific terminology, the core principles of medical physics			
		1.2	Explain the interactions of radiation with matter			
		1.3	Evaluate the principles of radiation protection in a medical physics setting			
2	Understand the biological effects and measurement of radiation	2.1	Explain the basic equipment to generate radiation and the clinical applications of radiation			
		2.2	Explain the biological effects of each type of radiation			
		2.3	Explain how each type of radiation is measured			
		2.4	Explain the possible health effects of each type of radiation			
3	Understand the procedures and need for evaluation of adverse incidents	3.1	Explain the procedure for identifying and reporting adverse incidents			
		3.2	Discuss the need for evaluation of adverse incidents			
		3.3	Discuss the potential impact of adverse incidents on patients, carers and healthcare professionals			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Understand the key roles of a healthcare science associate in medical physics	4.1	Explain the key roles of medical physics services			
		4.2	Explain the key role of a healthcare science associate in medical physics			
		4.3	Evaluate the impact of medical physics services on patients and the patient care pathway			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 107: Clinical Engineering Workshop Skills

Level: 4

Unit type: Optional

Credit value: 4

Guided learning hours: 32

Unit summary

In this unit, you will develop a range of engineering workshop knowledge and skills. You will be expected to develop your professional practice as you build your competence in the workplace.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

AC5.1: to include cables, switches, sensors, hoses, batteries, valves, pumps.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the practice of engineering in the clinical context, including good workshop practice requirements and undertaking workshop skills	1.1	Explain the range of workshop skills required in own area of work			
		1.2	Explain the health and safety requirements of working in a workshop			
		1.3	Explain how good workshop practice supports health, safety and quality in a workshop			
		1.4	Explain the management of a workshop			
		1.5	Explain the practice of engineering and the vocabulary typically used in engineering			
		1.6	Describe the scope of practice of clinical engineering			
		1.7	Explain how to manage own time and prioritisation of own workload effectively			
2	Be able to use workshop tools	2.1	Use hand tools to perform routine tasks			
		2.2	Use power tools to perform routine tasks			
		2.3	Explain examples of use of common power tools and the associated risks			
3	Be able to perform soldering techniques	3.1	Perform basic soldering techniques			
		3.2	Perform flow/surface mount soldering techniques			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to use test equipment	4.1	Use test equipment to measure current, voltage and resistance			
		4.2	Use bench test equipment, such as oscilloscopes, signal generators, medical equipment simulators, flow and press measuring devices			
		4.3	Use power supplies			
		4.4	Use equipment for assessing the electrical safety of equipment			
5	Be able to remove and replace/refit a range of components	5.1	Remove, replace or refit a range of components			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 108: The Medical Equipment Lifecycle

Level: 4

Unit type: Optional

Credit value: 6

Guided learning hours: 48

Unit summary

In this unit, you will acquire the knowledge and skills associated with the medical equipment lifecycle and medical equipment management system in own area of practice, together with practical application of appropriate engineering workshop skills. You will be expected to develop your professional practice as you build your competence in the workplace.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

AC1.3 could include:

- ISO 9001 – Quality management
- ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes
- BS 70000:2017 Medical physics, clinical engineering and associated scientific services in healthcare.

AC1.5 should include an explanation for **two** items of medical equipment.

AC2.1 includes:

- purpose
- use
- data security
- governance.

AC2.6 includes:

- internal quality control and internal quality management
- external quality control and external quality management.

LO3 should refer to the relevant service's medical device management system (MDMS) and its taxonomy.

AC3.2 includes:

- raise a service request for a range of lifecycle management activities
- extract information on job progress
- produce information reports for users from medical device management systems.

AC3.5 – GS1 DataBar (formerly known as RSS or Reduced Space Symbology) is a bar code symbology that was formally adopted by the global supply chain in January 2011.

AC3.6 includes:

- planned preventive maintenance
- repair
- calibration
- decontamination
- decommissioning etc.

AC4.1 includes:

- the need to develop and evaluate basic specifications to meet user and service requirements.

AC4.2 includes:

- pre-purchase
- assessment of need
- defining or evaluation of specification
- relevant standards
- compliance with legislation
- identification of suitable equipment
- application of risk management to selection
- purchase
- purchasing processes
- purchasing authority.

AC6.1 includes:

- the need to ensure that all legislation is up to date.

AC7.3 includes:

- handling of non-conforming products
- quality improvement suggestions.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the medical equipment lifecycle and its use	1.1	Explain each stage of the equipment management lifecycle and how it integrates with the wider medical device management policy and patient safety measures			
		1.2	Discuss how the medical equipment lifecycle is implemented in healthcare settings			
		1.3	Explain how quality assurance and quality management systems support the provision of high-quality, safe services in healthcare			
		1.4	Explain the importance of control of infection and decontamination within the equipment management lifecycle			
		1.5	Explain how items of medical equipment within own area of practice contribute to the care and treatment of the patient			
		1.6	Explain how the medical equipment lifecycle underpins safe and effective patient care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the process of medical equipment management	2.1	Explain how the medical equipment management policy applies in own area of work			
		2.2	Describe the purpose of the medical device information system			
		2.3	Know the current national recommendations and best practice relating to medical equipment management within the UK			
		2.4	Explain the policies for the handling of loan devices introduced into own area of practice			
		2.5	Explain how patient safety is ensured during the use of loan equipment, including the purpose of indemnity insurance for loan equipment			
		2.6	Discuss local quality management systems			
		2.7	Explain the role of internal audit			
		2.8	Explain the approach to the handling of safety alerts in own area of work			
		2.9	Know the processes and regulations relating to the safe decommissioning and disposal of medical equipment			
		2.10	Explain the process for responding to Medicines and Healthcare Products Regulatory Agency (MHRA) medical equipment alerts			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to operate medical device management systems (MDMS) and quality management systems (QMS) to support all aspects of equipment management activities	3.1	Discuss how MDMS and inventories, including asset registers, are used in practice			
		3.2	Explain key activities using the MDMS			
		3.3	Explain the role of Medical Device Tracking (Radio Frequency Identification/Real Time Locating System systems)			
		3.4	Explain the Medical Device Nomenclatures			
		3.5	Explain the purpose of bar coding and GS1 Data Bar			
		3.6	Add information to the MDMS			
		3.7	Maintain data integrity and security on the MDMS			
		3.8	Produce routine reports in line with local procedures			
4	Understand the process for the procurement of medical equipment	4.1	Discuss the procurement process for medical equipment that helps to ensure the equipment is fit for purpose			
		4.2	Explain the stages in the pre-purchase and purchase process			
5	Be able to assist in the procurement of medical equipment	5.1	Assist in the delivery and checking of equipment, accessories, or consumables following the procurement procedures			
		5.2	Complete the required documentation in line with local procedures			
		5.3	Explain the order authorisation and submission processes			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to assist in the management of rental and loan equipment	6.1	Evaluate the standard operating procedures for the management of rental and loan equipment, including an awareness of the Department of Health national Master Indemnity Agreement (MIA) scheme and the Health Research Authority role with medical devices involved in research			
		6.2	Select the appropriate indemnity form and NHS delivery form to be completed for given circumstances			
		6.3	Use information from the MIA register of suppliers appropriately			
		6.4	Use record systems to determine equipment on rental or loan and rental/loan period that applies			
		6.5	Use record systems to determine the responsibilities of the organisation with regard to rental/loan equipment			
7	Be able to perform quality-assurance tasks	7.1	Explain the procedures that underpin the safe and quality assured use of equipment			
		7.2	Perform quality-assurance tasks, following specified procedures			
		7.3	Explain issues that could affect the clinical performance of equipment			
		7.4	Explain how to resolve and escalate issues that can affect the clinical performance of equipment			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 109: Acceptance Testing of New Medical Equipment

Level:	**4**
Unit type:	**Optional**
Credit value:	**6**
Guided learning hours:	**48**

Unit summary

In this unit, you will acquire the knowledge of the acceptance process for new medical equipment within the equipment lifecycle and be able to perform acceptance and safety testing on a defined range of new medical equipment within own area of practice, together with the practical application of appropriate engineering workshop skills. You will be expected to build your professional practice as you build your competence in the workplace.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

AC1.3: the stages of acceptance are:

- visual inspections
- electrical safety testing
- mechanical safety testing
- test equipment
- functional testing
- purpose of measurements
- performing measurements
- assessing results.

AC2.6 includes:

- model
- serial number
- CE mark
- electrical type and classification etc.

AC4.11 includes:

- demonstrating the effect of multiple earth paths on medical systems and selecting earth bonding points.

AC4.12 includes:

- voltmeter
- ammeter
- voltage source.

AC5.2 includes:

- static calibrations of blood pressure monitors
- flow rate accuracy of infusion devices
- checking all controls work on hospital beds, to include operation of the patient and nurse handset
- using an ECG simulator to check that monitors recognise normal and abnormal rhythms, and alarm features function according to configuration
- functioning of gas-powered devices such as oxygen flow meters.

AC5.1 includes:

- other means or apparatus, e.g.:
    - comparing the device with a similar device that has been calibrated to verify the performance against a similar model that is not test equipment
    - use of physical measures such as volume of fluid delivered into a burette
    - test equipment could include the burette or powered laboratory equipment.

AC7.5 includes:

- the maintenance of stock levels
- goods inwards processes
- customer supplied product.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand how new medical equipment is introduced into own area of work	1.1	Explain the stages of acceptance and safety testing of new medical equipment			
		1.2	Explain the importance of visual inspections			
		1.3	Discuss the purpose of each stage of acceptance and safety testing of new medical equipment			
2	Be able to inspect new medical equipment	2.1	Examine the packaging for damage			
		2.2	Discuss how to deal with problems identified			
		2.3	Collect appropriate information from packaging and delivery notes, comparing it against the initial order and recording collected information			
		2.4	Unpack equipment in a safe manner			
		2.5	Confirm all items are as per the delivery note and the original order			
		2.6	Examine equipment, cables, accessories and consumables for damage, ensuring the equipment has appropriate markings			
		2.7	Complete acceptance documentation, collecting all relevant information for the equipment management system			
		2.8	Update the equipment management system			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to assemble equipment and fit any consumables according to instructions	3.1	Assemble equipment correctly, verifying performance against agreed operating procedures			
		3.2	Fit any consumables according to the instructions			
		3.3	Record quantifiable and objective evidence of device performance to a standard that can be discussed with senior colleagues			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to perform safety testing of new medical equipment in accordance with Standard Operating Procedures (SOPs)	4.1	Evaluate the SOP for electrical and mechanical safety testing			
		4.2	Apply the SOP for electrical and mechanical safety testing			
		4.3	Select suitable test and simulation equipment			
		4.4	Apply the appropriate standards and limits for the equipment under test			
		4.5	Perform a full range of visual inspections on the equipment			
		4.6	Operate a range of test and simulation equipment			
		4.7	Operate a medical grade portable appliance tester			
		4.8	Perform appropriate electrical safety test procedures, following manufacturer or locally agreed SOPs/protocols			
		4.9	Make appropriate measurements on equipment with multiple patient connections			
		4.10	Make safety measurements using discrete test equipment			
		4.11	Compare the use of a manual and automatic electro-medical test			
		4.12	Confirm the programmable features of the specialist equipment with the agreed equipment set-up			
		4.13	Perform appropriate mechanical safety test procedures, following manufacturer or locally agreed SOPs/protocols			
		4.14	Explain anomalous results that occur as part of testing processes			
		4.15	Complete all records in line with local procedures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to perform calibration or set up procedures and functional tests on new equipment in accordance with Standard Operating Procedures (SOPs)	5.1	Check the calibration of the equipment by confirming that the input or output is within the specification using test equipment or other means or apparatus			
		5.2	Perform appropriate functional tests where necessary, following manufacturer or locally agreed SOPs/protocols			
		5.3	Record clear and unambiguous information, including test results, according to the local SOPs/protocols			
6	Be able to store the equipment and consumables correctly	6.1	Communicate with the equipment user as required			
		6.2	Store the equipment correctly to ensure the equipment remains fit for purpose and ready for use			
		6.3	Store the consumables correctly to ensure the equipment remains fit for purpose and ready for use			
7	Be able to operate stock control systems	7.1	Explain the importance of maintaining adequate stock levels, including the potential impact on patients and healthcare			
		7.2	Explain the purchasing process in own area of practice, including purchasing authority			
		7.3	Operate stock control systems in own area of practice			
		7.4	Purchase spares and consumables within own area of practice			
		7.5	Participate in the management of spares and consumables			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 110: Planned Preventative Maintenance

Level:	**4**
Unit type:	**Optional**
Credit value:	**4**
Guided learning hours:	**36**

Unit summary

In this unit, you will acquire the knowledge of the purpose and process for planned preventative maintenance and be able to plan for, perform and record planned preventative maintenance tasks for a defined range of equipment within own area of practice, together with the practical application of appropriate engineering workshop skills. You will be expected to build your professional practice as you develop your competence in the workplace.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

AC1.1 includes:

- transducers involved
- simple block diagram of the equipment.

AC1.6: terminology could include/be related to:

- health and safety related legislation
- metrology terminology
- fundamental energy units
- medical device management system (MDMS) taxonomy covering assets and the organisation
- prevailing medical device management guidance, e.g. Managing Medical Devices (2005) published by Medicines and Healthcare products Regulatory Agency (MHRA).

AC1.7 includes:

- urgency
- time
- impact on services
- availability of other equipment.

AC2.4 includes identification, removal and renewing, refitting.

AC3.1 includes:

- working environment
- equipment in use
- materials and substances
- working practices that do not follow Standard Operating Procedures.

AC4.4 includes:

- multi-parameter monitors or writers, e.g.:
  - ECG monitor
  - ECG recorder
- the effect of poor electrode connections or application
- the effect of interference due to cable placement
- poor transducer placement or interface, e.g.:
  - SpO_2 monitor
  - temperature sensors
  - automatic blood pressure devices
- hazards associated with infusion devices, e.g.:
  - siphonage
  - free flow
  - occlusion
  - mechanical backlash
  - air in line
  - tampering
  - incorrect software set-up
  - incorrect consumables
- poor user maintenance, e.g.:
  - battery (e.g. life, connections, installation)
  - contamination (e.g. suction devices, tympanic sensors)
- patient movement.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the engineering principles on which the medical equipment operation is based	1.1	Explain the principles of equipment operation			
		1.2	Explain how to access manufacturer's support information such as operators and technical manuals			
		1.3	Describe the typical consumables and replacement parts used for planned preventative maintenance			
		1.4	Discuss the risks associated with equipment operation during clinical use, maintenance or testing			
		1.5	Explain the process for accessing tools and test equipment for maintenance activities			
		1.6	Know the engineering terminology and equipment management taxonomy of the medical device management system (MDMS) relevant to own area of practice			
		1.7	Explain the factors affecting decisions on maintenance activity			
		1.8	Explain the actions to take when a piece of equipment cannot be located for planned preventative maintenance (PPM)			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to prepare for planned preventative maintenance (PPM)	2.1	Prepare PPM, estimating the time and resources needed			
		2.2	Assess the potential impact of PPM on clinical service delivery			
		2.3	Interpret technical documentation in order to perform PPM successfully			
		2.4	Assess literature and service record to ensure there are no outstanding field service or central alerting system notices for the equipment			
		2.5	Deal with consumables as necessary when performing a PPM, adhering to infection prevention control techniques			
		2.6	Select correct tools and test equipment			
3	Be able to perform planned preventative maintenance procedures on a defined range of medical equipment in accordance with Standard Operating Procedures (SOPs)	3.1	Identify the hazards and risks associated with maintenance activities			
		3.2	Perform planned preventative maintenance following the appropriate protocol for the equipment under test			
		3.3	Dismantle and reassemble the equipment to module/component level			
		3.4	Explain the equipment component parts indicating their purpose			
		3.5	Adjust the settings to those previously agreed necessary for use in the clinical setting			
		3.6	Perform any appropriate electrical or mechanical safety testing procedures following manufacturer and local SOPs			
		3.7	Perform any appropriate functional tests, following manufacturer and locally agreed SOPs			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to complete the planned preventative maintenance process	4.1	Use written and electronic information processes and systems to record clear and unambiguous information relating to the planned preventative maintenance			
		4.2	Store equipment and consumables correctly to ensure the equipment and consumables remain fit for purpose and ready for use			
		4.3	Perform handover of equipment back into clinical service			
		4.4	Discuss sources of interference on a range of equipment and situations and the methods used to prevent them			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 111: Diagnosing and Rectifying Equipment Faults

Level: 4

Unit type: Optional

Credit value: 4

Guided learning hours: 32

Unit summary

In this unit, you will acquire the knowledge and skills to diagnose faults within medical equipment and systems and you will be able to apply appropriate engineering workshop skills. You will be able to work safely when diagnosing and rectifying equipment faults across a defined range of equipment, selecting and using appropriate methods and processes. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop the skills to promote continuous professional development.

Additional information

All procedures must be undertaken in accordance with the quality management system Standard Operating Procedures (SOPs), organisational polices and prevailing legislation.

Learning outcome 1: to include power supply-related, specification or range errors, rectification of physical damage.

Learners should select **three** medical devices, each from a different 'type of medical equipment' category, from the table below, as appropriate to the needs of their department:

Types of medical equipment	Medical devices
Beds and electromechanical equipment	• Wheelchairs (including, scooters) • Patient trolleys • Stair lifts; hoists; seating systems • Walking aids; commodes; bathing equipment; patient trollies • Adjustable beds; pressure redistribution and relief devices • Other specific AT equipment

Types of medical equipment	Medical devices
Cardiovascular equipment	• Blood pressure devices (excluding mercury sphygmomanometer) • Pulse oximeters; electrocardiography (ECG) machines; external temporary pacemaker box
Physiological monitoring	• Foetal heart monitoring devices • Apnoea devices • Physiological monitoring equipment • Ophthalmoscopes • Thermometers
Infusion equipment	• Infusion pumps • Syringe drivers • Patient controlled analgesia • Feeding pumps (including breast pump)
Therapeutic equipment	• Phototherapy devices • Radiant heater warmers • Oxygen delivery and monitoring devices
Resuscitation equipment	• Defibrillators • Suction equipment for airway clearance • Oxygen equipment – pipeline and cylinders • Capnography • Miscellaneous equipment, e.g. laryngoscopes, intraosseous drills
Operating theatre and surgical equipment	• Tourniquet devices • Gas monitoring devices; flow and pressure gauges • Surgical lighting equipment/examination lamps • Pneumatic drilling/sawing devices • Blood warmers; patient warmers; operating tables; patient beds
Therapeutic equipment	• Nerve stimulating devices • Nebulisers; continuous positive airway pressure devices • Interferential therapy devices; therapeutic ultrasound devices • Traction devices; heater lamps; exercise equipment
Laboratory equipment	• Centrifuges; coulter counters; particle counters • Blood and gas analysers; ion selective analysers • Flame photometers; chloride meters; pH meters • Spectrophotometers; roller beds; colorimeters

Types of medical equipment	Medical devices
Dental equipment	• Suction units; drilling units; dental air compressors • Descalers; dental hand pieces; polymerisation units • Floor utility service units; dental lighting • Amalgamators; amalgam separators
Renal equipment	• Haemodialysis machines; haemofiltration machines • Reverse osmosis units; water treatment plants • Water quality equipment; patency monitoring
Non-ionising radiation	• MRI scanners • Lasers • Optical light sources
Ionising radiation equipment **Imaging and therapeutic equipment**	Imaging equipment: • diagnostic x-ray • nuclear medicine • CT scanners Radiotherapy equipment: • linear accelerators • radiation monitoring equipment • mould room

AC1.1 includes:

- Control of Substances Hazardous to Health (COSHH) Regulations 2002
- personal protective equipment (PPE)
- Health and Safety at Work etc Act 1974
- Standard Operating Procedures.

AC1.2 includes:

- obtaining and using correct documentation:
  - company and/or manufacturer's drawings
  - maintenance documentation
- ensuring equipment has been decontaminated before and after the fault-diagnostic activities
- ensuring the safe isolation of equipment, including:
  - mechanical
  - electrical
  - gas
  - air
  - fluids
- providing and maintaining safe access and working arrangements for the maintenance area.

AC1.5 includes:

- inspection of equipment (such as breakages, wear/deterioration, signs of overheating, missing parts, loose fittings)
- operation (such as manual switching off and on, automatic switching/timing/sequencing, outputs)
- measurement (such as voltage, current, continuity, logic state, noise, frequency, signal shape and level)
- disconnecting or isolating components, or parts of circuits when appropriate, to confirm the diagnosis
- applying electrostatic discharge (ESD) protection procedures when handling sensitive components and circuit boards where appropriate
- identifying the fault and determine the appropriate corrective action
- completing the fault diagnosis within the agreed time and informing the appropriate people when this cannot be achieved.

AC1.8 includes:

- sight
- sound
- smell
- touch.

AC2.1 to include two of the following:

- six-point technique
- emergent sequence
- input/output technique
- half-split technique
- equipment self-diagnostics
- unit substitution
- function/performance testing
- injection and sampling.

AC2.2 to include four of the following:

- logic diagrams
- flow charts or algorithms
- probability charts/reports
- computer-aided test equipment
- fault analysis charts (such as fault trees)
- manufacturer's manuals
- troubleshooting guides
- electronic aids.

AC2.3 to include eight of the following:

- oscilloscope
- multimeter
- medical equipment simulators
- ammeter
- logic analyser
- logic probe
- voltmeter
- signal tracer
- signal generator
- electrical safety analyser
- special purpose testing equipment
- built-in test equipment (BITE)
- insulation resistance tester
- residual current (RCD) tester
- portable appliance tester (PAT)
- temperature measuring devices
- flow measuring devices
- pressure measuring devices.

AC2.6 includes:

- intermittent problem
- partial failure/out-of-specification output
- complete breakdown
- sources of interference and other reasons leading to degradation of equipment performance
- physical damage/missing components.

AC3.1 includes:

- step-by-step analytical report
- preventative maintenance log/report
- corrective action report
- company-specific reporting procedure
- record the outcome of the fault diagnosis
- feed back to the equipment user.

AC4.1 includes:

- prioritisation of jobs
- knowing when it is not cost effective to repair.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to diagnose different equipment faults in accordance with Standard Operating Procedures and legislation	1.1	Follow health and safety procedures and systems in place for risk assessment			
		1.2	Plan the fault diagnosis, using all available information			
		1.3	Explain the procedure to establish the background of the fault			
		1.4	Discuss the implications of the fault on the patient and healthcare services			
		1.5	Perform the fault-diagnostic activities, using approved procedures			
		1.6	Explain the importance of reporting any equipment adverse incidents to the regulatory authority			
		1.7	Explain how to analyse evidence and evaluate possible characteristics and causes of specific faults/problems			
		1.8	Explain how to evaluate sensory conditions			
		1.9	Explain how to evaluate the various types of information available for fault diagnosis			
		1.10	Explain how to prepare a report, or take follow-up action on completion of the fault diagnosis			
		1.11	Explain how to relate previous reports and records of similar fault conditions			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		1.12	Explain how to use the various aids and reports available for fault diagnosis			
		1.13	Explain the limitations of conducting physical repairs to equipment casings			
		1.14	Report on conclusion of the fault diagnosis			
2	Be able to investigate and establish the most likely causes of the faults	2.1	Collect clear information of the fault from the equipment user			
		2.2	Explain the essential information needed as part of the fault reporting process			
		2.3	Use diagnostic techniques, tools and aids to locate faults			
		2.4	Use appropriate test equipment to aid fault diagnosis			
		2.5	Establish faults in relation to breakdown categories in own area of work			
		2.6	Make valid conclusions about the nature and probable cause of the fault			
		2.7	Perform post-repair quality control procedures			
3	Be able to maintain accurate records of the outcome of the fault diagnosis	3.1	Record the outcome of the fault diagnosis following local procedures			
		3.2	Follow data protection policy and local procedures to maintain data records and confidentiality			
4	Be able to determine appropriate action and repair equipment	4.1	Set out the appropriate action to rectify the fault			
		4.2	Repair the equipment or escalate fault in accordance with local procedures			
		4.3	Record the actions taken in accordance with local procedures			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 112: Decommissioning and Disposal of Medical Equipment

Level:	**4**
Unit type:	**Optional**
Credit value:	**6**
Guided learning hours:	**48**

Unit summary

In this unit, you will acquire the knowledge and skills to diagnose faults within clinical engineering and medical physics and you will be able to apply appropriate engineering workshop skills. You will be able to work safely when decommissioning and disposing of equipment across a defined range of equipment, selecting and using appropriate methods and processes. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

AC1.5 includes:

- special waste
- clinical waste
- radioactive waste
- waste electrical and electronic equipment (WEEE)
- Restriction of hazardous substances (RoHS).

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the process of decommissioning and disposing of medical equipment	1.1	Evaluate the local procedures for decommissioning and disposal of medical equipment			
		1.2	Explain the legislation for decommissioning and disposal of medical equipment			
		1.3	Explain the decontamination techniques for medical equipment in own area of practice			
		1.4	Explain the infection control procedures for medical equipment in own area of practice			
		1.5	Explain the regulations for waste management			
2	Be able to prepare for decommissioning and disposal of medical equipment	2.1	Perform an initial risk assessment to identify any potential risks and determine the disposal process and the regulations that apply			
		2.2	Discuss routes of disposal and obtain authorisation for disposal			
		2.3	Decontaminate equipment ensuring correct local procedures/protocols are followed			
		2.4	Disable equipment following local procedures			
		2.5	Remove all data, especially confidential or identifiable data, from the equipment			
		2.6	Follow data protection policy and local procedures to maintain data records and confidentiality			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to organise decommissioning and disposal of medical equipment	3.1	Dispose of medical equipment in accordance with Standard Operating Procedures			
		3.2	Record clear and unambiguous information relating to the disposal from the equipment			
		3.3	Remove any unnecessary equipment documentation in line with local procedures			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 113: Medical Engineering in Practice

Level: 4

Unit type: Optional

Credit value: 15

Guided learning hours: 120

Unit summary

In this unit, you will develop the knowledge and skills to work as a healthcare science associate within a clinical engineering department working in medical engineering. You will be able to work safely in the medical engineering environment. You should be able to perform a range of risk assessments and tasks within the equipment management life cycle. You will also be introduced to equipment management and quality management systems, and their use in the medical engineering environment to manage the range of equipment used within a healthcare setting. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development.

All learners must complete all generic health and safety and mandatory training contextualised to own area of practice.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

Medical engineering covers a wide range of equipment shown in the table below. Learners should be competent to perform medical engineering activities on a minimum of **three** categories of medical equipment from the table below and a minimum of **three** devices within each category. Further guidance is given in the assessment criteria.

Types of medical equipment	Medical devices
Beds and electromechanical equipment	• Wheelchairs (including scooters) • Patient trolleys • Stair lifts; hoists; seating systems • Walking aids; commodes; bathing equipment; patient trollies • Adjustable beds; pressure redistribution and relief devices • Other specific AT equipment
Cardiovascular equipment	• Blood pressure devices (excluding mercury sphygmomanometer) • Pulse oximeters; electrocardiography (ECG) machines; external temporary pacemaker box
Physiological monitoring	• Foetal heart monitoring devices • Apnoea devices • Physiological monitoring equipment • Ophthalmoscopes • Thermometers
Infusion equipment	• Infusion pumps • Syringe drivers • Patient-controlled analgesia • Feeding pumps (including breast pump)
Therapeutic equipment	• Phototherapy devices • Radiant heater warmers • Oxygen delivery and monitoring devices
Resuscitation equipment	• Defibrillators • Suction equipment for airway clearance • Oxygen equipment – pipeline and cylinders • Capnography • Miscellaneous equipment, e.g. laryngoscopes, intraosseous drills

Types of medical equipment	Medical devices
Operating theatre and surgical equipment	• Tourniquet devices • Gas monitoring devices; flow and pressure gauges • Surgical lighting equipment/examination lamps • Pneumatic drilling/sawing devices • Blood warmers; patient warmers; operating tables; patient beds
Therapeutic equipment	• Nerve stimulating devices • Nebulisers; continuous positive airway pressure devices • Interferential therapy devices; therapeutic ultrasound devices • Traction devices; heater lamps; exercise equipment
Laboratory equipment	• Centrifuges; coulter counters; particle counters • Blood and gas analysers; ion selective analysers • Flame photometers; chloride meters; pH meters • Spectrophotometers; roller beds; colorimeters
Dental equipment	• Suction units; drilling units; dental air compressors • Descalers; dental hand pieces; polymerisation units • Floor utility service units; dental lighting • Amalgamators; amalgam separators
Renal equipment	• Haemodialysis machines; haemofiltration machines • Reverse osmosis units; water treatment plants • Water quality equipment; patency monitoring
Non-ionising radiation	• MRI scanners • Lasers • Optical light sources
Ionising radiation equipment **Imaging and therapeutic equipment**	• Imaging equipment: • diagnostic x-ray • nuclear medicine • CT scanners • Radiotherapy equipment: • linear accelerators • radiation monitoring equipment • mould room

AC1.1 includes:

- regulatory frameworks, including the Health and Safety at Work etc Act 1974
- legislation
- policy.

AC1.2 includes:

- quality management systems and good practice.

AC1.3 includes:

- control of infection risks in accordance with departmental protocols
- maintaining a tidy workplace, with exits and gangways free from obstruction
- using equipment safely and only for the purpose intended
- observing organisational safety rules, signs and hazard warnings
- taking measures to protect others from any harm resulting from the work that they are carrying out
- wearing eye protection and personal protective equipment (PPE)

AC2.1 includes:

- the public
- equipment users.

AC4.2 includes both around the workshop and the specific symbology used on medical equipment and medical device packaging.

AC4.6 should include performing **two** environmental risk assessments.

AC4.7 should include performing **two** risk assessments.

AC6.6 includes:

- regulators
- flow meters
- suction controllers
- pipeline systems and mechanisms designed to ensure system safety.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand safe working practices in medical engineering	1.1	Explain the health and safety policies and regulatory framework in medical engineering			
		1.2	Explain the quality-assurance processes underpinning safety and good practice in medical engineering			
		1.3	Identify appropriate sources of information and guidance on health and safety issues			
		1.4	Explain personal responsibilities regarding processes and procedures within own area of practice			
2	Be able to communicate effectively in the medical engineering environment in own area of work	2.1	Communicate scientific and engineering information at a level appropriate to the audience			
		2.2	Adapt communication to meet varying needs and overcoming barriers to understanding			
		2.3	Explain the importance of effective communication skills within the healthcare environment			
		2.4	Treat every patient/carer with compassion, dignity and respect, maintaining the highest standards of person-centred care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the work of the medical engineering department	3.1	Explain the role of medical engineering in healthcare and healthcare science			
		3.2	Explain the range of procedures undertaken in medical engineering			
		3.3	Explain the phases in the equipment life cycle and how it is used with medical engineering			
		3.4	Explain the potential impact of medical engineering on the patient, patient care, and staff healthcare services			
		3.5	Explain how the principles of patient-centred care are embedded in own area of practice			
4	Be able to perform a range of routine risk assessments appropriate to medical engineering	4.1	Explain the use of Control of Substances Hazardous to Health (COSHH) Regulations 2002 in own area of practice			
		4.2	Explain the types of symbols found in medical engineering, their meaning and implications			
		4.3	Explain the principles of risk assessment in medical engineering			
		4.4	Discuss potential medical equipment hazards in the patient environment			
		4.5	Perform a Control of Substances Hazardous to Health (COSHH) Regulations 2002 risk assessment			
		4.6	Perform environmental risk assessments in medical engineering			
		4.7	Perform risk assessments covering repair procedures for medical devices			
		4.8	Perform a risk assessment covering decontamination procedure(s)			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to contribute to incident reporting	5.1	Explain the local and national regulatory incident identification and escalation process			
		5.2	Explain the incident reporting process			
		5.3	Critically reflect on incident reports in own area of practice and the causes of the incidents			
		5.4	Contribute to the progress of an incident reporting process			
		5.5	Explain the process of equipment-related warning notice distribution			
6	Be able to perform routine maintenance on medical gas equipment	6.1	Explain the standards and guidance for the storage, use and maintenance of medial gas equipment in own area of practice			
		6.2	Explain the use of medical gases in own area of practice			
		6.3	Explain the safety features of medical gases, including storage, use and maintenance			
		6.4	Explain the risk of working with medical gases, specifically those around oxygen			
		6.5	Explain the system for identifying gas cylinders and specialist gas mixtures			
		6.6	Explain the principles of medical gas instrumentation that clinical engineering staff are involved with			
		6.7	Follow health and safety regulations and guidelines when working with medical gases, and medical gas equipment			
		6.8	Perform routine maintenance on medical gas equipment in line with local procedures			
		6.9	Seek advice in line with local procedures			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 114: Rehabilitation Engineering in Practice

Level:	**4**
Unit type:	**Optional**
Credit value:	**15**
Guided learning hours:	**120**

Unit summary

In this unit, you will acquire the knowledge and skills to work as a healthcare science associate within a clinical engineering department working in rehabilitation engineering. You will also build on your professional practice as you build your competence in the workplace. You will also be expected to demonstrate patient-centred, safe, high-quality care and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development. All learners in rehabilitation engineering will be expected to work with patients during their training.

All learners must complete all generic health and safety and mandatory training contextualised to own area of practice.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

AC1.2 includes:

- regulatory frameworks
- legislation
- policy
- quality management systems and good practice.

AC1.5 includes:

- the incident reporting process
- local and national regulatory incident identification and escalation process
- the process of equipment-related indent reporting to MHRA and equipment manufacturers
- the process of equipment-related warning notice distribution.

Learning outcome 5

In some instances, the patient may be present when a wheelchair is repaired. If a patient is present, learners must greet the patient and introduce themselves and their role, and communicate effectively with the patient.

Wheelchairs may be simple, electric or power assisted.

Learning outcome 6

At this level, learners will be given a clear specification for the equipment from the rehabilitation engineer or other registered healthcare professional. The focus for this learning outcome will be for learners to become familiar with the practical skills of preparing the aid for use by the patient. The aids for daily living are likely to be simpler aids at the level of a healthcare science associate.

In some instances, the patient may be present when an aid for daily living is issued. If a patient is present, learners must greet the patient and introduce themselves and their role, and communicate effectively with the patient.

AC6.7 includes:

- assessment procedures
- range of rehabilitation and aids for daily living equipment
- user's environment prior to the implementation of new aids.

Learning outcome 9 spans the maintenance, calibration and quality-assurance procedures on the equipment used to maintain simple wheelchairs and assess gait, and maintain assistive technology devices.

AC9.4 includes:

- equipment used to:
    - maintain simple wheelchairs
    - assess gait
    - maintain assistive technology devices.

AC9.7 includes:

- procedures to be followed in the event of identifying an issue of quality assurance.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand safe working practices in rehabilitation engineering	1.1	Explain the health and safety policies and regulatory framework in rehabilitation engineering			
		1.2	Explain the quality-assurance processes underpinning safety and good practice in rehabilitation engineering			
		1.3	Identify appropriate sources of information and guidance on health and safety issues			
		1.4	Explain personal responsibilities regarding processes and procedures within own area of practice			
		1.5	Explain incident report procedures in rehabilitation engineering			
2	Be able to communicate effectively in the rehabilitation engineering environment	2.1	Communicate scientific and engineering information at a level appropriate to the audience, including the public			
		2.2	Adapt communication to meet varying needs and overcoming barriers to understanding			
		2.3	Explain the importance of effective communication skills within the healthcare environment			
		2.4	Treat every patient/carer with compassion, dignity and respect, maintaining the highest standards of person-centred care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the work of the rehabilitation engineering department	3.1	Explain the role of rehabilitation engineering in healthcare and healthcare science			
		3.2	Explain the range of procedures undertaken in rehabilitation engineering within own area of practice			
		3.3	Explain the phases in the equipment life cycle and how it is used with rehabilitation engineering			
		3.4	Explain the potential impact of rehabilitation engineering on the patient, patient care, staff healthcare services			
		3.5	Explain how the principles of patient-centred care are embedded in own area of practice			
4	Be able to prepare the environment, equipment and patient for procedures	4.1	Explain the requirements for the procedure			
		4.2	Prepare the equipment for rehabilitation procedures			
		4.3	Calibrate the equipment used in the procedure			
		4.4	Prepare the environment for rehabilitation procedures			
		4.5	Discuss the potential special needs of patients referred for procedures and the relevant action required			
		4.6	Prepare the patient for rehabilitation procedures			
		4.7	Take remedial action to rectify common faults			
		4.8	Explain the impact of incorrect positioning or non-cooperation on the patient, the procedure and the outcome			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to maintain a wheelchair	5.1	Evaluate the Standard Operating Procedure for maintaining a simple wheelchair			
		5.2	Carry out maintenance of a simple wheelchair			
		5.3	Communicate the progress of repairs to users			
		5.4	Advise on contingency arrangements, reasons for fault, action taken and how to avoid reoccurrence			
		5.5	Discuss the potential impact of equipment repairs on patients			
		5.6	Explain the requirements for record keeping			
		5.7	Complete all records accurately, storing them in the correct location for future use			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to provide appropriate aids for daily living for routine referrals to rehabilitation engineering services	6.1	Explain the range of aids for daily living technology devices used to support patients referred to rehabilitation engineering			
		6.2	Select aid/s for daily living for routine referrals			
		6.3	Seek advice as required, following local procedures			
		6.4	Select appropriate test equipment			
		6.5	Perform electrical safety test procedures, undertaking functional tests or checks as required			
		6.6	Perform risk analysis, accounting for the patient's needs, the aids for daily living available and the environment, and document as appropriate			
		6.7	Explain the process to confirm the: • reason for referral • clinical need • objectives of assessment or prescription			
		6.8	Explain the process to confirm the nature, type and extent of measurements required to complete the assessment or the equipment to meet the prescription			
		6.9	Explain local risk assessment methodology			
		6.10	Discuss the recommended aids for daily living with the patient/carer/staff			
		6.11	Demonstrate appropriate aids for daily living, ensuring the patient is able to use the device appropriately			
		6.12	Evaluate the effective operation of the aid/s within the user environment (actual or simulated)			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		6.13	Document maintenance periods and requirements for equipment management			
		6.14	Establish and agree responsibility for equipment issued			
		6.15	Instruct the user and carers in the safe use, transport and general maintenance of the aid/s, and confirm understanding			
		6.16	Provide a full report of the aid/s issued in order to facilitate traceability			
		6.17	Carry out the process and outcomes of commissioning, including user training, ensuring that arrangements for further action are implemented			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Be able to assist in the routine assessment of gait	7.1	Explain the clinical indications and contraindications for gait analysis			
		7.2	Discuss the importance of informed consent, record keeping, data protection, confidentiality in accordance with trust procedures and governance process			
		7.3	Discuss how good practice with respect to professionalism and patient-centred care has a positive impact on patient care			
		7.4	Greet the patient and introduce yourself and your role			
		7.5	Assist in the routine assessment of gait			
8	Be able to assist in the assessment of a patient requiring assistive technology	8.1	Discuss the potential benefits of assistive technology to the patient			
		8.2	Explain the range of simple assistive technology available to support patients/carers/clinical staff/healthcare organisations			
		8.3	Greet the patient and introduce yourself and your role			
		8.4	Assist in the assessment of a patient requiring assistive technology			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
9	Be able to perform routine procedures in rehabilitation engineering	9.1	Justify current safety standards, including safety testing and routine maintenance			
		9.2	Explain and justify the requirements for accurate completion of equipment maintenance records			
		9.3	Perform routine maintenance on the equipment used in rehabilitation engineering			
		9.4	Complete equipment maintenance records			
		9.5	Perform the calibration of equipment used within rehabilitation engineering in own department			
		9.6	Define the terms quality control, quality assurance and quality management			
		9.7	Perform quality-assurance procedures on equipment used within rehabilitation engineering in own department			
		9.8	Discuss the purpose of quality assurance in rehabilitation engineering			
		9.9	Evaluate the requirements for quality-assured procedures in rehabilitation engineering			
10	Understand how to complete an incident report in accordance with local procedures in rehabilitation engineering	10.1	Explain the incident reporting process			
		10.2	Explain the local and national regulatory incident identification and escalation process			
		10.3	Explain the process of equipment-related indent reporting to MHRA and equipment manufacturers			
		10.4	Explain the process of equipment-related warning notice distribution			
		10.5	Complete an incident report under supervision in accordance with local procedures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
11	Be able to assist rehabilitation engineers in the provision of specialist medical device modifications and adaptations	11.1	Explain the local processes and procedures associated with device modifications and adaptations			
		11.2	Assist in the production, testing and introduction into service of devices modified for patient care			
		11.3	Complete elements of the documentation that support the records necessary for such modifications or adaptions to medical devices			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 115: Renal Technology in Practice

Level: 4

Unit type: Optional

Credit value: 15

Guided learning hours: 120

Unit summary

In this unit, you will acquire the knowledge and skills to work as a healthcare science associate working in renal technology. You will be able to work safely in the renal technology environment, with the emphasis on health and safety, risk management, risk assessment and equipment management. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development.

All learners must complete all generic health and safety and mandatory training contextualised to own area of practice.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedure and Good Manufacturing Practice.

AC.1. includes:

- renal units and equipment used in the patient's home.

AC1.2 includes:

- regulatory frameworks
- legislation
- policy
- quality management systems and good practice.

AC3.3 includes:

- renal unit
- intensive care unit
- patient's home.

AC6.3 includes:

- working in patients' homes
- lone working
- decontamination issues associated with renal equipment
- contingency plans for equipment failure.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand safe working practices in Renal Technology	1.1	Explain the health and safety policies and regulatory framework in Renal Technology			
		1.2	Explain the quality-assurance processes underpinning safety and good practice in Renal Technology			
		1.3	Describe appropriate sources of information and guidance on health and safety issues			
		1.4	Explain personal responsibilities regarding processes and procedures within own area of practice			
2	Be able to communicate effectively in the Renal Technology environment	2.1	Communicate scientific and engineering information at a level appropriate to the audience, including the public			
		2.2	Adapt communication to meet varying needs and overcoming barriers to understanding			
		2.3	Explain the importance of effective communication skills within the healthcare environment			
		2.4	Treat every patient/carer with compassion, dignity and respect, maintaining the highest standards of person-centred care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the work of the Renal Technology department	3.1	Explain the role of Renal Technology within the multidisciplinary team providing renal dialysis and treatment for patients			
		3.2	Explain the range of procedures undertaken in Renal Technology			
		3.3	Explain the range of areas where renal technology is used			
		3.4	Explain the phases in the equipment lifecycle and how it is used with Renal Technology			
		3.5	Explain the potential impact of Renal Technology on the patient, patient care, and staff healthcare services			
		3.6	Explain how the principles of patient-centred care are embedded in own area of practice			
4	Be able to assist in the routine maintenance of a water treatment plant	4.1	Explain the purpose of the water treatment system			
		4.2	Assist in the routine quality-assurance activities associated with water treatment systems			
		4.3	Demonstrate the necessary performance and safety checks and adjustments required as part of the routine maintenance of a water treatment plant			
5	Be able to assist in performing routine maintenance of renal dialysis equipment	5.1	Explain the key maintenance required by renal dialysis systems, including different types of dialysis			
		5.2	Assist in the planned maintenance of a range of dialysis systems			
		5.3	Discuss the impact of renal replacement therapy (RRT) on patients and their families			
		5.4	Critically reflect on the role of the renal technologist in promoting high-quality care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to perform a range of risk assessments within the renal environment in accordance with SOPs	6.1	Explain the principles of risk assessment using current statutory and professional guidance			
		6.2	Discuss the range of risk assessments performed, where they are filed and how to access them			
		6.3	Perform a range of risk assessments within the renal environment in accordance with SOPs			
		6.4	Explain the requirements for accurate record keeping			
		6.5	Complete all records accurately and store in correct location for future use			
7	Be able to complete an incident report in accordance with local procedures	7.1	Explain the incident reporting process			
		7.2	Explain the local and national regulatory incident identification and escalation process			
		7.3	Explain the process of equipment-related indent reporting to MHRA and equipment manufacturers			
		7.4	Explain the process of equipment-related warning notice distribution			
		7.5	Complete an incident report under supervision			
8	Understand the need for the effective management of other medical devices used in the renal dialysis environment	8.1	Explain the policies and procedures relating to the effective management of medical equipment in the clinical area, including: • specialist renal dialysis technology • other medical equipment			
		8.2	Discuss why effective lifecycle management of medical equipment is necessary			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 116: Ionising Radiation Engineering in Practice

Level: 4

Unit type: Optional

Credit value: 15

Guided learning hours: 120

Unit summary

In this unit, you will acquire the knowledge and skills to work as a healthcare science associate within a clinical engineering department working in radiation engineering. You will be able to work safely in the radiation engineering environment, with the emphasis on health and safety, risk management, risk assessment and responding to radiation equipment-related incidents. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development.

All learners must complete all generic health and safety and mandatory training contextualised to own area of practice.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

AC1.1 includes:

- the relevant safety features in radiotherapy treatment rooms
- relevant health and safety legislation and local policy in all work environments, including:
    - local rules for work with ionising radiation within the x-ray department
    - local rules for work with ionising radiation within the radiotherapy department
    - Ionising Radiation Regulations 1999
    - Ionising Radiation (Medical Exposure) Regulations 2000
- the restrictions that apply in controlled areas and the importance of these restrictions.

AC1.2 includes:

- regulatory frameworks
- legislation
- policy
- quality management systems and good practice.

AC1.11 includes:

- room design
- shielding
- interlocks.

AC3.1 includes:

- MDT providing diagnostic procedures and treatment to patients.

AC3.5 could include:

- x-ray
- cardiac catheterisation
- imaging.

AC4.1 includes an appreciation of the test equipment used to undertake the measurements.

Learning outcome 7 includes:

- diagnostic x-ray rooms
- radiotherapy treatment rooms.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand safe working practices in radiation engineering	1.1	Explain the health and safety policies and regulatory framework in radiation engineering			
		1.2	Explain the quality-assurance processes underpinning safety and good practice in radiation engineering			
		1.3	Identify appropriate sources of information and guidance on health and safety issues			
		1.4	Explain personal responsibilities regarding processes and procedures within own area of practice			
		1.5	Describe the local and national regulatory incident identification and escalation process			
		1.6	Explain the roles and responsibilities of staff, including the radiation protection advisor (RPA) and radiation protection supervisor (RPS)			
		1.7	Evaluate the organisation of radiological protection, radiation safety policies and local rules in own area of work			
		1.8	Explain the potential hazards and risks in diagnostic x-ray rooms			
		1.9	Explain the relevant safety features in diagnostic x-ray rooms			
		1.10	Explain the potential hazards and risks in radiotherapy treatment rooms			
		1.11	Explain the basic environmental requirements needed to support ionising radiation imaging and treatments			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to communicate effectively in the radiation engineering environment	2.1	Explain the importance of effective communication skills within the healthcare environment			
		2.2	Communicate scientific and engineering information at a level appropriate to the audience, including the public			
		2.3	Adapt communication to meet varying needs and overcoming barriers to understanding			
		2.4	Treat every patient/carer with compassion, dignity and respect, maintaining the highest standards of person-centred care			
3	Understand the work of the radiation engineering department	3.1	Explain the role of radiation engineering in healthcare and healthcare science			
		3.2	Explain the range of procedures undertaken in radiation engineering			
		3.3	Explain the phases in the equipment life-cycle and how it is used with medical engineering			
		3.4	Explain the potential impact of radiation engineering on the patient, patient care, staff healthcare services			
		3.5	Explain the common clinical uses of radiation			
		3.6	Explain how the principles of patient-centred care are embedded in own area of practice			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to assist in the measurement of the performance characteristics of an X-ray tube or linear accelerator	4.1	Explain the typical routine measurements that are undertaken to ensure the quality assurance of equipment that emits radiation			
		4.2	Contribute to the set-up of equipment for quality-assurance measurements			
		4.3	Assist in the procedure of obtaining measurements			
5	Be able to perform health and safety risk assessments in radiation safety in accordance with SOPs	5.1	Explain the principles of risk assessment using current statutory and professional guidance			
		5.2	Discuss the range of risk assessments performed, where they are filed and how to access them			
		5.3	Perform a health and safety risk assessment in accordance with SOPs			
		5.4	Explain the requirements for accurate record keeping			
		5.5	Complete all records accurately, storing in correct location for future use			
6	Be able to assist radiation engineers in a range of environments, adhering to safety restrictions and regulations	6.1	Assist radiation engineers working in diagnostic x-ray rooms			
		6.2	Assist radiation engineers working in radiotherapy rooms			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Understand how to complete an incident report in accordance with local procedures	7.1	Explain the incident reporting process			
		7.2	Explain the local and national regulatory incident identification and escalation process			
		7.3	Explain the process of equipment-related indent reporting to MHRA and equipment manufacturers			
		7.4	Explain the process of equipment-related warning notice distribution Complete an incident report under supervision			
		7.5	Explain the role of the radiation protection supervisor, medical physics expert and radiation protection adviser with regard to a radiation-related incident			
		7.6	Explain how to complete an incident report			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 117: Working Practices in Physical Sciences

Level: 4

Unit type: Optional

Credit value: 5

Guided learning hours: 35

Unit summary

In this unit, you will acquire the knowledge and skills to work as a healthcare science associate within a medical physics department. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development.

All learners must complete all generic health and safety and mandatory training contextualised to own area of practice.

Additional information

All procedures must be undertaken in accordance with the departmental Standard Operating Procedures (SOPs).

AC1.1 includes:

- Control of Substances Hazardous to Health (COSHH) Regulations 2002
- information governance
- fire safety
- infection control.

AC2.2 includes:

communicating:

- scientific and engineering information at a level appropriate to the audience, including the public
- effectively within own area of work
- effectively within multidisciplinary team
- effectively and empathetically with patients and the public:
    - listening
    - adapting communication to meet varying needs
    - overcoming barriers to understanding.

AC3.1 includes:

- the local and national regulatory incident identification and escalation process
- the process of equipment-related indent reporting to MHRA and equipment manufacturers.

AC3.2 includes:

- Radiation Protection Advisor (RPA)
- Radiation Protection Supervisor (RPS)
    - the role of a manager with regard to a radiation-related incident.

AC4.5 includes:

- infection control
- information governance
- fire safety.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand how to work safely in a medical physics environment	1.1	Explain the health and safety policies, legislation and regulatory framework in own area of practice			
		1.2	Explain the quality-assurance processes underpinning safety and good practice in own area or practice			
		1.3	Know departmental local rules relating to Ionising Radiation Regulations 1999			
		1.4	Explain the procedures relating to Ionising Radiation (Medical Exposure) Regulations 2000 in own area of work			
		1.5	Explain personal responsibilities regarding processes and procedures within own area of practice			
		1.6	Explain the Environmental Permitting (England and Wales) Regulations 2016			
2	Be able to communicate effectively within the healthcare environment	2.1	Explain the importance of effective communication skills within the healthcare environment			
		2.2	Communicate within the healthcare environment			
		2.3	Summarise complex information at an appropriate technical level for the intended audience orally and in writing			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the incident reporting structure and roles and responsibilities of staff in own area of work	3.1	Evaluate the incident reporting process in own area of work			
		3.2	Explain the roles and responsibilities of medical physics staff			
		3.3	Evaluate the hospital organisation of radiological protection; radiation safety policies and local rules			
		3.4	Explain own position within the department and multidisciplinary teams			
4	Be able to work professionally in a medical physics environment	4.1	Follow safe working practice within own area of work			
		4.2	Follow departmental local rules relating to Ionising Radiation Regulations 1999			
		4.3	Follow to organisational procedures relating to Ionising Radiation (Medical Exposure) Regulations 2000			
		4.4	Follow Environmental Permitting (England and Wales) Regulations 2016			
5	Be able to undertake routine administrative duties	5.1	Input information into patient or other information systems			
		5.2	Produce daily work lists			
		5.3	Book patient appointments			
		5.4	Extract information from patient or other information systems			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 118: Radiotherapy Physics in Practice

Level: 4

Unit type: Optional

Credit value: 20

Guided learning hours: 160

Unit summary

This unit will ensure that you have acquired the knowledge and skills to work as a healthcare science associate within a medical physics department working in radiotherapy physics. You will be able to work safely in the radiotherapy physics environment, with the emphasis on health and safety, risk management, risk assessment and equipment management. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development.

All learners must complete all generic health and safety and mandatory training contextualised to own area of practice.

Additional information

All procedures must be undertaken in accordance with the departmental Standard Operating Procedures (SOPs).

AC1.2 includes:

- regulatory frameworks
- legislation
- policy
- quality management systems and good practice.

AC2.2 includes:

- megavoltage units and other radiotherapy treatment units (e.g. high dose rate brachytherapy, tomotherapy units)
- radiation dosemetry checks on linear accelerator (photons and electrons)
- MV and kV imaging systems associated with linacs
- CT and (if available) conventional simulators.

AC2.3 includes:

- orthovoltage treatment units
- megavoltage units and other radiotherapy treatment units (e.g. high dose rate brachytherapy, tomotherapy units)
- radiation dosemetry checks on linear accelerator (photons and electrons)
- MV and kV imaging systems associated with linacs
- CT and (if available) conventional simulators
- treatment planning systems.

AC2.4 includes:

- sign-out of radioactive source (usually strontium) under the local rules
- connection and power-up of the dosemeter and electrometer combination(s) to be tested.

AC2.6 includes:

- orthovoltage – in air measurements
- megavoltage x-ray
- electron measurements.

AC3.1 includes:

- preparation of the clinic room for the patient procedure
- considering the individual needs of each patient
- positioning patient appropriate to the procedure and take relevant measurements and impressions
- manufacturing immobilisation devices to meet the specification required to deliver treatment
- selecting appropriate thickness of lead shielding
- producing a lead mask or cut-out that meets the department's quality standard
- producing a tissue equivalent substance (bolus) to meet the treatment specification requirements.

AC3.3 includes:

- preparing the patient according to the radiotherapy request form
- explaining the process and answering questions
- completing the necessary documentation for set-up reproduction.

AC4.1 includes:

- open patient files on the treatment planning system
- registering new patients and importing images to begin the planning process.

AC4.4 – typical body sites and plan techniques would include selecting three common sites:

- treatment of breast cancer using opposed tangential fields
- treatment of prostate cancer using inverse-planned intensity-modulated radiation therapy (IMRT)
- treatment of lung cancer using inverse-planned Intensity-Modulated Radiation Therapy (IMRT).

AC4.6 includes:

- low dose rate (LDR) prostate
- high dose rate (HDR) gynaecological/ interstitial implant.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the practice and principles of radiotherapy physics underpinning the role of a healthcare science associate	1.1	Explain the basic principle of radiotherapy – dose to tumour while minimising dose to healthy tissue			
		1.2	Explain the basic components of a linac and other treatment equipment			
		1.3	Explain the physics of high energy x-ray production			
		1.4	Explain the basis of treatment planning and the steps involved in generating and optimising a treatment plan			
		1.5	Explain the steps in order of the patient pathway through radiotherapy			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to assist in routine machine quality assurance	2.1	Demonstrate the ability to run up and operate the radiotherapy systems safely			
		2.2	Gather the relevant documentation and equipment necessary for performing the quality-assurance tests of key radiotherapy systems			
		2.3	Assist in the performance of quality-control procedures for radiotherapy systems			
		2.4	Gather the appropriate documentation and equipment for routine stability checks of radiotherapy dosemeters			
		2.5	Assist in the performance of measurements to deliver routine stability testing of therapy level dosemeters			
		2.6	Assist in making routine output measurements of treatment units			
3	Be able to assist in preparation of patient positioning devices	3.1	Assist in the production of safe and appropriate immobilisation devices for patients			
		3.2	Use hand and machine tools safely and effectively during procedures associated with the mould room			
		3.3	Assist in preparing the patient treating the patient with respect and compassion			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to assist in the preparation of radiotherapy treatment plans	4.1	Perform basic tasks associated with radiotherapy treatment planning			
		4.2	Use semi-automated tools of the planning systems to fuse images and generate contours of certain body regions			
		4.3	Explain the basics of dose assessment in treatment planning using dose-volume-histograms			
		4.4	Able to complete a set of standard training plans to meet the plan requirements			
		4.5	Evaluate the plans produced against the departmental criteria in terms of dose to tumour and dose to healthy tissues			
		4.6	Demonstrate knowledge of at least one type of brachytherapy technique			
5	Be able to assist in the preparation of and evaluation of in-vivo dosemetry measurements	5.1	Organise thermoluminescent dosemeter (TLD) or diode dosemeters ready for quality assurance (QA)/calibration			
		5.2	Demonstrate the ability to read out thermoluminescent dosemeter (TLD) or diode dosemeters			
		5.3	Demonstrate the ability to assist in evaluation of in-vivo dosemeter results versus expected doses			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 119: Nuclear Medicine in Practice

Level: 4

Unit type: Optional

Credit value: 20

Guided learning hours: 160

Unit summary

This unit will ensure that you have acquired the knowledge and skills to work as a healthcare science associate within a medical physics department working in nuclear medicine. You will be able to work safely in the nuclear medicine environment, with the emphasis on patient centred care. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development.

All learners must complete all generic health and safety and mandatory training contextualised to own area of practice.

Additional information

All procedures must be undertaken in accordance with the departmental Standard Operating Procedures (SOPs).

AC2.1 includes:

- patient preparation
- equipment availability
- staff availability
- patient transport arrangements
- premedication.

AC2.2 includes:

- performing basic operating features of the imaging equipment and its accessories:
    - bed operation
    - gantry movement
    - collimators
    - positioning controls
    - emergency stop, etc.

AC2.3 includes:

- providing relevant information and guidance to the patient/carer.

AC2.4 includes:

- operating the acquisition control and information processing system in respect of the nuclear medicine data (i.e. not the CT component).

AC2.5 includes:

- preparation and monitoring of the therapy room/suite
- monitoring of the room after the patient treatment is complete
- monitoring and disposal of waste
- completion of associated documentation.

AC4.1 includes:

- checking and confirming that the air handling unit workstations/isolators are working within specification
- checking the environmental integrity (room and cabinet pressures) and be aware of the action levels
- completing operator tests
- reviewing work for the session and ensuring consumables are available for the session as required
- preparing the environment and completing necessary cleaning tasks to maintain GMP standard environment
- completing the documentation for the receipt of both active and non-active products
- opening parcels, transferring radioactive material to the appropriate location and completing necessary documentation
- disposal of packaging materials and associated monitoring as part of disposal
- keeping clear and accurate documentation that meets the requirements in place through protocols, procedures, guidance, local rules and legislation.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the practice and principles of nuclear medicine underpinning the role of a healthcare science associate	1.1	Explain the basic principles of isotope imaging and different isotope types			
		1.2	Explain the components of a gamma camera (including the CT part)			
		1.3	Describe the production of radiopharmaceuticals, including Tc generators			
		1.4	Explain a range of nuclear medicine imaging examinations and their clinical purpose			
		1.5	Explain a range of nuclear medicine non-imaging examinations and their clinical purpose			
		1.6	Explain the basis of 131-I therapy for thyroid disease			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to assist with diagnostic imaging and therapy in nuclear medicine	2.1	Assist with the scheduling of appointments for nuclear medicine therapy			
		2.2	Assist with the preparation of the gamma camera and room			
		2.3	Assist with the preparation of the patient for nuclear medicine therapy, treating them with respect and compassion			
		2.4	Assist with a range of acquisition and recording techniques used when carrying out diagnostic imaging procedures			
		2.5	Assist with a range of nuclear medicine therapy procedures used in the clinical treatment pathway of patients			
		2.6	Demonstrate the ability to use a suitable phantom and acquisition mode, operate equipment gamma camera to investigate the effect of: • counts/time statistics • positioning and orientation • image manipulation and presentation			
3	Be able to perform quality control on a gamma camera using an appropriate source and standardised parameters and be aware of action thresholds	3.1	Explain the quality-assurance programme for nuclear medicine gamma cameras and the action thresholds for daily, weekly and monthly quality-assurance tests			
		3.2	Perform daily and weekly quality control on a gamma camera using an appropriate source and standardised parameters			
		3.3	Describe action thresholds and the reporting/escalation path			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Assist in routine radiopharmacy procedures	4.1	Demonstrate the ability to work in a radiopharmacy safely and within the legislative and statutory framework			
		4.2	Assist with the preparation and dispensing of radiopharmaceuticals for use in the diagnosis or treatment of patients			
5	Perform routine contamination monitoring, perform decontamination and dispose of waste in a medical physics department	5.1	Perform radioactive contamination monitoring in a thorough and comprehensive manner			
		5.2	Explain the risks of further spreading contamination on clothing/footwear			
		5.3	Perform decontamination following local procedures			
		5.4	Monitor and dispose of waste safely and appropriately			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 120: Radiation Physics in Practice

Level: 4

Unit type: Optional

Credit value: 20

Guided learning hours: 120

Unit summary

This unit will ensure that you have acquired the knowledge and skills to work as a healthcare science associate within a medical physics department working in radiation physics. You will be able to work safely in the radiation physics environment, with the emphasis on patient-centred care, health and safety, risk management, risk assessment and equipment management. You will be expected to build your professional practice and use critical reflection to review and improve your performance in the workplace and develop skills to promote continuous professional development.

All learners must complete all generic health and safety and mandatory training contextualised to own area of practice.

Additional information

All procedures must be undertaken in accordance with the departmental Standard Operating Procedures (SOPs).

AC2.1 includes:

- calibration of monitoring equipment
- analysis of personnel monitoring dosemeters
- quality-assurance/quality-control surveys of x-ray rooms and equipment.

AC2.2 includes:

- ionising radiation
- non-ionising.

AC2.3 includes:

- instrument types, range of probes
- ionisation chambers, Geiger counters, scintillation counters
- dose and dose-rate meters
- contamination monitors
- diagnostic x-ray quality-assurance instruments for tube output and kV.

AC3.1 includes:

- requirements of the user/worker
- the dosemeter being used
- dose limits.

AC5.1 includes:

- prepare dosemeters ready for use
- carry out quality-assurance checks on the thermoluminescence dosimeter TLD reader
- read dosemeters and check validity of results.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the practice and principles of radiation physics underpinning the role of a healthcare science associate	1.1	Explain the principle of the production of x-rays			
		1.2	Explain the basics of the interaction of x-rays with matter			
		1.3	Explain the principles of radiation protection – distance, shielding, time			
		1.4	Describe the use of dosimetry in healthcare setting			
		1.5	Describe the purpose of performance testing and traceability			
2	Be able to assist in routine activities within radiation physics	2.1	Collate and update information on QA/QC reports			
		2.2	Assist with general QA/QC measurements on equipment that produce both diagnostic x-rays and non-ionising radiations			
		2.3	Assist in the calibration of monitoring equipment			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Assist in the analysis of personnel monitoring dosemeters	3.1	Explain the difference between whole-body and extremity dosemetry			
		3.2	Demonstrate the ability to: • select the appropriate calibration factor for a dosemeter or batch of dosemeters • prepare dosemeters for reading • load dosemeters into the reader • ensure output data is uploaded for checking			
		3.3	Explain the action levels in dosemeter readings and reporting/escalation path for unusual/high readings			
4	Perform basic contamination monitoring	4.1	Perform radioactive contamination monitoring where tasks include: • selecting the appropriate instrument • understanding the risks of further spreading contamination on clothing/footwear • performing the monitoring in a thorough and comprehensive manner • documenting results • performing decontamination following local procedures • monitoring and dispose of waste			
5	Perform routine TLD measurement for personal monitoring	5.1	Demonstrate an ability to perform routine TLD measurement for personal monitoring			
		5.2	Assist in the calibration of the system			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 121: Introduction to Data Science and Data Management in Clinical Bioinformatics

Level: 4

Unit type: Optional

Credit value: 10

Guided learning hours: 80

Unit summary

A major challenge that current and future health analytic technologies will create is data – both in terms of volume and complexity of the governance. Clinical informatics and genomics will create some of the largest data sets that have ever been used within the NHS. Managing and working with data of this scale safely and effectively creates data management challenges for the existing NHS information technology infrastructure.

In this unit, you will acquire the data science and data management knowledge and skills within a clinical bioinformatics environment. You will be expected to develop your professional practice as you build your competence in the workplace.

Additional information

AC1.1 includes:

- patient demographic data
- results of scans and screens
- history of hospital admissions
- lifestyle information.

AC1.3 includes:

- informed consent
- risks of collating (extracted) data from multiple sources
- governance, safeguarding and privacy of personal data
- the risks of data sharing and accidental disclosure of personal data
- potential for misinterpretation of data and consequences
- patient rights, including the opportunity to opt in or opt out of the sharing of patient-specific data outside the NHS
- communicating with patients, carers and families.

AC2.2 includes:

- definition of good practice
- the legislation, regulatory guidance and NHS protocols regarding the security, confidentiality and appropriate sharing of patient-identifiable information
- Caldicott Guardian role and guidelines
- the different arrangements and the associated responsibilities of clinical staff for the security of all types of clinical information, especially electronically held, and for using such data for 'secondary' purposes
- specific process and procedures in own area of work.

AC2.3 includes:

- record keeping and records management
- physical security of manual and computer records
- data protection
- access to person identifiable data
- confidentiality and the use of person identifiable information, including information sharing protocols when needed
- telephone enquiries
- safe haven procedures
- legal requirements, including 'subject access' and 'freedom of information' requests
- building security
- risk of non-identifiable information being cross-referenced with other databases to make it possible to identify individuals.

AC3.2 includes:

- impact of data quality on analysis
- concepts of provenance and reproducibility.

AC3.3 includes:

- techniques
- software
- verbal and written communication in the form of reports or presentations.

LO5: data software includes:

- Excel® speadsheets and Access® databases
- a range of software relevant to own area of work
- appropriate programming language for the software used.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the sources of health data in own organisation and area of work	1.1	Explain the sources and use of health data in own organisation			
		1.2	Explain the sources and use of health data in own area of work			
		1.3	Describe the use of health data in patient care pathways and decision making			
2	Understand the principles of information governance and how data is kept securely and stored in own organisation and own area of work	2.1	Explain the terms information governance and clinical governance			
		2.2	Describe the legislation and standards that underpin information governance			
		2.3	Explain how data is kept securely in own organisation and area of work			
3	Understand how data is analysed and results communicated	3.1	Describe the sources of data and data types in own area of work			
		3.2	Explain the importance of quality control of data and the quality-control processes underpinning data management in own area of work			
		3.3	Explain the purpose of data visualisation			
		3.4	Communicate results of data analyses to a range of professionals			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to send, receive and store communications containing patient/clinical information safely and securely in accordance with policy, protocols, legislation and codes	4.1	Apply information governance principles and best practice in the workplace, including confidentiality			
		4.2	Create and use patient-related data, applying data and information security best practice in a clinical context			
		4.3	Store and manage records and patient information appropriately, safely and securely			
		4.4	Share records and patient information appropriately, safely and securely with others, including patients/clients			
5	Be able to work with data software in own area of work	5.1	Discuss how data software is used with own area work to support high-quality, safe healthcare			
		5.2	Enter and manipulate data			
		5.3	Interrogate data and produce reports and data visualisations			
		5.4	Evaluate the reports and amend the data			
		5.5	Describe the principles and purpose of spreadsheets and databases in own area of practice			
		5.6	Describe the data security and confidentiality processes required within spreadsheets and databases			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to interpret and present data using presentation software	6.1	Explain the principles of effective oral presentation			
		6.2	Explain the effective use of presentation systems, including data software to create presentations			
		6.3	Develop and deliver a short presentation with emphasis on data visualisation to a group of peers			
		6.4	Design a feedback form, gather audience feedback and analyse the feedback			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 122: Introduction to Clinical Bioinformatics (Genomics)

Level: 4

Unit type: Optional

Credit value: 10

Guided learning hours: 80

Unit summary

In this unit, you will be introduced to the role of clinical bioinformatics and the clinical bioinformatician in genomics and will gain the knowledge and skills to be able to perform tasks within a clinical bioinformatics (genomics) environment. You will be expected to develop your professional practice as you build your competence in the work base.

Additional information

AC1.3: large-scale whole genome sequencing projects, for example the 100,000 Genomes Project.

AC2.1 to include:

- raw reads
- mapped reads
- coverage metrics.

AC5.2 to include:

- how clinicians use these terms
- why they are important for genomic diagnoses.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the role of clinical bioinformaticians in healthcare	1.1	Explain the term Clinical Bioinformatics			
		1.2	Describe the national and local genomic infrastructure with respect to service delivery and genomic education and training			
		1.3	Explain the purpose of large-scale whole genome sequencing projects			
		1.4	Discuss how whole genome sequencing projects are resulting in changes in patient care			
		1.5	Describe the role of the clinical bioinformatician in own area of work			
		1.6	Discuss how personalised medicine is/could be used in the diagnosis and recommended treatment of **one** condition appropriate to own area of work			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine processes to support a genome study	2.1	Explain the role of Standard Operating Procedures in Clinical Bioinformatics			
		2.2	Explain the purpose of a genomic informatics pipeline			
		2.3	Assist in the routine application of the most appropriate pipeline to genomic data analysis			
		2.4	Perform housekeeping processes following whole genome sequencing or other genomic processes			
		2.5	Receive and process emails and notifications from Genomics England Ltd GEL and other third-party providers			
		2.6	Describe the relevant best practice guidelines for development and validation of a bioinformatics pipeline			
3	Be able to review the quality of genomic data	3.1	Review data generated at various stages of a bioinformatics pipeline, to ensure it meets the required quality standards			
4	Be able to perform tasks to support audit programmes with own area of work	4.1	Assist senior staff undertaking departmental audits			
		4.2	Assist in the analysis of audit data			
		4.3	Assist in the presentation of the outcome of departmental audits			
5	Be able to work with human phenotype ontology(HPO) Clinical Phenotypes	5.1	Describe what is meant by human phenotype ontology(HPO)			
		5.2	Review submitted HPO terms for completeness in readiness for submission to a genome study			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 123: Introduction to UNIX

Level:	**4**
Unit type:	**Optional**
Credit value:	**3**
Guided learning hours:	**22**

Unit summary

In this unit, you will acquire the knowledge and skills to be able to perform tasks in UNIX within a clinical bioinformatics environment. You will be expected to develop your professional practice as you build your competence in the work base.

Additional information

AC1.1 includes:

- files and processes
- the directory structure
- files and directories
- passwords: logins
- owners and groups.

AC1.3 includes:

- ordinary files
- special files
- directories.

AC1.4 includes:

- directory management
- home directory
- absolute/relative pathnames.

AC1.5 includes:

- permissions
- file access modes
- directory access modes
- process to change permissions.

AC2.7 includes using a range of Unix commands such as:

- redirecting output to a file
- concatenating files
- wildcards
- gzip and zcat
- man, whatis and apropos commands
- using a CLI editor such as Vi, emacs or nano.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles of UNIX applied to own area of work	1.1	Explain the purpose of UNIX operating systems in own area of work			
		1.2	Describe the architecture of UNIX operating systems in own area of work			
		1.3	Describe UNIX file types			
		1.4	Describe the organisation of UNIX files			
		1.5	Describe UNIX data security features			
2	Be able to perform routine tasks in UNIX in own area of work following Standard Operating Procedures	2.1	Demonstrate the ability to start a UNIX terminal			
		2.2	Demonstrate the ability to list, create and rename directories in UNIX			
		2.3	Search the contents of a file in UNIX			
		2.4	Display the contents of a file on the screen			
		2.5	Copy and move files in UNIX			
		2.6	Remove files and directories in UNIX			
		2.7	Create and edit UNIX files using a CLI editor			
		2.8	Write simple scripts in Bash following quality-assurance processes			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 124: Safe Use of Information Communication Technology within the Clinical Environment

Level:	**4**
Unit type:	**Optional**
Credit value:	**10**
Guided learning hours:	**80**

Unit summary

In this unit, you will gain the knowledge and skills to safely use information communications technology (ICT) within a clinical environment. The unit includes the legislation and guidance underpinning the safe use of ICT, the safeguarding of information and health data and the skills to transfer information safely.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of practice.

AC1.1 includes:

- Data Protection Act 1998
- Computer Misuse Act 1990
- Freedom of Information Act 2000.

AC1.2 includes:

- data security
- network management
- clinical data storage
- clinical data archiving
- exchange and access
- sharing and interoperability.

AC1.4 includes:

- informed consent
- limits of consent
- role of the Caldicott Guardian.

AC1.6 includes:

- governance
- safeguarding and privacy of personal data.

AC1.7 includes:

- the role of the Medicines and Healthcare products Regulatory Agency (MHRA)
- the Food and Drug Administration (FDA)
- the International Electrotechnical Commission (IEC), and its role in Conformance European (CE) marking
- the IEC 80001 family of standards.

AC1.8 includes:

- the use of electrical isolation (optical and magnetic)
- the safe limits for current applied to a patient
- the 'patient environment' as described in IEC60601-1; 2005:12.

AC1.9 includes:

- various promulgation routes such as airborne and surface-borne
- the common pathogens in healthcare (e.g. MRSA, norovirus, Clostridium difficile (C-diff))
- common protection regimes for equipment.

AC1.10 includes:

- protection against malware (e.g. antivirus)
- software security (e.g. passwords)
- hardware security (e.g. Kensington locks)
- ensuring the system remains compliant (e.g. safety alerts, OS patches).

AC1.13 with reference to:

- the Data Protection Act 1998 and Freedom of Information Act 2000 –especially exemptions.

AC1.16 e.g. in a legal or political setting.

AC2.1 includes:

- virtualisation and cloud computing, including third-party storage of clinical data
- mobile computing and applications (both between professionals and involving citizens)
- integration with social media and other streamed data sources.

AC2.2 includes:

- Digital Imaging and Communications in Medicine (DICOM)
- Healthcare Level 7 (HL7).

AC2.4 includes:

- Transmission Control Protocol (TCP)
- Hypertext Transfer Protocol (HTTP)
- Secure Shell (SSH).

AC2.5 includes:

- national and institutional requirements
- the requirements for research and teaching data.

AC2.9 includes:

- encryption
- file transfer protocols (FTP, SSL etc.)
- checksums and verification
- anonymisation and minimum data sets.

AC3.1 includes:

- patient consent
- levels of access (by professionals)
- sharing protocols, risks and issues
- social media – risks and issues.

AC4.4 should include **three** clinical data pathways.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the legislation and guidance underpinning the safe use of information and communications technology (ICT) in own area of practice	1.1	Explain the legislation and standards that underpin the safe use of ICT within the clinical environment			
		1.2	Explain the legislation and guidance documents relating to the use of medical devices in own area of practice			
		1.3	Explain own responsibilities for data security			
		1.4	Explain the security issues arising from the collection, storage and analysis of health data in own area of work			
		1.5	Describe the antivirus and security update systems in use in own area of work			
		1.6	Explain the mechanisms required to maintain data confidentiality, integrity, access and storage			
		1.7	Describe the additional safeguards when the computer acts as a medical device			
		1.8	Explain the electrical safety issues associated with medical systems			
		1.9	Explain the microbiological safety issues associated with medical systems			
		1.10	Explain the operational safety issues associated with medical systems			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		1.11	Discuss the process in the event of non-compliance in accordance with the critical incident reporting			
		1.12	Explain the risks of data sharing with particular reference to Caldicott2			
		1.13	Explain patient rights, including the opportunity to opt in or opt out of sharing patient-specific data outside the NHS			
		1.14	Explain the risks of collating extracted data from multiple sources			
		1.15	Discuss the risk and mitigation of accidental disclosure of personal data			
		1.16	Describe a situation where there is the potential for misinterpretation of data			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the policies and procedures underpinning the transfer of health data in own area of work safely and securely	2.1	Discuss the uses, value and risk of access to data and information			
		2.2	Explain the common standards in own area of work			
		2.3	Explain the purpose of data exchange standards			
		2.4	Describe the network and communication protocols used in own area of work			
		2.5	Explain the governance arrangements for the protection of clinical data in own area of work			
		2.6	Describe the networking systems in common clinical use in own area of work			
		2.7	Evaluate the information technology policies in own organisation			
		2.8	Describe common data compression technologies for storage and transmission			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand how to safeguard health data and information	3.1	Explain the mechanisms in own area of work to maintain privacy, confidentiality and integrity of electronic clinical data			
		3.2	Explain the mechanisms in own area of work to access clinical data held electronically			
		3.3	Explain the requirements in own area of work for: • information and clinical governance • safeguarding personal data • confidentiality • privacy • data protection • data exchange			
		3.4	Describe clinical data pathways in own area of practice and the safeguards to protect data within each			
		3.5	Discuss how database systems, data management and modern software processes contribute to patient pathways and the provision of high-quality safe and effective patient care			
4	Be able to use information communication technology in own area of work	4.1	Send and receive information from other professionals in accordance with local policies and procedures			
		4.2	Transfer health data safely and securely in accordance with local policies and procedures			
		4.3	Archive and retrieve data and/or images in own area of work			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 125: Informatics for Physical Sciences

Level: 4

Unit type: Optional

Credit value: 9

Guided learning hours: 76

Unit summary

In this unit, you will gain knowledge of informatics and the skills to use it in a physical science setting. You will use databases and spreadsheets, and develop the ability to develop software in a high-level language.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of practice.

AC1.4 includes:

- in medical devices and personalised care/wearable devices
- telemedicine devices, including robotics
- use of mobile devices/applications
- genomics.

AC2.4 includes as Microsoft Access® and MySQL®.

AC2.11 includes:

- primary key
- joins, etc.

AC2.13 should include **two** common information analysis tools.

AC5.2 should include **two** different high-level language programs, e.g. C++, VB.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the contribution of informatics to health and healthcare in own area of work	1.1	Explain the application of clinical informatics in own area of practice			
		1.2	Describe the principles of effective quality control and validation of data			
		1.3	Discuss the impact of poor-quality data on management and healthcare outcomes			
		1.4	Discuss scientific and technical trends and new and emerging technologies			
		1.5	Discuss how social media and information networks give guidance to patients/clients, the public and other professionals			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to create and use databases in own area of work	2.1	Explain the purpose of databases in own area of practice			
		2.2	Explain the basic principles of a database			
		2.3	Describe the data security and confidentiality processes required within databases			
		2.4	Use database environments in own area of practice			
		2.5	Create a database in own area of practice			
		2.6	Enter and manipulate data in own area of practice			
		2.7	Interrogate a database and produce reports in own area of practice			
		2.8	Evaluate the database created in own area of practice			
		2.9	Amend the database created in own area of practice			
		2.10	Discuss how a range of databases is used with own area work to support high-quality, safe healthcare			
		2.11	Describe relational database concepts			
		2.12	Explain the use of information analysis tools			
		2.13	Describe common information analysis tools used in own area of work			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to create and use spreadsheets in own area of work	3.1	Explain the purpose of spreadsheets in own area of practice			
		3.2	Explain the principles of spreadsheets			
		3.3	Describe the data-security and confidentiality processes required within spreadsheets			
		3.4	Create a spreadsheet in own area of practice			
		3.5	Enter and manipulate data in own area of practice			
		3.6	Interrogate a spreadsheet and produce reports in own area of practice			
		3.7	Evaluate the spreadsheet created in own area of practice			
		3.8	Amend the spreadsheet created in own area of practice			
		3.9	Discuss how a range of spreadsheets is used with own area of work to support high-quality, safe healthcare			
4	Be able to interpret and present data using spreadsheet software	4.1	Explain the use of spreadsheet software to create presentations			
		4.2	Explain the principles of effective oral presentation			
		4.3	Explain the effective use of presentation systems			
		4.4	Create a short presentation using spreadsheet software			
		4.5	Apply appropriate techniques and design slides for the presentation			
		4.6	Deliver the presentation to a group of peers			
		4.7	Design a feedback form to gain feedback on the presentation			
		4.8	Gather feedback from the audience in relation to the presentation			
		4.9	Analyse the feedback to inform amendments to the presentation			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to develop software in a high-level language	5.1	Explain the key principles of software development			
		5.2	Discuss different high-level language programs			
		5.3	Assess the requirement for bespoke software in physical sciences with users, clinical colleagues and other relevant stakeholders			
		5.4	Write a specification for the development of bespoke software			
		5.5	Write the program to develop bespoke software			
		5.6	Test the program in relation to its effectiveness in developing the bespoke software			
		5.7	Implement the program in own area of practice			
6	Understand the integration of medical devices and information systems in healthcare	6.1	Explain how to integrate medical devices with electronic medical records			
		6.2	Explain the benefits of integrating mobile applications (apps) with wearable sensors and electronic health records			
		6.3	Assess the cyber security of hospital network and connected medical apps installed in mobile devices of clinical staff and patients			
		6.4	Discuss the impact of medical and hospital robots on healthcare			
		6.5	Discuss the use of telemedicine, including tele-pathology in own organisation			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 126: Technical Support for Computerised Medical Devices

Level: 4

Unit type: Optional

Credit value: 10

Guided learning hours: 80

Unit summary

In this unit, you will gain the knowledge and skills you need to be able to provide technical support for computerised medical devices.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of practice.

AC1.1 includes:

- security issues and antivirus and security update systems
- user administration and management:
  - user accounts, passwords and privileges
- networking and accessibility:
  - firewall set-up
- data backup:
  - integrity, automation, security
- IP addresses and connection protocols.

AC1.5 includes:

- storage services:
  - backup, archiving, business continuity and disaster recovery
  - RAID, SAN
- server virtualisation
- cloud computing
- web services (SOAP and REST)
- security and governance for cloud services.

AC1.6 includes third-party storage of clinical data.

AC1.10 includes:

- network specification
- available architectures
- performance issues
- scalability
- bridging versus routing
- cabling infrastructure
- hubs
- traffic management.

AC1.11 includes:

- Digital Imaging and Communications in Medicine (DICOM)
- Healthcare Level 7 (HL7)
- links to hospital administration systems.

AC2.1 includes:

- the role of a help desk
- the role of a ticket system.

AC2.4 includes:

- the installation of systems and applications.

AC3.1 includes:

- spreadsheets
- flat-file and structured databases
- online reference
- collaborative resources.

AC3.8 includes a focus on how data quality is ensured and the methods by which data are transferred and processed.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the underpinning principles of system administration procedures in a local area network	1.1	Explain the principles and practice of system administration			
		1.2	Describe the range of hosting environments within own area of work			
		1.3	Explain the uses, value and risk in cloud computing			
		1.4	Describe the typical networks used within own organisation			
		1.5	Explain the advantages and limitations of networking devices within own work area			
		1.6	Evaluate the key principles of local and wide area networks			
		1.7	Describe common data exchange protocols in healthcare settings			
		1.8	Explain how to apply appropriate data, information and IT standards to support the delivery of a safe and secure health informatics service			
		1.9	Describe change-management processes in relation to system administration			
2	Be able to undertake system administration procedures in a local area network	2.1	Set up user accounts, passwords and privileges and manage ad hoc requests from users in own area of work			
		2.2	Set up and manage firewalls in own area of work			
		2.3	Support data backup activities in own area of work			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to construct and install hardware and software systems in own work area	3.1	Explain the process for requesting user support in own area of work			
		3.2	Provide support to users requesting support in accordance with departmental procedures			
		3.3	Describe the use of personal computers in own area of work			
		3.4	Perform specialist hardware and software support of personal computers in own area of work			
		3.5	Use configuration control in relation to PC software installations and local area networks			
		3.6	Perform specialist hardware and software support of UNIX workstations			
4	Understand how Information and Communications Technology (ICT) supports clinical activity	4.1	Explain the range of general purpose computer software in common use			
		4.2	Explain the use of an application programme interface			
		4.3	Discuss the interconnectivity of ICT equipment and computer systems within the clinical environment			
		4.4	Explain the ICT workflow from patient referral and appointment, through modality work list, data acquisition, archiving and reporting			
		4.5	Explain how ICT is used to support research studies and clinical trials			
		4.6	Explain the ethical and governance processes underpinning the use of data			
		4.7	Explain own responsibilities when undertaking work to support research studies and clinical trials			
		4.8	Discuss the limits to which routinely collected clinical data can be used for research			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to utilise equipment management and asset databases	5.1	Use an equipment management database to record, track and report on the progress of support calls			
		5.2	Use an asset-tracking database to locate equipment			
		5.3	Use an equipment management database to correctly record a new item, including classification			
		5.4	Assist in data processing for a clinical trial			
6	Be able to undertake one-to-one training of users in the safe and effective use of hardware and software	6.1	Explain the principles of teaching and learning practical skills			
		6.2	Plan the one-to-one training session			
		6.3	Deliver the training in line with the training plan			
		6.4	Gather user feedback on the training session			
		6.5	Evaluate the feedback to inform the development of future training			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 127: Project Management

Level: 4

Unit type: Optional

Credit value: 5

Guided learning hours: 40

Unit summary

In this unit, you will gain core knowledge and skills of project management within a clinical environment.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures (SOPs) in own area of practice.

AC1.1 includes:

- development of draft project specification
- development of user specifications
- development of prototypes and evaluation of software
- project acceptance
- documentation, maintenance and further development
- quality-management and quality-assurance processes.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to plan a new project within the framework of formal project-management methodology within own area of work	1.1	Explain the project-management life cycle within own area of work			
		1.2	Discuss the nomenclature in project documentation within own area of work			
		1.3	Explain the purpose of identifying risks and hazards			
		1.4	Agree the formal project methodology to be used			
		1.5	Develop a specification of requirements for the project			
		1.6	Work with users to develop a detailed specification of user requirements			
		1.7	Evaluate the solution, establishing its appropriateness and limitations			
		1.8	Develop a validation plan for the planned project			
		1.9	Develop a verification plan for the planned project			
		1.10	Develop user documentation and training for the planned project			
		1.11	Develop technical documentation for the planned project			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to execute and close the project within the framework of formal project-management methodology within own area of work	2.1	Execute the project			
		2.2	Maintain a hazard and risk log for the project			
		2.3	Perform end-stage review against the planning documentation and project specification			
		2.4	Close out the project completing all documentation			
		2.5	Critically evaluate the project and make recommendations for further action			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 128: Clinical Bioinformatics in Practice (Cancer Genomics)

Level: 4

Unit type: Optional

Credit value: 20

Guided learning hours: 160

Unit summary

In this unit, you will acquire the knowledge and skills to be able to perform routine tasks to support the bioinformatics pipelines used in the diagnosis and treatment of patients with a range of acquired or inherited cancers within a clinical bioinformatics environment. You will be expected to develop your professional practice as you build your competence in the work base.

Additional information

AC1.2: learners should illustrate with **two** examples from own area of work

AC1.6: learners should use **one** example

AC2.3: bioinformatics resources such as databases and online tools.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand how clinical bioinformaticians support the diagnosis, treatment and clinical care of patients and/or populations with cancer	1.1	Explain how cancer starts, following changes in the cell			
		1.2	Explain how a molecular diagnosis is made in patients suspected of having cancer			
		1.3	Discuss the impact of genomics on the diagnosis, treatment and clinical care of patients with cancer			
		1.4	Explain the role of clinical bioinformaticians in the diagnosis, treatment and clinical care of patients with cancer			
		1.5	Discuss the role of the multidisciplinary team with respect to the diagnosis, treatment and clinical care of patients with cancer			
		1.6	Discuss the potential impact of a diagnosis of cancer on the patient and family			
		1.7	Discuss how personalised medicine can have a positive impact on a patient with cancer			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine clinical bioinformatics procedures following Standard Operating Procedures	2.1	Apply quality control processes of the data analysis processes to genomic data from patients with cancer			
		2.2	Integrate phenotypic and other clinical data with whole genome sequencing from patients with cancer			
		2.3	Apply bioinformatics resources to genomics data from patients/populations with cancer			
3	Understand the human genome and how variation results in cancer	3.1	Explain the overall structure and organisation of the human genome			
		3.2	Describe how inherited and acquired cancers arise			
		3.3	Explain the major types of genetic variation that arise in cancer			
		3.4	Describe the commonly used technologies to detect genomic variation in cancer			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 129: Clinical Bioinformatics in Practice (Infectious Diseases)

Level:	**4**
Unit type:	**Optional**
Credit value:	**20**
Guided learning hours:	**160**

Unit summary

In this unit, you will acquire the knowledge and skills to be able to perform routine tasks to support the genomics pipelines used to support the diagnosis and treatment of infectious diseases within a clinical bioinformatics environment. You will be expected to develop your professional practice as you build your competence in the work base.

Additional information

AC1.4: includes intervention measures taken to stop further spread of disease.

AC1.7: learners should give **one** example.

AC3.1: using TB, Staphylococcus aureus and HIV as examples.

AC2.3: bioinformatics resources such as databases and online tools.

AC3.2: including how this is applied to determine both the pathogenic potential of a single pathogen isolate and the relationship between multiple isolates of the same species.

AC3.4: including both vertically-inherited variation and horizontally-acquired DNA such as plasmids.

AC3.5: including how genomics can be used to determine the potential source of an outbreak.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand how clinical bioinformaticians support the diagnosis, treatment and clinical care of patients and/or populations with infectious diseases	1.1	Define the term 'infectious disease'			
		1.2	Describe genotype/phenotype relationship and how this applies to understanding infectious disease			
		1.3	Explain the role of clinical bioinformaticians in the diagnosis, treatment and clinical care of patients with infectious diseases			
		1.4	Explain the role of the clinical bioinformatician in the intervention measures to prevent further spread of disease			
		1.5	Discuss the role of the multidisciplinary team with respect to the diagnosis, treatment and clinical care of patients with infectious diseases			
		1.6	Discuss the role of public health bodies in the prevention, diagnosis and treatment of infectious diseases			
		1.7	Discuss the potential impact of a diagnosis of an infectious disease on the patient and/or population			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform routine Clinical Bioinformatics procedures following Standard Operating Procedures	2.1	Apply quality control processes of the data analysis processes to genomic data from patients/populations with infectious disease/s			
		2.2	Integrate phenotypic and other clinical data with whole genome sequencing from patients/populations with infectious disease/s			
		2.3	Apply bioinformatics resources to genomics data from patients/populations with infectious disease/s			
3	Understand the molecular basis of infectious disease	3.1	Explain the overall structure and organisation of microbial genomes			
		3.2	Describe the commonly used technologies to detect genomic variation in infectious diseases			
		3.3	Explain how a molecular diagnosis is made where patients are suspected of having an infectious disease			
		3.4	Explain how changes in DNA of microbes can increase the virulence of an organism			
		3.5	Explain how epidemics can be tracked both locally and internationally			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 130: Clinical Bioinformatics in Practice (Rare Diseases)

Level:	**4**
Unit type:	**Optional**
Credit value:	**20**
Guided learning hours:	**160**

Unit summary

In this unit, you will acquire the knowledge and skills to be able to perform routine tasks to support the genomics pipelines in the diagnosis and treatment of patients with rare diseases within a clinical bioinformatics environment. You will be expected to develop your professional practice as you build your competence in the work base.

Additional information

AC1.2: learners should choose at least one example from each group to compare and contrast (congenital, paediatric and adult onset).

AC1.3: learners should give one example.

AC1.6: learners should give one example.

AC2.3: bioinformatics resources such as databases and online tools.

AC3.2: to include autosomal dominant, autosomal recessive, x-linked, mitochondrial and de novo and how this information is important in determining the bioinformatics strategy.

AC3.3: to include single-nucleotide variants (SNVs), small insertions and deletions, copy number variation (CNVs), rearrangements, chromosome abnormalities.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand how clinical bioinformaticians support the diagnosis, treatment and clinical care of patients with rare diseases	1.1	Define the term 'rare disease'			
		1.2	Compare and contrast the clinical presentation and course of rare diseases			
		1.3	Explain how a molecular diagnosis is made where patients are suspected of having a rare disease			
		1.4	Explain the role of clinical bioinformaticians in the diagnosis, treatment and clinical care of patients with rare diseases			
		1.5	Discuss the role of the multidisciplinary team with respect to the diagnosis, treatment and clinical care of patients with rare diseases			
		1.6	Discuss the potential impact of the diagnosis of a rare disease on the patient and family			
2	Be able to perform routine clinical bioinformatics procedures following Standard Operating Procedures	2.1	Apply quality control processes of the data analysis processes to genomic data from patients with rare diseases			
		2.2	Integrate phenotypic and other clinical data with whole genome sequencing from patients with rare diseases			
		2.3	Apply bioinformatics resources to genomics data in patients/populations with rare diseases			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Understand the genome and how variation results in disease	3.1	Explain the overall structure and organisation of the human genome			
		3.2	Describe the major patterns of inheritance seen in rare disease			
		3.3	Explain the major types of genetic variation that can result in disease			
		3.4	Describe the commonly used technologies to detect genomic variation in rare diseases			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 131: Measurement of Toe Pressure by Photoplethysmography (PPG)

Level: 4

Unit type: Optional

Credit value: 10

Guided learning hours: 80

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to perform the quality-assured, safe measurements of toe pressure by photoplethysmography (PPG). You will be expected to build your patient-centred professional practice to enable you to safely undertake this skill in the workplace.

Additional information

Learners completing this unit must also complete *Unit 102: Measurement of Ankle Brachial Pressure Index*.

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP) in own area of practice.

AC1.2 includes:

- equipment safety
- patient safety
- staff safety
- accuracy
- potential errors and how to minimise/correct errors.

AC1.3 includes:

- when ankle pressures are significantly elevated in comparison to the brachial pressure, suggesting incompressible lower limb arteries due to the presence of arterial calcification or oedema
- patients referred with critical limb ischaemia/tissue loss
- when specifically requested.

AC1.5 includes:

- cuff size – ensure that the cuff length and width is adequate size for the limb/digit
- room temperature – an environment that is too hot or too cold will cause vasodilation or vasoconstriction, which may affect toe pressure measurements
- patients with cardiac arrhythmia, e.g. rapid atrial fibrillation
- not all patients are able to lie flat, elevation of the upper body may cause the pressure in the lower limbs to be falsely elevated.

AC2.1 includes:

- the method of obtaining a TBI (toe brachial index)
- potential errors and how to minimise/correct errors (including patient position).

AC2.2 includes:

- measuring the brachial pressure in each arm using continuous wave Doppler
- selecting the correct size of cuff
- positioning the cuff around the great toe
- securing the PPG sensor to a clean area of skin distal to the toe cuff
- checking that arterial pulse is present
- inflating the cuff until the pulse signal is lost
- slowly deflating the cuff and records the pressure where the pulse first returns (the toe pressure)
- taking care in performing PPG measurements due to the cuff's sensitivity to movement
- ensuring the cuff isn't too tight around the toe to avoid compression/occlusion of the digital arteries.

AC2.5 includes:

- introducing self by name and explaining role
- appropriate use of non-verbal communication
- providing information in a timely manner in appropriate language
- listening to the patient and addressing questions or seeking advice from senior colleagues
- communication during and after the test
- communicating in a way that:
    - respects the dignity, rights, privacy and confidentiality of the patient/carer
    - considers and addresses potential cultural differences (undressing etc.), determining when it may be necessary to invite a family member to be present.

AC2.6 includes:

- normal values for TBI in accordance with local protocols.

AC2.8 could include:

- bypass grafts
- stents
- angioplasty
- amputation.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of measuring toe pressures by photoplethysmography	1.1	Explain the structure and function of the arterial and venous blood vessels supplying the lower limbs, including the toes			
		1.2	Explain the measurement principles underpinning toe pressures measurement by photoplethysmography			
		1.3	Explain the indications and contraindications for measuring toe pressures			
		1.4	Explain the limitations of the measurement of toe pressures			
		1.5	Evaluate the potential errors associated with the measurement of toe pressures			
		1.6	Explain the process of gaining informed consent for the measurement of toe pressures			
		1.7	Discuss when to seek advice from senior colleagues when a patient is likely to need further investigation			
		1.8	Explain the potential impact of peripheral arterial disease on the quality of life of the patient			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to measure toe pressures by photoplethysmography in accordance with the standard operating procedure	2.1	Evaluate the Standard Operating Procedure for the measurement of toe pressures to obtain a TBI (toe brachial index)			
		2.2	Measure toe pressures in a range of patients with calcified arteries or critical limb ischaemia			
		2.3	Know when and how to refer to senior colleagues in the event of being unable to obtain a reading			
		2.4	Evaluate the technical quality of the toe pressure measurement			
		2.5	Calculate the toe brachial index			
		2.6	Communicate effectively with the patient throughout the procedure			
		2.7	Prepare a report documenting the results and actions taken in accordance with the Standard Operating Procedure in own area of work			
		2.8	Discuss potential treatment options for patients with PVD			
3	Be able to clean and decontaminate equipment, and leave in a suitable condition for reuse	3.1	Evaluate the protocols for cleaning and decontaminating equipment used to record toe pressures			
		3.2	Decontaminate equipment, leaving it in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

Unit 132: Measurement of Transcutaneous Oxygen (TCPO2)

Level: 4

Unit type: Optional

Credit value: 10

Guided learning hours: 80

Unit summary

In this unit, you will gain the knowledge, understanding and skills needed to be able to perform the quality-assured, safe measurement of transcutaneous oxygen ($TCPO_2$). You will be expected to build your patient-centred professional practice to enable you to safely undertake this skill in the workplace.

Additional information

Learners completing this unit must also complete *Unit 102: Measurement of Ankle Brachial Pressure Index* and *Unit 129: Measurement of Toe Pressure by Photoplethysmography (PPG)*

All procedures must be undertaken in accordance with the Standard Operating Procedure (SOP) in own area of practice.

AC1.1 includes:

- $TCPO_2$ is a non-invasive monitoring of the oxygen tension in the skin
- $TCPO_2$ is a direct indication of the microvascular function enabling mapping of the actual oxygen supply available for the skin tissue cells
- $TCPO_2$ also responds to macrocirculatory events, e.g. change in blood pressure and provocation manoeuvres.

AC1.2 includes:

- equipment safety
- patient safety
- staff safety
- site selection – an ideal site would be located over a homogeneous capillary bed without large veins, skin defects, or hair
- ambient temperature 21–23 °C (70–73 °F)
- stable patient status.

AC1.3 includes:

- diagnosis of ischemia
- prediction of wound healing
- evaluation of vasodilators
- predicting amputation
- amputation level healing prognosis.

AC1.5 includes:

- placing the electrode directly over a bone if a change in body position causes skin to be pulled against a protruding bone
- severe oedema.

AC1.6 includes:

- introducing self by name and explaining role
- appropriate use of non-verbal communication
- providing information in a timely manner in appropriate language
- listening to the patient and addressing questions or seeking advice from senior colleagues
- communication during and after the test
- communicating in a way that:
    - respects the dignity, rights, privacy and confidentiality of the patient/carer
    - considers and addresses potential cultural differences (undressing etc.), determining when it may be necessary to invite a family member to be present.

AC2.2 includes:

- calibrating the $TCPO_2$ electrode
- how to select the measurement site/s
- selecting the measuring site/s
- cleaning the selected measuring site with alcohol or other skin-preparation solution
- applying the electrode/s
- allowing the readings to stabilise.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of measuring transcutaneous oxygen ($TCPO_2$)	1.1	Explain the purpose of $TCPO_2$ measurement			
		1.2	Explain the principles underpinning the measurement of $TCPO_2$			
		1.3	Explain the indications and contraindications for measuring $TCPO_2$			
		1.4	Explain the limitations of the measurement of $TCPO_2$			
		1.5	Evaluate the potential errors associated with the measurement of $TCPO_2$			
		1.6	Explain the process of gaining informed consent for the measurement of $TCPO_2$			
		1.7	Discuss when to seek advice from senior colleagues when a patient is likely to need further investigation			
2	Be able to measure transcutaneous oxygen ($TCPO_2$) in accordance with the Standard Operating Procedure	2.1	Evaluate the Standard Operating Procedure for the measurement of $TCPO_2$			
		2.2	Measure $TCPO_2$in patients with critical limb ischaemia and tissue loss at rest			
		2.3	Know when and how to refer to senior colleagues in the event of being unable to obtain a reading			
		2.4	Communicate effectively with the patient throughout the procedure			
		2.5	Document the results and actions taken in accordance with the Standard Operating Procedure in own area of work			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to clean and decontaminate equipment, and leave in a suitable condition for reuse	3.1	Evaluate the protocols for cleaning and decontaminating equipment used to measure $TCPO_2$			
		3.2	Decontaminate equipment, leaving in a suitable condition for reuse			

Learner name: _____

Learner signature: _____

Assessor signature: _____

Internal verifier signature: _____
(*if sampled*)

12 Further information and useful publications

To get in touch with us visit our 'Contact us' pages:

- Edexcel, BTEC and Pearson Work Based Learning contact details: qualifications.pearson.com/en/support/contact-us.html
- books, software and online resources for UK schools and colleges: www.pearsonschoolsandfecolleges.co.uk

Key publications

- Adjustments for candidates with disabilities and learning difficulties, Access Arrangements and Reasonable Adjustments, General and Vocational qualifications (Joint Council for Qualifications (JCQ))
- Supplementary guidance for reasonable adjustments and special consideration in vocational internally assessed units (Pearson)
- General and Vocational qualifications, Suspected Malpractice in Examinations and Assessments: Policies and Procedures (JCQ)
- Equality Policy (Pearson)
- Recognition of prior learning policy and process (Pearson)
- UK Information Manual (Pearson)
- Pearson Edexcel NVQs, SVQs and competence-based qualifications – Delivery Requirements and Quality Assurance Guidance (Pearson)

All of these publications are available on our website: qualifications.pearson.com

Further information and publications on the delivery and quality assurance of NVQ/competence-based qualifications are available at our website on the Delivering BTEC pages. Our publications catalogue lists all the material available to support our qualifications. To access the catalogue and order publications, please go to the resources page of our website.

13 Professional development and training

Professional development and training

Pearson supports customers with training related to our qualifications. This support is available through a choice of training options offered on our website.

The support we offer focuses on a range of issues, such as:

- planning for the delivery of a new programme
- planning for assessment and grading
- developing effective assignments
- building your team and teamwork skills
- developing learner-centred learning and teaching approaches
- building in effective and efficient quality-assurance systems.

The national programme of training we offer is on our website. You can request centre-based training through the website or you can contact one of our advisers in the Training from Pearson UK team via Customer Services to discuss your training needs.

Training and support for the lifetime of the qualifications

Training and networks: our training programme ranges from free introductory events through sector-specific opportunities to detailed training on all aspects of delivery, assignments and assessment. We also host some regional network events to allow you to share your experiences, ideas and best practice with colleagues in your region.

Regional support: our team of Regional Quality Managers, based around the country, are responsible for providing quality-assurance support and guidance to anyone managing and delivering NVQs/cmpetence-based qualifications. The Regional Quality Managers can support you at all stages of the standard verification process as well as in finding resolutions of actions and recommendations as required.

To get in touch with our dedicated support teams please visit our website at qualifications.pearson.com/en/support/contact-us.html

Online support: find the answers to your questions in *Knowledge Base*, a searchable database of FAQs and useful videos that we have put together with the help of our subject advisors to support you in your role. Whether you are a teacher, administrator, Assessment Associate (AA) or training provider, you will find answers to your questions. If you are unable to find the information you need please send us your query and our qualification or administrative experts will get back to you.

14 Contact us

We have a dedicated Account Support team, across the UK, to give you more personalised support and advice. To contact your Account Specialist:

Email: wblcustomerservices@pearson.com
Telephone: 0344 576 0045

If you are new to Pearson and would like to become an approved centre, please contact us:

Email: wbl@pearson.com
Telephone: 0344 576 0045

Annexe A: Assessment Strategy

Assessment Principles and Strategy for Level 4 Diploma in Healthcare Science, July 2017

1. Introduction

1.1 The healthcare science associate supports the work of healthcare science practitioners and clinical scientists in performing high-quality, safe diagnostic, therapeutic and monitoring technical and scientific procedures from conception to end of life in job roles within hospitals, general practice and other settings in the healthcare sector and across all areas of healthcare science.
they perform a wide range of routine technical and scientific procedures, with minimal supervision, within one of the divisions in healthcare science following specific protocols and in accordance with health, safety, governance and ethical requirements.

1.2 This document sets out the minimum expected principles and approaches to assessment, and should be read alongside qualification regulatory arrangements and any specific requirements set out for particular qualifications. Additional information and guidance regarding assessment can be obtained from the awarding organisation.

1.3 The information is intended to support the quality-assurance processes of Awarding Organisations that offer qualifications in the sector.

1.4 Throughout this document the term unit is used for simplicity, but this can mean module or any other similar term.

1.5 In all work, we would expect assessors to observe and review learners practising core values and attitudes required for quality practice. All those involved in any form of assessment must know and embrace the values and standards of practice set out in these documents.

2. Assessment Principles

Good practice dictates the following.

2.1 Learners must be registered with the Awarding Organisation before formal assessment commences.

2.2 Assessors must be able to evidence and justify the assessment decisions that they have made.

2.3 Assessment systems should, where possible, be integrated with employers' training and career development programmes.

2.4 Assessment decisions for competence-based learning outcomes (e.g. those beginning with 'be able to') must be made during the learners' normal work activity by an occupationally qualified, competent and knowledgeable assessor.

2.5 Any knowledge evidence integral to competence-based learning outcomes may be generated outside of the work environment, but the final assessment decision must be within the real work environment.

2.6 Assessment decisions for competence-based learning outcomes must be made by an assessor qualified, or working towards a qualification, to make assessment decisions. It is the responsibility of the Awarding Organisation to confirm that their assessors are suitably qualified to make assessment decisions.

2.7 Competence-based assessment must include direct observation as the main source of evidence. However, other assessment methods such as professional discussion and assignments may sometimes also be appropriate in certain patient-facing situations, where observation is not appropriate.

2.8 The Healthcare Science Sector holds the view that simulation is a practical and effective tool for establishing skill and understanding where naturally occurring evidence of competence is rarely available. However, simulation may not be used as an assessment method for competence-based learning outcomes except where this is specified in the assessment requirements. In these cases, the use of simulation should be restricted to obtaining evidence where the evidence cannot be generated through normal work activity.

2.9 The environment in which simulation takes place must be designed to match the characteristics of the working environment.

Simulation must not be used as the sole form of evidence for any unit within this qualification.

2.10 Where the assessor is not occupationally competent in a specialist area, expert witnesses can be used for direct observation where they have occupational expertise in the specialist area. The use of expert witnesses should be determined and agreed by the assessor, who remains responsible for the final assessment decision.

2.11 Witness testimony from others can enrich assessment and make an important contribution to assessment decisions.

2.12 Assessment of knowledge-based learning outcomes (e.g. those beginning with 'know' or 'understand'):

- may take place in or outside of a real work environment
- must be made by an occupationally qualified and knowledgeable assessor, who has achieved or is working towards a recognised assessor qualification
- must be robust, reliable, valid and current; any assessment evidence using preset automated tests, including e-assessment portfolios, must meet these requirements and can only contribute to overall decisions made by the assessor.

2.13 It is the responsibility of the Awarding Organisation to ensure that those involved in assessment can demonstrate their continuing professional development, up-to-date competence, knowledge and understanding of practice at or above the level of the unit.

3. Quality Assurance

3.1 Internal quality assurance is key to ensuring that the assessment of evidence is of a consistent and appropriate quality. Those carrying out internal quality assurance must be occupationally knowledgeable in the unit they are assuring and be qualified to make quality-assurance decisions. It is the responsibility of the Awarding Organisation to confirm that those involved in internal quality assurance are suitably qualified, or working towards a qualification, for this role.

3.2 Those involved in internal quality assurance must have the authority and the resources to monitor the work of assessors. They have a responsibility to highlight and propose ways to address any challenges in the assessment process (e.g. to ensure suitable assessors are assigned to reflect the strengths and needs of particular learners).

3.3 Those carrying out external quality assurance must be occupationally knowledgeable and understand the policy and practice context of the qualifications in which they are involved. It is the responsibility of the Awarding Organisation to confirm that those involved in external quality assurance are suitably qualified, or working towards a qualification, for this role.

3.4 Those involved in external quality assurance have a responsibility to promote continuous improvement in the quality of assessment processes.

3.5 These principles are supplemental to, and should be read in conjunction with, the Awarding Organisation's own quality assurance principles. Please refer to the documentation provided on the Awarding Organisation's website.

4. Definitions

4.1 Occupationally competent

This means that each assessor must be capable of carrying out the full requirements of the area they are assessing. Occupational competence may be at unit level for specialist areas: this could mean that different assessors may be needed across a whole qualification while the final assessment decision for a qualification remains with the main assessor. Being occupationally competent means also being occupationally knowledgeable. This occupational competence should be maintained annually through clearly demonstrable continued learning and professional development.

Occupationally knowledgeable

This means that each assessor should possess relevant knowledge and understanding. Occupationally knowledgeable assessors may assess at unit level for specialist areas within a qualification, while the final assessment decision for a qualification remains with the main assessor. This occupational knowledge should be maintained annually through clearly demonstrable continued learning and professional development.

4.2 Qualified to make assessment decisions

This means that each assessor must hold, or be working towards holding, a qualification suitable to support the making of appropriate and consistent assessment decisions. The Awarding Organisation will determine what will qualify those making assessment decisions according to the unit of competence under assessment.

4.3 Qualified to make quality-assurance decisions

Awarding Organisations will determine what will qualify those undertaking internal and external quality-assurance to make decisions about that quality assurance.

4.4 Expert witness

an expert witness must:

- have a working knowledge of the units for which they are providing expert testimony
- be occupationally competent in the area for which they are providing expert testimony
- have EITHER any qualification in assessment of workplace performance OR a work role that involves evaluating the everyday practice of staff within their area of expertise.

4.5 Witness testimony

Witness testimony is an account of practice that has been witnessed or experienced by someone other than the assessor and learners. Witness testimony can have particular value in confirming reliability and authenticity, in avoiding tokenistic assessment and in the assessment of practice in sensitive situations. Witness testimony provides supporting information for assessment decisions and should not be used as the only evidence of competence.

Appendix A: Codes and Standards of Conduct

Academy for Healthcare Science – Good Scientific Practice (Dec 2012)

www.ahcs.ac.uk/wordpress/wp-content/uploads/2013/09/AHCS-Good-Scientific-Practice.pdf

November 2017

For information about Edexcel, BTEC or LCCI qualifications visit qualifications.pearson.com