SPECIALIST ACCREDITATION COMMITTEE MEDICAL TRAINING PROGRAMME - CHEMICAL PATHOLOGY

The Trainee's Record Book and Trainer's Report Book are attached

Training Programme in Chemical Pathology
Malta College of Pathologists

Created October 2009

1. TITLE

Outline of Training Programme in Chemical Pathology (Including Toxicology)

2. ENTRY REQUIREMENTS

Recognised First Degree in Medicine.
Full registration with the Medical Council of Malta.

3. DURATION

3.1. Five years, full-time

3.2. Flexible training
'Flexible training' is the term used to describe doctors undertaking training on a less than full-time basis, normally between five and eight sessions per week. The aim of flexible training is to provide opportunities for doctors in the health service who are unable to work full time. Doctors can apply for flexible training if they can provide evidence that "training on a full-time basis would not be practicable for well-founded individual reasons".
Flexible trainees must accept two important principles outlined in European law (Directive 93/16/EEC):

i. part-time training shall meet the same requirements (in depth and breadth) as full-time training
ii. the total duration and quality of part-time training of specialists must be not less than those of a full-time trainee. In other words, a part-time trainee will have to complete the minimum training time for their specialty pro rata.

3.3. Trainees who are in possession of a postgraduate degree, at Masters level in any relevant Pathology discipline (e.g. Clinical Biochemistry, Toxicology, Molecular biology) will be exempted from 12 months of the proposed Training Programme.

3.4. Trainees who are in possession of the MRCP will be exempted from 12 months of the proposed Training Programme.

3.5. Exemptions up to 12 months will also be granted to trainees who have been/ are involved in research (vide 4.1.8.i&ii) leading to an MPhil/PhD

3.6. The maximum amount of time that may be granted automatically for exemption from the Training Programme is 12 months. Trainees may be eligible for further exemptions in excess of 12 months but this would require application to and approval by the SAC/ College of Pathologists

4. MAIN AREAS COVERED (competencies to be acquired)

4.1. Outline of Training Programme
The trainee will be attached to a consultant chemical pathologist/ toxicologist and will be exposed to all procedures and techniques that the consultant deals with. The trainee will also be attached to consultant physicians performing clinical work in Out-Patient clinics and on wards.
Stages of training and learning

There are four stages in the chemical pathology curriculum. Trainees may not progress to the next stage of training until they have satisfactorily completed the preceeding stage.

4.1.1
Stage A (BST 1)
The trainee has a comprehensive understanding of the principles and practices of chemical pathology under direct supervision.
Stage A of training is 12 months whole-time equivalent. This stage of the curriculum will begin with a formal introduction to the basic principles of chemical pathology. Following the induction period, the trainee will receive instruction and practical experience in further aspects of chemical pathology. This stage of training will involve working solely in the laboratories, and will consist mostly of work at bench level. It will be formally assessed by the PGTC Chemical Pathology Year 1 Assessment.
In order to satisfactorily complete stage A of chemical pathology training, trainees must have:

i. satisfactorily completed stage A of the chemical pathology curriculum and a minimum training period of 12 months (whole-time equivalent)
ii. performed satisfactorily in the PGTC Year 1 Assessment

In order to retain clinical skills, the trainee will be required to participate in on-call duties within the Department of Medicine or within an equivalent department where he/she will be exposed to acute medical cases.

4.1.2
Stage B (BST II)
The trainee has a good general knowledge and understanding of most principles and practices under indirect supervision. He/she should be able to deal with most of the day-to-day issues in a hospital chemical pathology laboratory to an adequate level but will still require consultant input with regard to complex management and clinical issues.
Stage B of training is between month 13 and month 24 of whole-time equivalent training. During Stage B of training, the trainee will continue to broaden their experience and understanding of chemical pathology. During this stage, the trainee will be expected to gain clinical exposure in acute and non-acute settings. Trainees will also be expected to participate in out-patient sessions in branches of medicine that are heavily involved in metabolic & endocrine aspects of disease eg diabetes and endocrine clinics, parenteral nutrition, toxicology, metabolic bone disease, dynamic function testing. The knowledge gained during this stage of training will be assessed by the FRCPath Part 1 examination or equivalent.

In order to complete stage B of chemical pathology training, trainees must have:

i. satisfactorily completed a total of at least 24 months of training (whole-time equivalent) of which at least 12 months should be in Stage B
ii. passed the FRCPath Part 1 examination in clinical biochemistry

Completion of this stage of training entitles the trainee to apply for an HST post.

4.1.3

Stage C (HST 1 & 2)

Stage C of training is between month 25 and month 48 of whole-time equivalent training. This stage of the curriculum enables the trainee to undertake further specialised general chemical pathology training. This stage of training will in part be summatively assessed by the FRCPath Part 2 examination.

In order to complete stage C of chemical pathology training, trainees must have:

i. satisfactorily completed a total of at least 42 months of training (whole-time equivalent) of which at least 12 months should be in Stage C (HST1)
ii. passed the FRCPath Part 2 examination in clinical biochemistry or equivalent
iii. undertaken a Penultimate Year Appraisal (PYA)

4.1.4

Stage D (HST3)

The trainee has an in-depth knowledge and understanding of the principles of chemical pathology. He/she should be competent to discuss and deal with the subject (or, where appropriate, perform the task/procedure), demonstrating a level of clinical or professional judgement commensurate with independent professional practice at consultant level. It is anticipated that a trainee at this level should have consultant input readily available at all times where required.

Stage D of training is between month 48 and month 60 of whole-time equivalent training. This stage of the curriculum prepares the trainee for their consultant post.

The PYA undertaken near the end of Stage C should identify goals for the trainee to achieve during their final year of training. By the end of Stage D, the trainee should be able to demonstrate a level of knowledge and skill indicating suitability for independent professional practice in chemical pathology.

In order to complete stage D of chemical pathology training, trainees must have:

i. satisfactorily completed a total of at least 60 months of training (whole-time equivalent) of which at least 12 months should be in Stage D
ii. satisfactorily completed all core and generic areas of the chemical pathology curriculum
iii. a final assessment indicating a final record of satisfactory progress, leading to the award of the CCST.

Training programmes

Training programmes should include suitable rotational arrangements to cover all the necessary areas of the curriculum and should include an appropriate balance between hospital laboratories, wards and clinics (this may vary from six months to two years, depending on the interests and experience of the trainee) and specialist units such that each trainee gains the breadth of training required for satisfactory completion of the curriculum and a wide exposure to different content, educational supervisors and methods.

The exact rotational arrangements will vary according to the number of placements on the training scheme and the number of other trainees on the training programme. Efforts will be made to accommodate any particular subspeciality interests of the trainee but the exigencies of the service and its continued provision remain an over-riding necessity.

Rotational arrangements will cover placement in the Clinical Biochemistry lab and the Toxicology lab. Clinical exposure will be offered, by prior arrangement with the respective departments, in General Medicine, ITU, in Obs&Gynae, gastro-enterology, paediatrics, endocrine and diabetes, in order to offer exposure to general biochemistry, nutrition and parenteral nutrition, toxicology, infertility, endocrinology, diabetes, etc

The training scheme should be organised in such a way as to give each trainee some experience in most recognised areas of subspecialisation. Trainees are expected to undergo secondment to obtain specialized training overseas, of a duration of 12 – 24 months. This secondment should ideally take place at HST 2 &/ or 3 level.

4.2. Basic knowledge and skills

4.2.1. Laboratory aspects of chemical pathology

The trainee should aim to become a competent analyst with a thorough understanding of method development, performance and application. Extensive experience of all laboratory techniques is not expected but trainees should gain in-depth practical experience of techniques used for the most commonly measured analytes, and of other more specialised techniques available in their training programme as required to provide a critical insight into laboratory methodology. They should at least have observed all other techniques listed in the curriculum.

Theoretical knowledge of the analytical techniques is essential in order to develop a critical attitude to the principles underlying methods and instrumentation, their performance and usefulness in the clinical setting.

Laboratory problems should be used to create learning opportunities.

Trainees must become proficient in the theory and application of data handling and statistical methods.

4.2.2. Management and communication

Trainees must gain experience under supervision in formulating departmental policies and clinical guidelines and in applying the leadership and teamwork skills that are necessary to implement them. Understanding the organisation and operation of a modern laboratory service, both within the hospital and in primary care, and how different staff groups contribute to the pre-, intra- and post-analytical processes is a key skill to be acquired.

Communication skills should be developed by report writing, presentation of data at meetings, through contributions to group discussions and attendance at departmental business meetings.

Trainees should experience strategic planning, preparation of a business plan, contracting processes, service level agreements and departmental and directorate budgeting.

Formal training should be gained by attending suitable management courses. Trainees, as colleagues, should sit on departmental, directorate and committee meetings as observers in order to gain experience of committee procedures, aspects of confidentiality, decision-making and the importance of maintaining good interpersonal relationships.

4.3.1. Clinical governance, clinical audit and evidence-based medicine
Clinical governance is the framework through which health service organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish.
In chemical pathology, trainees must acquire knowledge of the lines of accountability, quality improvement programmes, clinical audit, evidence-based practice, clinical standards and guidelines, managing risk and quality assurance programmes. Training in these areas must continue throughout all stages of the curriculum.

4.3.2. Clinical training
Trainees must acquire a detailed understanding of biochemical processes and the changes that occur in disease. They must then develop the skills to use this knowledge in the diagnosis and management of disease. They must also develop an understanding of the rationale for investigation and treatment of disease and the clinical usefulness and limitations of laboratory tests in these settings. Trainees are not required to know every aspect, as certain conditions are rare. Knowledge of where to obtain relevant information is required.

4.3.3. Direct patient care in the outpatient setting
This forms an important part of training. The specialty experience gained will vary but the majority of trainees will gain expertise in at least two areas, e.g. lipidology and nutrition.

4.3.4. Recent advances in the clinical and laboratory aspects of the subject as published in scientific literature
The curriculum outlines the knowledge, skills, attitudes and expertise that a trainee is expected to obtain in order to achieve the award of the CCST. It is expected that every trainee should undertake the core training outlined below but it is recognised that the sequencing of learning and experience will differ according to the programme.

4.4. Learning Experiences
The following teaching/learning methods will be used to identify how individual objectives will be achieved:

a. observation of, assisting and discussion with senior staff
b. task specific on the job training
c. observation of laboratory methods
d. personal study
e. attendance to appropriate modules in under-graduate courses eg BSc Medical Lab Science
f. appropriate postgraduate education courses
g. tailored clinical experience
h. laboratory and clinical team meetings
i. undertaking a laboratory-based project
j. practical bench work.

4.5. Core Chemical Pathology Curriculum (Stage A)

4.5.1. Introduction

This curriculum indicates the level of theoretical knowledge, and clinical and laboratory skills which might reasonably be expected to be achieved by a trainee during their first year of training in chemical pathology.

i. knowledge of laboratory techniques that underpin clinical laboratory practice
ii. gained knowledge of laboratory practice including health and safety and quality assurance
iii. a basic knowledge of the presentation, differential diagnosis and natural history of the common chemical pathology disorders
iv. sufficient understanding of chemical pathology to offer basic advice on the interpretation of laboratory results.

4.5.2. LABORATORY COMPETENCIES

Introduction to chemical pathology

Objective: to achieve sufficient knowledge of laboratory chemical pathology to offer basic advice on the interpretation of results.

A. Operation of automated analysers. Understand the principles of the operation of automated analysers.

a) Interpretation of results generated.
b) Identification of invalid results.
c) Knowledge of specimen collection, handling, transport and sample storage
d) Understanding the use of specific preservatives and possible interference in assays
e) Familiarity with the functions of pathology reception, the phlebotomy service.
f) Comprehending the problems associated with 24 hour urine collections.
g) Principles of health and safety Application to the working laboratory and avoiding risks.
h) IT and communication skills. Familiarity with fundamental aspects of computing within the laboratory, databases, spreadsheets, internet use on a day-to-day basis.
i) Proactive attitude to new technology.
j) Principles of quality control and assurance Basic understanding of quality control and quality assurance.
k) Understanding the use of External Quality Assurance (EQA) and National External Quality Assurance Service (NEQAS)
l) Evaluation of internal/external quality assurance data so as to identify the possible cause of aberrant data, including the constraints due to instrumentation, reagents and operations.
m) Presentation, diagnosis and management of common chemical pathology disorders
n) Recognition of disorders in the laboratory and advice on the differential diagnosis and initial management of common chemical pathology disorders.
o) Awareness of the need to consult about results that are not understandable.
p) Work as part of the clinical team.
q) Ability to relate laboratory results to patient care.
r) Understanding the role of other specialties.

B. Presentation, diagnosis and management of common chemical pathology disorders

a) Recognition of the biochemical/metabolic features of diseases and their abnormal findings in the laboratory.
b) Advice on the differential diagnosis and initial management of common chemical pathology disorders.
c) Supervised participation in Duty Biochemist rota.
d) Awareness of the need to consult about results that are not understandable.
e) Work as part of the clinical team.
f) Ability to relate laboratory results to patient care.
g) Understanding the role of other specialities.

C. Analytical Techniques and Instrumentation

a) Basic laboratory techniques and centrifugation
b) Methods of standardisation and calibration.
c) Identification of common method interferences.
d) Use of pipettes.
e) Preparation and storage of reagents.
f) Use and maintenance of centrifuges.
g) Experience of techniques and knowledge of the performance and limitations of widely used methods in chemical pathology.
h) Detection of errors and sources of error.
i) Taking responsibility for assays.
j) Ensuring analytical competence.
k) Ability to establish a close rapport and understanding with laboratory staff working as part of a multidisciplinary team.
l) Learning experience with all laboratory staff.
m) Ensure liaison between laboratory and clinical staff.
n) Laboratory problems create learning opportunities
o) Assay interference; understanding the mechanisms by which common interferents affect laboratory assays (haemolysis, jaundice, lipaemia). Heterophilic antibodies.
p) Practical experience of investigating assay interference.

D. Automated instrumentation - Random access, immunoassay analysers, robotics and modular systems.

a) Understand the technology and design of biochemistry analysers and appreciate their limitations and benefits.
b) Spectrometric methods Spectrometry: visible, Ultra-violet (UV), Turbidimetry, Experience of the application of some of these methods.
c) Osmometry Principle of technique. Experience of use of technique.
d) Electrometric methods Ion selective electrodes Na^+ , K^+, H^+ , pO_2, pCO_2, Ca^{2+}; Experience of the application of some of these methods.
e) Enzymology Fixed interval, kinetic assays, isoenzymes, enzymes as reagents. Experience of the application of some of these methods.
f) Immunochemical techniques Immuno -assay, -metric. Labels enzyme, fluorimetric, and chemiluminescent. Experience of the application of some of these methods.
g) Electrophoresis Principles of technique. Experience of the application of some of these methods. Cellulose acetate, Agarose, PAGE, (SDS, gradient), isoelectric focusing.
h) Chromatography Principles of techniques Experience of the application of some of these methods. Thin layer chromotgraphy (TLC), column, ion exchange, affinity, gas chromotography (GC), high pressure liquid chromotgraphy (HPLC). Sample preparation: desalting, liquid extraction, derivitisation.
i) Point of care testing Advantages/disadvantages of point of care testing. Glucose, Bilirubinometers, Blood gas, Ion –specific electrodes, urinanalysis. Experience of the use of point of care testing in hospital.
j) Solid/dry phase chemistry Dipstick, thin film

E. Evaluation of an Analytical Method

a) Practicability
b) Optimisation of reaction conditions
c) Recognition of critical parameters (robustness)
d) Bias
e) Imprecision
f) Sensitivity
g) Specificity
h) Investigation of common interferences
i) Range
j) Criteria for acceptability
k) Contribute to establishing and validating a new method.
l) Write the standard operating procedure of the method and place a copy in your portfolio.
m) Critical attitude to assay performance.

4.5.3. CLINICAL GOVERNANCE AND AUDIT COMPETENCIES
Objectives: knowledge of the lines of accountability, quality improvement programmes, clinical audit, evidence-based practice, clinical standards and guidelines, managing risk and quality assurance programmes.

A. Clinical governance

a) Recognising roles, responsibility and accountability. Patient care is the prime concern.
b) Investigative protocols; Participation in risk assessment; Share best practice with others.
c) Service Quality Monitoring/reporting adverse events.
d) Availability and adherence to agreed protocols for investigations of common conditions.
e) Turnaround time, complaint analysis
f) Learn from mistakes and complaints.
g) Maintenance of probity in clinical and laboratory practice.
h) Clinical Audit Philosophy of clinical effectiveness: role of clinical effectiveness. Recognise the benefit of audit to clinical care and Clinical Effectiveness and audit:

B. Concept of systematic reviews and evidence-based medicine; audit in achieving this, methods of clinical audit in healthcare.

a) Plan, undertake, report, and present at least one audit and undertake follow up.
b) The multidisciplinary nature of clinical audit.
c) Attendance at audit meetings in the department, other disciplines where appropriate, and possibly regional and national audit meetings.
d) Role of audit in the hospital; Use audit to gather evidence provided by formal audit cycle; review of practices and clinical performance that highlights the resources required.
e) Taking responsibility for an audit.
f) Participation in regular clinical audit, within and between departments, at the interface with primary care and at regional level.
g) Understanding that clinical audit provides the evidence, indicates change needed, highlights the resources required, addresses quality requirements and the needs of governance are being met.

4.5.4. COMPETENCIES IN THE CHEMICAL PATHOLOGY OF DISEASE
Objective: to relate understanding of normal human biochemistry and physiology to the chemical pathology of screening, diagnosis and monitoring of disease.
Should be fully conversant with generic aspects.

a) Generic aspects Physiology, biochemistry, pathogenesis, pathophysiology, natural history, epidemiology, presentation, diagnosis, causes, classification, complications, molecular biology,
b) Diagnostic methods required in the curriculum should be acquired throughout training.
c) Biochemical, haematological and radiological techniques required for the investigations, diagnosis and screening.
d) Knowledge of the pharmacology of the therapeutic agents required in management.
e) Molecular biology to identify genetic disorders.
f) Advising on the appropriate use and interpretation of the results of the laboratory investigations in screening for disease, to establish (differential) diagnosis, to monitor progress and treatment.
g) Liaison and clear communication with colleagues and other clinical teams in primary and secondary care both verbally and via clinic letters.
h) Acting as an effective interface between laboratory and clinical staff, as part of team.
i) Effective interaction with members of multidisciplinary teams in hospital, GP and community.
j) Recognition of the importance of good communication and supportive care for successful patient outcomes.
k) Relationship of theoretical knowledge and laboratory results to patient management and clinical practice.
l) Error
    a) Biological variability Reference values and population statistics
    b) Common reference intervals
    c) Inter- and intra-individual variation
    d) Assessment and application of biological variance data in setting analytical goals
    e) Assessing utility of reference values
    f) Significance of changes in serial results.
    g) The effect of genetic and environmental influences such as age, sex, nutrition, time of day, stress, posture, hospitalisation and therapeutic agents on biochemical results.

4.5.5. COMPETENCIES IN THE INTERPRETATION OF LABORATORY DATA

Objectives: with supervision, ability to advise safely on the interpretation of laboratory results in diagnosis, treatment and monitoring of patients.

To attain a level of knowledge of clinical practice, giving the ability to conduct a dialogue with clinical colleagues:

a) Appropriate selection of tests
b) Interpretation of their results
c) Initiation of further investigation based on these results.
d) Interpretation of laboratory data
e) Nature of biochemical investigations undertaken and provision to other specialties.
f) Competent contribution at ward rounds and case presentations.
g) Competence to take part in duty biochemist and reporting rota with supervision.
h) Appropriate comments when reporting laboratory results.
i) Critical appreciation of the role of biochemical tests.
j) Liaison with clinical colleagues.
k) Follow-up of abnormal investigations.
l) Participation in a multidisciplinary team.

4.5.6. COMPETENCIES IN RESEARCH AND DEVELOPMENT
Objectives: critical assessment of published work and an understanding of basic statistical methods.

a) Knowledge Skills and knowledge application Attitudes
b) Principles of critical review Critical review and appraisal of literature. Assessment of the validity of data, experimental design and problem solving techniques.
c) Implementation of evidence-based chemical pathology.
d) Using library and IT facilities.
e) Use of evidence-based medicine in support of patient care.
f) Data handling and statistical methods
g) Statistical interpretation of:
    i. laboratory and population data
    ii. standard deviation and error
    iii. median and mean
    iv. linear regression and correlation methods
    v. methods of assessing agreement
    vi. concept of significance and related statistics
    vii. confidence intervals
    viii. non-parametric statistics
    ix. predictive value: positive and negative
    x. specificity and sensitivity
    xi. receiver operating characteristic curves.
h) Computer use within the laboratory: spreadsheets, databases.
i) Correct analysis of results using appropriate statistical tools.
j) Seek statistical advice before embarking on a project.

4.5.7. COMPETENCIES IN DIRECT PATIENT CARE

Generic aspects of clinical management

Objective: competent in the generic clinical and communication skills required for assessment and treatment of patients, referred for a specialist biochemical opinion, within an outpatient setting. Regular attendance at appropriate outpatient clinics under Consultant supervision is required.

Elicit a comprehensive history including social,

Awareness of the impact of the disorder/ pathophysiology natural history, epidemiology, family and dietary aspects. diagnosis/chronic disease on the patient and family.

Presentation, diagnosis, causes, classification, complications, molecular biology,

a) Recognise presenting features and conduct the examination competently.
b) Act with empathy in communicating and managing the disorder and its complications.
c) Use appropriate investigations to establish diagnosis
d) Explain planned treatment to the patient.
e) Work as part of multidisciplinary team.
f) Formulate management and treatment plans.
g) Document clearly in the patient notes.
h) Explain the diagnosis, treatment and side effects to the patient and relatives.
i) Liaise and communicate with colleagues, teams in primary and secondary care, both verbally and in writing.
j) Recognise the importance of good communication and supportive care for successful patient outcomes.
k) Relate theoretical knowledge and laboratory results to patient management and clinical practice.
l) Educate patients about their disease, investigations, lifestyle, treatment
m) Inform clearly both verbal and in writing.
n) Advise patients about access to patient groups and information.
o) Involve patients in developing their treatment and care.

4.6 CORE CHEMICAL PATHOLOGY CURRICULUM (STAGES B – D)

There is no intention to use completion of this curriculum and appendices as a measure of aptitude or achievement. It is simply an indication of the range and level of experience that could be reasonably expected of trainees. The level of knowledge gained within each of the areas described below will vary between trainees.
However, for each disease process listed, it is recommended that the trainee possesses at least a basic level of knowledge. A detailed curriculum for clinical and laboratory training is set out here.

4.6.1. LABORATORY COMPETENCIES

Objective: to achieve sufficient knowledge of laboratory chemical pathology to offer basic advice on the interpretation of results.

A. Knowledge skills and knowledge application; Attitudes

a) Operation of automated analysers. Explain the principles behind automated analysers.
b) Interpretation of results-generated identification of invalid results.
c) Knowledge of specimen collection, handling, transport and sample storage
d) Understanding of the use of specific preservatives and possible interference in assays
e) Familiarity with the functions of pathology reception, the phlebotomy service.
f) Comprehension of the problems associated with 24hour urine collections.
g) Principles of health and safety – familiarity with all aspects of health and safety in the laboratory.
h) Awareness of the pathologist's legal obligations.
i) Clinical Pathology Accreditation (CPA) standards to obtain and retain full laboratory accreditation.
j) Application to the working laboratory and avoiding risks.

B. IT and communication skills

a) Understanding the Data Protection Act
b) Familiarity with fundamental aspects of computing within the laboratory, databases, spreadsheets, internet.
c) Use on a day-to-day basis.
d) Proactive attitude to new technology.
e) Principles of audit Familiar with audit through participation in multidisciplinary clinical audit.
f) Recognition of the benefit of audit.
g) Principles of quality control and assurance - full understanding of quality control and quality assurance.
h) Understanding EQA and NEQAS
i) Use of external NEQAS and the processing of data by these schemes.
j) Critical evaluation of external quality assurance data so as to identify the possible cause of aberrant data, including the constraints due to instrumentation, reagents and operations.
k) Application of principles to laboratory.

C. Presentation, diagnosis and management of common chemical pathology disorders. The trainee must:

a) Recognise the disorder in the laboratory and advise on the differential diagnosis and initial management of common chemical pathology disorders.
b) Be aware of the need to consult about results that are not understandable.
c) Work as part of the clinical team.
d) Relate laboratory results to patient care.
e) Understand the role of other specialties.

5. LABORATRY CURRICULUM

5.1. Analytical techniques and instrumentation
Objective: to become a competent analyst with appreciation of a range of analytical techniques, their performance, comparative usefulness and applications so as to be competent in the management of the chemical pathology laboratory.

5.1.1. Basic laboratory techniques and methods of standardisation
The trainee is encouraged to acquire a wide experience of techniques, together with an in-depth experience of certain techniques. The trainee should be fully conversant with the performance and limitations of widely used methods in chemical pathology.

a) Centrifugation
b) Calibration.
c) Identification of common method interferences.
d) Use of pipettes.
e) Preparation and storage of reagents.
f) Use and maintenance of centrifuges.
g) Ultrafiltration.
h) Ultracentrifugation.
i) Detection of errors and sources of error.
j) Taking responsibility for assays.
k) Ensuring analytical competence.
l) Understanding with laboratory staff ; working as part of a multidisciplinary team; Learning experience with all laboratory staff.
m) Ensuring liaison between laboratory and clinical staff.
n) Using laboratory problems to create learning opportunities.
o) Assay interference Understands the mechanisms by which common interferents affect laboratory assays (haemolysis, jaundice, lipaemia). Heterophilic antibodies.
p) Practical experience of investigating assay interference.
q) Automated instrumentation Random access, immunoassay analysers robotics and modular systems.
r) Understand the technology and design of biochemistry analysers and appreciate their limitations and benefits.

5.1.2. Methodologies

a) Spectrometric methods Spectrometry: visible, UV, reflectance, bichromatic, derivative, linear diode array, infra red.
b) Turbidimetry, nephelometry, densitometry, fluorimetry,
c) Nuclear magnetic resonance.
d) Mass spectrometry
e) Flame emission spectrometry.
f) Atomic absorption: flame, furnace.
g) Experience of the application of some of these methods.
h) Osmometry Principle of technique. Experience of use of technique.
i) Electrometric methods Ion selective electrodes Na^+, K^+, Cl, H^+, pO_2, pCO_2, Ca^{2+} , $NH4^+$, Mg^{2+} , Li^+
j) Enzymology Fixed interval, kinetic assays, isoenzymes, enzymes as reagents.
k) Radioisotope counting .- and ß-counting.
l) Immunochemical techniques Immuno-assay, -metric assays, -fixation, -diffusion
m) Electrophoresis,
n) Labels enzyme, fluorimetric, and chemiluminescent.
o) Electrophoresis Cellulose acetate, Agarose, PAGE (SDS, gra dient), isoelectric focusing.
p) Chromatography Thin layer chromotgraphy (TLC),column, ion exchange, affinity, gas chromotography (GC), high pressure liquid chromotgraphy (HPLC).
q) Sample preparation: desalting, liquid extraction, derivitisation.
r) Point of care testing Glucose, bilirubinometers, blood gas, ion–specific electrodes, urinanalysis, cardiac markers.
s) Solid/dry phase chemistry Dipstick, thin film.
t) Undertake and advise on QA schemes,
u) Interdisciplinary liaison.
v) DNA/RNA/chromosomal Analyses, PCR, Southern blotting. Interpret mutation analysis across a variety of disorders, micro satellite analysis, sequencing reactions. Comprehend their application to diagnoses and family studies.

5.1.3. Evaluation of an analytical method
Objective: competence to establish and validate a new method.

a) Practicability
b) Optimisation of reaction conditions
c) Recognition of critical parameters (robustness)
d) Bias
e) Imprecision
f) Sensitivity
g) Specificity
h) Investigation of common interferences
i) Range
j) Criteria for acceptability
k) Establish and validate a new method.
l) Write the standard operating procedure of the method and place a copy in your portfolio.
m) Involvement in the introduction of new methods.

5.2. LABORATORY MANAGEMENT COMPETENCIES

Objectives: to develop skills to take independent responsibility for the direction and management of the service.

5.2.1 General

a) General Request initiation, specimen transport and what contributes to error.
b) Organisation of the analytical and reporting process.
c) Principles of successful management.
d) The structure and organisation of the NHS, where decision making occurs, process of change and ways of influencing decisions.
e) Practical experience of business
f) Formal training in reception.
g) Appreciate the place of laboratory automation and IT.
h) Management course training.
i) Personnel management including industrial relations.
j) Shadowing senior departmental staff involved in business planning, writing business case, contracting, finance and resource management.
k) Establishes rapport, respect and understanding with laboratory staff.
l) Show respect for others' opinions.
m) Recognise good advice.
n) Recognise own limitations.
o) Enthusiasm, integrity, imagination, determination, professional credibility.
p) Aware of equity in health care access and delivery. planning, finance, financial control, costing, pricing, contracting, purchasing, resource management.
q) Practical aspects of personnel management, industrial relations, team building, staff training, motivation, continuing education, appraisal, dealing with problems, colleagues.
r) Apply the concepts of accreditation, e.g. CPA, good laboratory practice.
s) Conversant with legal requirements and Department of Health guidance.
t) Multidisciplinary working patterns.
u) Participation where appropriate in appointment of junior staff.
v) Participation in departmental staff appraisal programme, using appraisal to developing your own skills.
w) Attendance at departmental management meetings.
x) Understanding mentoring and supervision relative to personal and professional development, prioritising work, time management, delegation, planning, staff motivation.

5.2.2. Quality

a) Appreciation that compliance with CPA standards ensures that training facilities are adequate.
b) Undertaking accreditation review of a section of the laboratory.
c) Quality assurance
d) Control the quality of a method
e) Internal quality control programmes.
f) Quality control rules.
g) Use of external quality assurance programmes.
h) Laboratory accreditation.
i) Interpretation of quality control/quality assurance data and advise on subsequent course of action.
j) Acting/assisting laboratory quality control officer and attending laboratory quality control meetings.
k) Application to point of care testing.

5.2.3. Safety

a) Health and safety Health and safety and COSHH.
b) Individual and collective responsibility.
c) Handling potentially infectious samples and noxious chemicals.
d) Radiation protection measures.
e) Mechanical, fire and electrical safety.
f) Dealing with an accident.
g) Current safety guidelines.
h) Attending laboratory safety committee meetings.
i) Observe safe working practices.

5.2.4 Informatics

a. Selection of analytical equipment
b. Specification and evaluation of an analytical system.
c. Financial issues relating to analyser installation (capital purchase, reagent rental, competitive tendering).
d. Participation in the local process.
e. IT The role of IT in delivery and management of service
f. Stages in producing results and problems with turnaround time.
g. Instrument interfaces.
h. Links to other computers.
i. Reporting/authorisation procedures.
j. Patient identification and methods of ensuring accuracy.
k. Management statistics.
l. E-mail and intra/internet.
m. Data protection act.
n. Retention of records.
o. Review of pathology services.
p. Freedom of Information act.
q. IT affecting all aspects of chemical pathology.
r. Proactive attitude to new technology.

5.2.5 Communication

a. Communication skills. Acquiring skills to operate with organisations, scientific and medical communities and the public.
b. Principles of effective negotiation, influencing colleagues.
c. Resolving technical, scientific, clinical and management problems through leadership skills and promoting morale.
d. Explaining laboratory procedures to patients, their relatives and visitors.
e. Working within a team, communicating with clinical, managerial and other health care staff.
f. Preparing, presenting, explaining scientific reviews/data/findings, both orally and in writing.
g. Understanding yourself, conflict resolution.
h. Understanding the need to involve patients, staff, and colleagues.
i. Act with empathy, honesty and sensitivity.

6. MEDICAL CURRICULUM

A. Gastrointestinal tract Physiology and biochemistry of digestion.

a) The gut as an endocrine organ.
b) Gastrointestinal hormones.
c) Pathology: peptic ulcer disease, Zollinger Ellison syndrome
d) pyloric obstruction
e) intrinsic factor, pernicious anaemia, anaemias and haematinics (iron, iron binding capacity, ferritin, B12 and folate deficiencies)
f) pancreatitis (acute and chronic)
g) malabsorption
h) coeliac disease
i) inflammatory bowel disease
j) disaccharidase deficiency
k) intestinal obstruction
l) short gut syndrome
m) intestinal failure
n) gastrointestinal malignancy
o) carcinoid syndrome
p) peptide secreting tumours of the entero-pancreatic system
q) drain fluids
r) investigation of malabsorption: carbohydrate probe molecules, breath tests
s) investigation of chronic pancreatic dysfunction by tubeless tests
t) serological markers of coeliac disease.
u) Faecal analysis: occult blood, elastase.

B. Liver

a) Functions of the liver.
    a. Formation of bilirubin.
    b. Enterohepatic circulation and bile salts.
b) Jaundice:
    a. adult,
    b. children,
    c. newborn: familial hyperbilirubinaemias, haemolytic jaundice, intra-hepatic jaundice , obstructive jaundice.
c) Diseases of the liver:
    a. viral hepatitis,
    b. cirrhosis ,
    c. haemochromatosis ,
    d. Wilson's disease,
    e. alcohol/drug hepatotoxicity,
    f. non-alcoholic fatty liver disease,
    g. cholestasis,
    h. biliary obstruction,
    i. gall stones and their composition
    j. hepatoma.
    k. Hepatic failure and encephalopathy.
d) Liver transplantation.
e) Assessment of hepatic function:
    a. liver function tests
    b. prothrombin time
    c. ammonia
    d. alpha-fetoprotein.

C. Urogenital tract

a) Renal physiology:
    a. glomerular filtration
    b. tubular function
    c. salt and water homeostasis
    d. hydrogen ion homeostasis
    e. renin, erythropoeitin, vitamin D.
b) Renal disease:
    a. uraemia: pre, post
    b. acute, chronic, acute-on-chronic
    c. calculi
    d. glycosuria
    e. tubular defects and Fanconi syndrome
    f. metabolic disease and the kidney.
c) Normal and abnormal urine composition.
    a. Abnormal pigments
    b. Urinary deposits
    c. Renal stones.
    d. Proteinuria:
        i. nephrotic syndrome
        ii. differential protein clearances
        iii. tubular proteins.
d) Laboratory assessment of renal function:
    a. glomerular filtration rate including in vivo techniques
    b. Modification of Diet in Renal Disease (MDRD) formula
    c. markers of renal function
    d. renal plasma flow
    e. tubular function tests
    f. protein/creatinine ratios
    g. drug interference in urine analysis.
e) Renal replacement therapy:
    a. haemodialysis
    b. peritoneal dialysis
    c. assessment of dialysis adequacy
    d. renal transplantation
    e. markers of transplant rejection.
f) Prostatic diseases.
g) Semen analysis.

D. Respiratory

a) Gas transport and Physiology of normal respiration, O2, CO2, transport, buffers.
b) Advise on the investigation of H+ metabolism
c) Respiratory and renal mechanisms in acid-base homeostasis.
d) Respiratory disease.
e) Causes and assessment of acid-base disturbances: measurement of H+ pCO2,
f) pO2, satn.
g) Concept actual bicarbonate, standard bicarbonate, base excess.
h) Determinants and assessment of tissue oxygenation.
i) Acid-base disorders and management.
j) Water and electrolytes Distribution of water and electrolytes.
k) Turnover of body fluids.
l) Regulation of extracellular fluid, osmolality and volume:
    a. antidiuretic hormone
    b. renin-angiotensin-aldosterone
    c. natriuretic peptides.
m) Water depletion and excess.
n) Hypo- and hypernatraemia.
o) Hypo- and hyperkalaemia.
p) Metabolic effects of trauma/surgery/stress.
q) Principles of intravenous fluid therapy.
r) Advise on management of fluid balance and on investigation of electrolyte disturbances.

E. Proteins Principles of measurement.

a) Properties and functions of the principal plasma proteins including:
    a. albumin
    b. protease inhibitors
    c. transport proteins
    d. ceruloplasmin
    e. clotting factors
    f. complement
    g. immunoglobulins.
b) Hypoalbuminaemia and investigation.
c) Paraproteinaemias and investigation.
d) Cryoglobulinaemia.
e) Proteins of inflammation.
f) Plasmapheresis.
g) Immunoglobulin deficiencies.
h) Alpha-1-antitrypsin deficiency.
i) Cytokines.
j) Advise on the laboratory investigation of normality and disease.

F. Lipids Apolipoproteins and lipid metabolism.

a) Metabolic basis inherited and acquired hyper- and hypo-lipoproteinaemias.
b) Biochemical basis for atheroma, coronary heart disease and associated risk
c) factors.
d) Patient classification: familial hypercholesterolaemia, familial combined dyslipidaemia, type III dyslipidaemia, polygenic hypercholesterolaemia,
e) Atherogenic lipoprotein phenotypes, secondary causes.
f) Primary and secondary cardiovascular disease prevention.
g) Laboratory investigation and principles of management of hyperlipidaemia.
h) Advise on the investigation and management of hyperlipidaemia, identification of patients with secondary causes, screening family members in case of familial dyslipidaemia.
i) Cardiovascular system Atheroma, coronary heart disease, stroke and associated risk factors.
j) Current methods of calculating risk and their shortcomings.
k) Use of biochemical markers for risk stratification in acute coronary syndromes.
l) Biochemical markers of myocardial damage/ventricular function.
m) Hypertension (biochemical investigation and management).
n) Advise appropriately on estimation of cardiovascular risk.

G. Diabetes mellitus and Glucose metabolism.
Glucose measurement Classification of diabetes.

a) Diagnostic criteria: diabetes, impaired glucose tolerance (IGT), impaired fasting glucose (IFG).
b) Pathophysiology of diabetes:
    a. insulin-dependant, type 1 diabetes
    b. insulin-resistance, type 2 diabetes
    c. secondary.
c) diagnosis, investigation and management.
d) Distinguish between the various causes of diabetes.
e) Complications of diabetes:
    a. Acute metabolic
        i. diabetic ketoacidosis
        ii. hyperosmolar non ketotic
        iii. hypoglycaemia.
    b. Chronic:
        i. Microvascular:
            1. nephropathy, microalbuminuria
            2. neuropathy and retinopathy.
        ii. Macrovascular:
            1. lipid abnormalities
            2. coronary heart disease
            3. peripheral vascular disease.
f) Principles of treatment of diabetes and monitoring of diabetic control:
    a. use of insulin and other pharmacological agents
    b. dietary modification
    c. home monitoring with meters
    d. continuous overnight glucose monitoring.
    e. Extra laboratory glucose monitoring.
    f. Glycated haemoglobin, insulin, C-peptide, microalbumin assays.
g) Causes and laboratory investigation of hypoglycaemia in adults and children.

H. Endocrinology:

a) acromegaly and dwarfism Interpretation and reporting on adult and paediatric
b) prolactinoma/macroprolactin
c) diabetes insipidus
d) dynamic function testing
e) isolated hormone deficiency and panhypopituitarism.

Adrenal cortex:

a) steroid production
b) Cushing's syndrome
c) insufficiency: assessment of reserve
d) Conn's syndrome
e) congenital adrenal; hyperplasia, diagnosis, management, intersex.

Adrenal medulla:

a) catecholamine metabolism
b) phaeochromocytoma
c) neuroblastoma
d) measurement and interpretation of catecholamines and metabolites.
e) results of investigations and monitoring therapy.
f) Appreciation of the role of imaging, scans.

Experience of insulin, TRH, GnRH, glucagon, pituitary function, growth hormone secretion and water deprivation tests
Experience of tests of adrenal function
Advising on appropriate monitoring of replacement therapy.

Thyroid:

a) congenital hypothyroidism and screening programmes
b) hypo- and hyper-thyroidism
c) autoimmune disease, autoantibodies
d) adenoma/carcinoma
e) radioactive iodine in vivo studies
f) investigation and monitoring therapy
g) problems of interpretation: binding proteins, drug effects, sick euthyroid
h) Ability to advise on the appropriate choice of tests to investigate and monitor thyroid disease, according to clinical circumstances.
i) Medullary carcinoma of the thyroid
j) Able to interpret and report on the results of investigations and monitoring therapy.

Gonads:

a) adult and paediatric pituitary-gonadal axis
b) sexual differentiation
c) precocious and delayed puberty
d) ovarian cycle
e) metabolism of testosterone
f) ovarian failure and menopause
g) polycystic ovarian syndrome
h) investigation of female; infertility, hirsutism, virilisation
i) Ability to advise appropriately on the investigation of female andro-genisation. syndrome.
j) hormone-replacement therapy
k) oral contraceptives - metabolic effects
l) investigation of male infertility, gynaecomastia, feminisation, testicular tumours, testicular failure
m) monitoring of fertility treatment.

Endocrine effects: cancer, ectopic hormones.
Multiple endocrine neoplasia.

Calcium, magnesium, Calcium, magnesium, phosphate, parathyroid hormone (PTH) and vitamin Advise on the laboratory

a) bone D metabolism.
b) Hyper- and hypo-parathyroidism.
c) Hyper and hypocalcaemia:
d) Calcium sensor abnormalities.
e) Hypo- and hyper-phosphataemia.
f) Hypo- and hyper-phosphatasaemia.
g) Disorders of magnesium.
h) Osteoporosis inc. steroid therapy and chronic malabsorption.
i) Osteomalacia:
j) Renal osteodystrophy.
k) Paget's disease.
l) Chemical pathology of collagen.
m) Assays: calcium (total, adjusted, ionised), PTH, vitamin D, biochemical markers of bone disease.
n) investigation of normality and disease to establish diagnosis and monitor treatment.

I. Nutrition Protein-energy malnutrition.

a) Markers of nutritional status.
b) Effects and investigation of vitamin deficiency or excess.
c) Trace element deficiency or excess.
d) Principles and practical nutritional support – parenteral and enteral.
e) Re-feeding syndrome.
f) Biochemistry of starvation.
g) Obesity: investigation, classification, risk factors, complications.
h) Nutritional management of disease.
i) Advising on the biochemical assessment of nutritional deficiencies, treatment, appropriate clinical and laboratory monitoring of patients receiving nutritional
j) support.
k) Effective participation with other professionals in a team approach to management of nutritional problems.
l) Nutrition & Malnutrition: protein-energy, disease related in:
    a. Acute disease: stroke, myocardial infarction, acute renal failure, nephrotic syndrome, acute liver failure.
    b. Chronic disease: inflammatory bowel disease, coeliac disease, short bowel syndrome, cancer, gall bladder disease, malabsorption.
    c. Pre- and post-op nutritional assessment, management for oesophagectomy, malignancy, major abdominal surgery.
    d. Burns, multiple injury, systemic sepsis.

J. Haemoglobin and Haemoglobin metabolism.

a) Assessment iron status.
b) Detection abnormal haemoglobins: inherited and acquired.
c) Metabolic basis of thalassaemia and sickle cell disease, screening.
d) Red cell enzyme defects.
e) Porphyria: metabolic basis, investigation, diagnosis, monitoring.
f) investigation of normality and disease.

K. Enzymology Stability, induction.

a) Isoenzymes – structural basis, separation, quantitation.
b) Assays:
    a. amylase and lipase
    b. alkaline phosphatase
    c. aminotransferases
    d. angiotensin converting enzyme
    e. creatine kinase
    f. lactate dehydrogenase
    g. gamma-glutamyl transferase
    h. cholinesterase and variants.
c) Advise on the laboratory investigation of normality and disease.

L. Genetics

a) The application of Mendelian biology
b) structure of nucleic acids
c) meiosis and mitosis
d) simple Mendelian and complex diseases
e) mitochondrial inheritance
f) mode of inheritance for genetic counselling, antenatal diagnosis and
g) screening.

M. Protein synthesis:

a) Transcription and translation defects in protein synthesis arising from genetic mutations.
b) Molecular pathology of single gene disorders
c) Gene therapy.
d) genetics and Bayes Theorem, and the calculation of pre-and post-test probabilities in genetic counseling.

N. Pregnancy Maternal and foetal physiology, complications, detection.

a) Screening: Down's syndrome, foetal malformations, neural tube defects, hydatidiform mole, choriocarcinoma, ectopic pregnancy.
b) Pre-natal investigation: inborn errors.
c) Monitoring phenylketonuria, diabetes, thyroid disease, liver disease.
d) Effects of pregnancy on routine biochemical tests.
e) Biochemical, statistical and ethical issues surrounding antenatal screening.
f) Interact effectively with medical and midwifery staff.

O. Newborn Biochemical problems in the newborn:

a) fluid balance
b) jaundice
c) liver disease
d) hypoglycaemia
e) calcium and phosphate homeostasis; metabolic bone disease of prematurity
f) hypomagnesaemia
g) hyperammonaemia
h) sweat tests
i) nutrition.
j) Factors affecting method selection and biochemical results in newborns.
k) Appropriate specimen collection.

P. Childhood

a) Hypoglycaemia.
b) Calcium and phosphate disturbances.
c) Hyperammonaemia.
d) Reye's syndrome.
e) Fanconi syndrome and tubular defects.

Principles of common Inherited metabolic disorders: Trainees are not expected to have in-depth knowledge of all inherited metabolic defects but show ability to collaborate with other professionals (paediatricians, nurses ,the major dieticians in disorders

Q. Quantitative and qualitative enzyme abnormalities.

a. Biochemical consequences of a primary enzyme block in a metabolic pathway and the way in which intermediate metabolites are produced.
b. Trainees should be aware of clinical and pathological signs, presentation, investigation, principles of treatment (coenzyme supplementation, enzyme inhibition, dietary manipulation
c. Methods and monitoring of treatment
d. Detection:
    a. -screening: principles, methods
    b. -evaluation of detection programmes
    c. -prenatal diagnosis. Pre-natal investigation of the foetus.
    d. inheritance, scope of prenatal and new-born diagnosis,
e. Ability to interact well with patients and relatives.
f. Amino acid, carbohydrate, cerebral lipidosis, fatty acid oxidation,
g. The effects of inborn errors on
    a. lysosomal,
    b. metal,
    c. mitochondrial,
    d. mucopolysaccharide,
    e. organic acid,
    f. peroxisomal,
    g. purine and pyrimidine (primary and secondary),
    h. transport,
    i. urea cycle disorders.
h. Advise on appropriate specimens for investigation of
    a. encephalopathy,
    b. hyperammonaemia.
    c. possible inherited metabolic conditions
i. Analysis:
    a. amino acids,
    b. organic acids,
    c. carnitine and acylcarnitines,
    d. hypoglycaemia.
    e. enzyme assay,
    f. mucopolysaccharides,
    g. tissue culture,
    h. DNA

The effects of metabolic stress upon patients with inborn
errors such as PKU, fatty acid oxidation defects, glycogen storage and urea cycle defects.

R. Neuromuscular system

a) Formation and composition of cerebro spinal fluid (CSF).
b) Multiple sclerosis, muscular dystrophy.
c) Parkinson's disease.
d) Biochemistry of psychiatric disease.
a. Biochemistry of muscle disease.
b. Use of CSF in diagnosis and monitoring disease.

S. Cancer

a) Nature of malignancy and tumour growth.
b) Biochemical effects and treatment:
c) Tumour markers:
    i. prostate,
    ii. lung,
    iii. breast,
    iv. ovary,
    v. gastro-intestinal (GIT),
    vi. pancreas,
    vii. thyroid,
    viii. pituitary,
    ix. adrenal,
    x. neuroblastoma,
    xi. hepatoblastoma,
    xii. teratoma.
d) Use of biochemical markers in diagnosis and monitoring of tumours.

T. Metabolic response to Surgery, trauma, burns, shock.
Advise on biochemical investigations, monitoring and management, especially patients in ITU/HTU.

U. Therapeutic drug monitoring and toxicology

a. Pharmacokinetics, half-life, dosage prediction.
b. Metabolic effects of ethanol.
c. Monitoring of drug therapy, e.g: digoxin, lithium, antiepileptics, theophylline, caffeine, methotrexate, immunosuppressive, antibiotics.
d. Overdose, e.g: salicylate, barbiturate, paracetamol, tri-cyclic antidepressants, benzodiazepines.
e. Drug addiction: opiates, amphetamine, methylenedioxy-methamphetamine (MDMA), benzodiazepines, cocaine, alcohol.
f. Appreciation of factors affecting drug action or metabolism.
g. Effects of post-mortem changes on the results of laboratory investigations.
h. May require secondment to a specialist unit.
i. Poisoning, e.g. lead, mercury, aluminium, carbon monoxide, paraquat, iron, ethylene glycol, methanol, organophosphate compounds.

V. Laboratory investigation of the unconscious and deceased patient.
Awareness of legal procedure surrounding investigation of death.

7. COMPETENCIES IN THE INTERPRETATION OF LABORATORY DATA

Objectives: ability to advise on the interpretation of laboratory results in diagnosis, treatment and monitoring of patients.
To attain a level of knowledge of clinical practice, giving the ability to conduct a dialogue with clinical colleagues, confidently and competently, in relation to:

a. Appropriate selection of tests
b. Interpretation of their results
c. Initiation of further investigation based on these results
d. Contribution to the construction, organisation and interpretation of clinical research projects.
e. Processes under investigation in the laboratory.
f. Nature of biochemical investigations undertaken and provided to other specialties.
g. Contribute competently at ward rounds and case presentations.
h. Competent to take part in duty biochemist and reporting rota.
i. Competent in the knowledge of other diagnostic disciplines and their relevance to chemical pathology.
j. Appropriate comments when reporting laboratory results.
k. Critical appreciation of the role of biochemical tests.
l. Liaison with clinical colleagues.
m. Follow-up of abnormal investigations.
n. Act as part of a multidisciplinary team.

8. COMPETENCIES IN RESEARCH AND DEVELOPMENT

Objectives: experience in research and development to develop skills in independent and team-driven problem solving, critical assessment of published work and for gaining analytical expertise.

All trainees to undertake at least one research project during their first three years of training. The project should be consistent with the research and development programme of the laboratory or hospital and should be sufficiently novel and timely to be suitable for presentation at a scientific meeting and publication in a peer-reviewed journal. Research for a higher degree, or for a dissertation for the Part 2 examination may be initiated during this period.

a. Scientific and research ability Formulate research questions and develop appropriate experimental design.
b. Undertake analytically and clinically based research and/or development projects.
c. Design, cost, undertake and evaluate experiments.
d. Troubleshoot methods, make appropriate modifications and test for validity.
e. Statistics appropriate to clinical and laboratory practice.
f. Writing reports.
g. Maintain an enquiring attitude.
h. Obtain consent for the use of patient samples in research.
i. Maintain a questioning and critical approach to all aspects.
j. Maintenance of probity in research.

Principles of critical review Critical review and appraisal of literature.

a. To assess the validity of data, experimental design and problem solving techniques.
b. Implementing evidence-based chemical pathology.
c. Using library and IT facilities.
d. Use evidence-based medicine in support of patient care.
e. Research presentation skills
f. Produce work of publishable quality
g. Present a poster and publish a paper in a peer-reviewed journal.
h. Data handling and statistical methods
i. Statistical interpretation of:
    a. laboratory and population data
    b. standard deviation and error
    c. median and mean
    d. linear regression and correlation methods
    e. methods of assessing agreement
        i. F-test
        ii. analysis of variance
    f. independent events
    g. concept of significance and related statistics
        i. t- test
        ii. confidence intervals
    h. non-parametric statistics
    i. predictive value: positive and negative
    j. specificity and sensitivity
    k. receiver operating characteristic curves
    l. odds ratios
    m. relative risk
    n. chi-square tests
    o. curve fitting routines
    p. power calculations.

Computer use within the laboratory: spreadsheets, databases.
Correct analysis of results using appropriate statistical tools.

The educational programme provides:

i. experience of laboratory practice to enable the trainee to attain an understanding of biochemical processes associated with pathological change,
ii. the rationale for investigation and treatment of disease
iii. the rationale for the interpretation of test results
iv. a basis for research activity
v. experience of the diagnostic techniques required to become technically competent in practical work, and to master the underlying analytical and clinical principles
vi. the opportunity to gain knowledge of the metabolic changes that occur in disease
vii. the opportunity to gain knowledge of specialist areas such as paediatric chemical pathology and toxicology, in order to be able to provide specialist advice
viii. training in the communication and teaching skills necessary for effective practice
ix. familiarity with the use of IT relevant to the practice of pathology
x. the acquisition of the ability to provide specialist opinion in chemical pathology
xi. the acquisition of management skills to lead a department providing an effective service
xii. experience of research and development projects and critical assessment of published work so as to contribute in a team and individually to the development of the service
xiii. the acquisition of life-long habits of reading, literature searches, consultation with colleagues, attendance at scientific meetings, and the presentation of scientific work that are essential for continuing professional development (CPD)
xiv. experience of the practice of clinical governance and audit (specialist and multidisciplinary) through evaluation of practice against the standards of evidence-based medicine, which underpin biochemistry practice. learn the concepts of audit and quality control; Trainees need to participate in the departmental audit and quality control programmes and to present audit projects.

The balance between practical laboratory and clinical training will be influenced by educational background, personal interests and guidance from supervisors. At least 1 full year at BST1 level is expected to be devoted to laboratory training and in later years, at least 2 days per week attendance in the lab will be expected. The time frames devoted towards clinical training will be weighted according to the direction that the trainee will specialize, but 3 month rotations will be encouraged as a minimum.
The acquisition of clinical competence is required in at least two of the areas listed in Direct Patient Care , depending on the training experience available during the programme. Trainees in chemical pathology will acquire clinical competence in nutrition, inborn errors of metabolism, disorders of lipid metabolism and cardiovascular risk

assessment, disorders of calcium metabolism and bone and diabetes mellitus and endocrinology.

8.1. Research

Time will be allocated for research activity, which will be encouraged and supervised.
A trainee may wish to spend a period of time in research, either before entering Chemical Pathology training or as 'Out-of-Programme Experience' (OOPE) after entering a Chemical Pathology programme.

i. Research undertaken prior to entry to a chemical pathology training programme

- Trainees who have undertaken a period of research that includes clinical and/or scientific work directly relevant to the chemical pathology curriculum, prior to entering a chemical pathology training programme, can have a maximum of up to one year accepted towards their CCST.

Following satisfactory completion of BST training, trainees may apply to have the relevant competencies gained in research approved by the College. It is expected that the trainee's trainer should assess their progress to determine the suitability of their previous research to be counted towards the CCST. Any research to be counted towards the CCST should be agreed by the Post-graduate Training Co-ordinator, who will be required to make a recommendation to the College.

ii. Research undertaken during a chemical pathology training programme

Trainees who undertake a period of research as out-of-programme experience after entering a chemical pathology training programme, can have up to one year accepted by the Post-Graduate Training Committee (PGTC) towards their CCST. Prior to beginning the period of research, trainees must inform the PGTC in order that the trainer can ensure that the trainee will comply with the requirements of the CCST programme. The period of research must include clinical and/or laboratory work directly relevant to the chemical pathology curriculum. For those undertaking an extended period of research after entering a programme, a further limited amount of additional educational credit (up to six months) may be granted at the discretion of the Chemical Pathology trainer for clinical and/or laboratory work relevant to the programme undertaken in the course of research beyond the initial year. This concession does not apply to those undertaking research prior to entry to a specialist training programme.

9. TRAINING OUTSIDE MALTA

Following a minimum of three years in Malta, the trainee will require further training in a specialist centre/ centres, for a minimum of one year.

10. ACADEMIC MEETINGS

The trainee is guaranteed a minimum of four hours protected time per week to regularly attend the academic meetings within the department. At present these include the following:

1. weekly Departmental Case Conference
2. weekly Dermathopathology Case Conference (attending clinician)
3. monthly Clinicopathological Case Conference
4. monthly Trainee Case Presentation
5. monthly Trainee Unknown Case Conference

The trainee is expected to attend regularly the following Interdepartmental Meetings:
1. Medical Clinicopathological Conference weekly
2. Surgical Clinicopathological Conference weekly
3. Wednesday Plenary Session
4. Thursday Dedicated Session for BSTs in the afternoon
5. MRCP Coaching Session

11. CRITERIA for COMPLETION OF PROGRAMME and AWARD of SPECIALIST CERTIFICATE

11.1. Annual Review
The trainee is to keep a record of training and experience, which must be endorsed annually by the Trainer. Trainees can only progress to the next year of the Training Programme following a successful assessment.

An annual review must also be carried out by a Board nominated by the Pathology Postgraduate Training Committee, composed of three members, including the Head of Training for Chemical Pathology, to identify any problems encountered by the trainee and any deficiencies of the training programme.

11.2. Postgraduate Qualification
Once the trainee has satisfactorily completed the Training Programme outlined above, he/she will be entitled to obtain the Certificate of Completion of Specialist Training (CCST), subject to obtaining a relevant Postgraduate Qualification, by Examination.

The College will identify the Examination and Examination Boards that it recognises for the award of a Postgraduate Qualification.

Candidates are strongly encouraged to seek the advice of the College before enrolling in any examination to ensure that any qualification obtained would be suitable for CCST purposes.

11.3
The CCST will be awarded by the Specialist Accreditation Committee, on the recommendation of the College provided the College Council is satisfied of the trainee's proficiency in the discipline concerned.

12. TRAINERS

12.1 Qualifications for trainers

A Post-Graduate Training Co-ordinator will be responsible for implementation of this Training Programme. The Co-ordinator is to set up and chair a single Specialist Training Committee for all pathology disciplines, including Chemical Pathology, which will be responsible for the management and administration of Training Programmes in Pathology. The Committee will be composed of Pathology Trainers and must include the Chairman of Pathology. Each Pathology specialty will have a Head of Training.

The Post-graduate Training Co-ordinator and the trainers must be on the Specialist Register of the Medical Council and should have practised the specialty for at least 5 years.

Trainers are expected

i. to have substantial experience in the specialty,
ii. to have demonstrated an interest in training,
iii. to have appropriate teaching resources,
iv. to be involved in annual reviews, to participate in training programmes for trainers
v. to liaise closely with the Post-Graduate Co-ordinator.

The teaching staff may include specialists in training and non-medical graduates but they must be practicing pathology or any other relevant topic, e.g. information technology, medicine

12.2. DUTIES OF TRAINERS

Each trainee will have a Trainer, whose main responsibility is to perform continuous assessment of the progress of the trainee, throughout the duration of the training period. The Trainer will be responsible to the Specialist Training Committee and the Post-graduate Co-ordinator.

In particular, the Trainer will have the following duties:

i. to supervise all aspects of training
ii. to meet regularly with the trainee to discuss the programme, progress and deficiencies
iii. to perform an official appraisal every 6 months, at which the trainee is also expected to give feedback
iv. to liaise with individual trainers in the specialty, to assess the trainee's progress

13. OBLIGATIONS OF TRAINEE

13.1. Learning Objectives

By the end of a five year training programme, the trainee should have acquired:

i. a broad based knowledge of chemical pathology with special emphasis on pathogenesis and morphology of disease
ii. skills in diagnostic interpretation, appropriate reporting and good communication with clinical colleagues;
iii. skills in providing advice on further lines of investigation and management in various clinical situations
iv. familiarity with routine and specialised techniques performed in the laboratories
v. familiarity with the processes required to achieve and maintain accreditation in pathology
vi. basic competence in the application of information technology
vii. managerial skills in relation to administrative issues
viii. basic skills in the concepts of research
ix. an appreciation for the need of Continued Professional Development
x. familiarity with laboratory aspects of Health and Safety.
xi. clinical competence sufficient to manage patients with relevant problems in metabolic medicine, either in an independent fashion or as part of a multi-disciplinary team

To this end the trainee is required to keep a log book.

13.2. Continued Professional Development

The trainee is expected to:

i. read major clinical biochemistry journals
ii. keep abreast of current literature in diabetes medicine, endocrinology, metabolic bone disease, nutrition
iii. attend local activities accredited by the Malta College of Pathologists for CPD purposes
iv. attend conferences abroad.

A list of activities recognised by the Malta College of Pathologists for CPD points is published.

13.3. Teaching

The trainee is expected to take part in the Undergraduate Teaching of the University Pathology Department as follows:

i. lectures and tutorials to Medical Students
ii. lectures and tutorials to BSc MLS students
iii. supervision of dissertations for BSc MLS students

iv. training to Laboratory Technical Staff.

LOG BOOK BST I & 2

a) Automated analysis
b) Immunoassays – automated, manual, ELISA
c) Electrophoresis
d) Chromatography including HbA1c, toxicology
e) Enzymology including MFT
f) Urinalysis
g) Spectrophotometry
h) IT
i) Audit project
j) Metabolic cases encountered in course of on-call duties/ out-patients
k) Procedures eg dynamic function testing