Course Information Manual

Version 5.0

Students Commencing 2011

M.Sc. in Clinical Chemistry

09 September 2011

www.medicine.tcd.ie/clinical_biochemistry

Lectures are held at the Trinity Centres for Health Sciences at the Adelaide and Meath Hospital Dublin Incorporating the National Children’s Hospital, Tallaght, Dublin 24 and St. James’s Hospital, James’s Street, Dublin 8

Postal Address: Department of Clinical Biochemistry School of Medicine, Trinity Centre for Health Sciences, Tallaght Hospital, Dublin 24
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1. Introduction

Clinical Chemistry or Clinical Biochemistry is a sub-discipline of pathology which is represented in virtually every clinical hospital laboratory in the State. Staffed by a mix of medical scientists, clinical biochemists and medical staff (chemical pathologists), these laboratories carry out a wide range of biochemical investigations in ever increasing numbers in a complex automated and computerised working environment.

The key to safeguarding the quality of investigations, and hence patient safety, is to have a highly educated and motivated workforce with a detailed understanding of the underlying medical science and biochemistry, analytical technology and computer systems, and automation. Clinical Biochemistry Departments are also frequently involved in clinical trials work, audit and research and so require a detailed knowledge of the effects of disease on biochemical measurements.

Most trainee medical scientists and clinical biochemists holding service posts in a hospital laboratory choose to pursue a postgraduate qualification in order to improve their knowledge and further their career prospects.

There is an increasing trend towards monospecialisation within the pathology disciplines and this has led to demand for an MSc Course in Clinical Biochemistry at an advanced level.

It is also intended that the MSc, which will require 6 academic terms in a 2 year cycle, will assist eligible candidates in their subsequent preparation for Fellow of the Royal College of Pathologists in Clinical Biochemistry.
2. Clinical Chemistry/Clinical Biochemistry

2.1 The discipline

Clinical Chemistry/Clinical Biochemistry is the discipline of pathology (or laboratory medicine) that is concerned with the detection and measurement of biochemical changes in disease. Virtually every hospital in-patient will require at least one biochemical investigation and it is common to investigate for the presence of disease with panels of biochemical tests (e.g. for renal disease, electrolyte disturbances, drug levels and toxic agents, blood gas and acid-base status, bone disease, diabetes, coronary heart disease risk and hypercholesterolaemia, liver disease, inflammation, endocrine and metabolic disorders, inborn errors of metabolism, etc). Biochemistry Laboratories are highly technologically advanced and computerised and are an essential component of all pathology laboratories. The discipline is also represented academically on medical school undergraduate and postgraduate curricula. Scientific staff in clinical biochemistry come from two different streams: medical scientists and clinical biochemists who differ in their mode of entry (both are now graduate entry). Medical practitioners in the discipline are known as Chemical Pathologists. They work closely with Endocrinologists and other physicians, and are usually also clinically responsible for patients with a range of metabolic disorders.

2.2 Clinical Biochemistry at TCD

An academic Department of Clinical Biochemistry has existed at TCD within the Division of Laboratory Medicine for many years, headed until recently by Professor Rory O’Moore. The present staff consists of two part-time lecturers (Dr Gerard Boran, and Dr. Vivion Crowley), assisted by 3 clinical tutors. The current MSc Course Director is Dr Gerard Boran, and the course co-ordinator is Dr Margaret Sinnott. Geraldine Power is the course Executive Officer (email) geraldine.power@tcd.ie Telephone: 01 8963721. The Clinical Biochemistry Office is located in Room 1.03 on the first floor of the Trinity Health Science Centre at AMNCH, Tallaght, Dublin 24.
3. Programme aims

The aims of the course are as follows:

- To offer a high quality postgraduate Master’s course dedicated to Clinical Biochemistry to laboratory professional staff including those from medical scientist, clinical biochemist or medical backgrounds.

- To offer a mix of theoretical knowledge delivered in lecture format combined with continuous development and assessment of clinical reasoning skills and practical knowledge of techniques as taught in workshops and “take-home” exercises in the candidate’s own laboratory.

- To offer a course structure which is feasible for full-time laboratory staff.

- To give all students, regardless of their professional laboratory background, a comprehensive understanding of the principles of Clinical Biochemistry.

- To give students from a Health Sciences/Medical background a sound knowledge of the underlying scientific and technological principles of Clinical Biochemistry.

- To provide students from a laboratory biomedical or scientific background a sound knowledge of the clinical principles underlying the application of Clinical Biochemistry investigations in human disease.

- To foster an interest in audit, research and development, and effective information management in the discipline.
4. Learning outcomes

At the end of the course students will

- Understand the medical, scientific and technological principles of Clinical Biochemistry and its interrelationship with other disciplines.
- Have a detailed knowledge of the applications of Clinical Biochemistry for the diagnosis and monitoring of human disease and its contribution to biomedical research.
- Be able to assess the effectiveness of individual tests, strategies and protocols for the investigation of disease
- Acquire a detailed knowledge of laboratory techniques, instrumentation and informatics
- Understand the principles of laboratory management
- Appreciate new trends including molecular diagnostics, robotics, point of care and self testing
- Develop their clinical, scientific and research skills

5. Target participants

The target groups of laboratory staff will include Clinical Biochemists, Medical Scientists, and medical doctors with an interest in Pathology or Medicine. Prospective candidates will also be able to obtain course information from the course website at www.medicine.tcd.ie/clinical_biochemistry. Applicants will normally be expected to be in full-time employment, or in a suitable supernumerary post, in a Clinical Biochemistry Laboratory or have access to a Clinical Biochemistry laboratory for performing the practical exercises. It may be possible to arrange unpaid supernumerary attachments for applicants wishing to study in Ireland.

There will be a maximum of 20 students annually (includes year 1 and year 2) with an annual intake of not more than 10 students. The course will initially be offered part-time on a two-year cycle admitting students every year. This policy will be kept under review.
6. Admission requirements

Application for admission to the course should be made to the TCD Faculty of Health Sciences office (see website), to be received normally not later than 30th June for the proposed year of entry. Late applications (up to the end of September) will be considered provided places are available, but candidates are urged to get their applications in as early as possible.

Applications will be accepted from those who satisfy ONE of the following requirements:

(a) hold an honours degree (first, upper or lower second class) in any health sciences or biomedical discipline, or a medical, dental or nursing degree, OR

(b) are Members or are eligible for Membership of the Academy of Medical Laboratory Sciences, or possess Part 1 or Part 2 Fellowship of the Institute of Biomedical Science, OR

(c) have 2 years current or previous work experience in clinical biochemist or medical scientist posts

Applicants under (b) should provide documentary evidence, such as a letter from the Academy of Medical Laboratory Sciences, confirming their Membership or eligibility for Membership.

Applicants under (c) should provide full details of their current and previous experience with their application.

Applicants meeting these requirements may be required to attend for interview to assess knowledge and aptitude.
7. Structure of the MSc (and the Diploma exit option)

The course is offered only for entry via the MSc register. Students on the MSc register can have an exit option via a Postgraduate Diploma (in the circumstances described in section 9.2) which, once awarded, will prevent the student from returning to the course to register to continue for the MSc degree.

This year’s programme will commence in October and will extend over a period of 2 years for the MSc degree. Instruction will be class-based, supported by on-line course material. Students for the MSc (which is expected to be the norm) will be required to obtain credit for all of the following three activities:

1. Five Instruction Modules consisting of lectures and case presentations delivered over 2 years and assessed by a written examination (2 papers) together with a Final 2-hour OSPE\(^1\) and Oral Examination at the end of the Trinity term in the second year of the course. Revision Sessions will be provided prior to the final examination.

2. Participation in a series of Techniques Workshops and Clinical Laboratory Interface Workshops. The Techniques Workshops will include practical instruction, and demonstrations of practical techniques including research methods and statistical techniques. The Clinical Laboratory Interface Workshops will consist of instruction in the interpretation of clinical laboratory data, techniques for case presentation and report writing, and the conduct of clinical audits using laboratory data. Each student will be required to submit ten written assignments over the two years. Assignments may include case reports, essays, or a short report on a clinical audit or analytical topic requiring some analysis in their base laboratory. There will be a 1 paper written examination at the end of the first year: this will count as one assignment.

3. A Research Dissertation of approximately 12,000 words on a topic relevant to the practice of Clinical Chemistry/Clinical Biochemistry.

Students will be required to register at the outset for the MSc. Students will be strongly encouraged to study for the MSc and participate in all of the Lecture Modules and Workshops as well as submit the Dissertation. Registration for the MSc at the outset will allow early planning and preparatory work for the dissertation in the first year of the course as well as ensure full library rights. Note that

\(^{1}\) Objective Structured Pathology Exercise (a structured practical assessment similar to a “spot” practical)
a full MSc rather than a Diploma is normally required for career progression purposes in the health services. **Students for the Diploma will not be required to submit a research dissertation.** The course will be run on a part-time basis on Friday mornings and afternoons during term times in the first and second year with a total of 8 contact hours per week. These will consist of a mixture of lectures, tutorials/group teaching, laboratory work and a 30 minutes break for networking. The fee for the Diploma and MSc and for years 1 and 2 will be the same, given that most costs are related to the taught components of the course and these costs are similar in both years.

8. **Syllabus**

The course will be run on a modular basis, each module consisting of a total of between 21 and 63 contact hours including lectures, tutorial/group and laboratory work. Each module will be completed during one term, ranging in duration from 3 to 9 weeks.

Given the potential heterogeneity of the intake, it will be necessary to adapt the modules offered during any one term to accommodate the particular cohort. Students will be required to successfully complete all 6 modules to be eligible for the award of the diploma exit option. Each Module is also associated with a number of Techniques Workshops and Clinical Laboratory Interface Workshops, which are designed to develop practical skills and case reasoning/presentation/interpretation skills respectively. Details of the Modules which students will take are given in Appendices 2 and 3.

8.1 **European Credit Transfer System (ECTS) and Diploma Supplement**

European Credit Transfer System (ECTS) credits have been calculated for the various course modules and are shown in the table below. The ECTS credits are based on 25 hours of input (equivalent to one ECTS credit) and take into account the amount of material covered, the number of contact hours, the number and complexity of assignments, the amount of private study required, taking of examinations, preparatory work for the research project including background research into methods and statistical tools, and the preparation of the dissertation. The MSc course rating is as a 90 ECTS course, with 60 ECTS assigned to the coursework/lectures and 30 ECTS for the dissertation.
Module descriptors suitable for the Diploma Supplement (when applicable) have been identified and are included in the detailed syllabus (see Appendices 2 and 3).

<table>
<thead>
<tr>
<th>Module</th>
<th>Module Descriptor</th>
<th>Term</th>
<th>ECTS Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CC</td>
<td>Clinical Chemistry</td>
<td>Michaelmas</td>
<td>10</td>
</tr>
<tr>
<td>2 CCGPB</td>
<td>Clinical Chemistry and General Paediatric Biochemistry</td>
<td>Hilary</td>
<td>10</td>
</tr>
<tr>
<td>3EM</td>
<td>Endocrinology and Metabolism</td>
<td>Michaelmas</td>
<td>15</td>
</tr>
<tr>
<td>4 EIEM</td>
<td>Endocrinology and Inborn Errors of Metabolism</td>
<td>Hilary</td>
<td>15</td>
</tr>
<tr>
<td>5 QAALM</td>
<td>Quality Assurance and Laboratory Management</td>
<td>Michaelmas</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>

The course will be delivered over 2 years with the opportunity for a new intake of students each year. The following table illustrates the schedule of modules over the period 2009-2012:

<table>
<thead>
<tr>
<th>Term</th>
<th>2011 Intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michaelmas Term</td>
<td>2011 CC</td>
</tr>
<tr>
<td>Hilary Term</td>
<td>2012 CC GPB</td>
</tr>
<tr>
<td>Trinity Term</td>
<td>2012 Revision and Examinations</td>
</tr>
<tr>
<td>Michaelmas Term</td>
<td>2012 QAALM /EM</td>
</tr>
<tr>
<td>Hilary Term</td>
<td>2013 EI EM</td>
</tr>
<tr>
<td>Trinity Term</td>
<td>2013 Revision and Examinations</td>
</tr>
</tbody>
</table>
9. Assessment and Examination

9.1 MSc

Students will be expected to register for the MSc option at the outset of the course.

Students for the MSc will be required to obtain credit for all of the following four activities:

- Five Instruction Modules consisting of lectures and case presentations delivered over 2 years and assessed by examination:
  - Year 1: Written paper and OSPE
  - Year 2: Written paper, OSPE and Viva Voce

- Participation in a series of Techniques Workshops and Clinical Lab Interface Workshops

Each student will be required to submit six short assignments over the two years. Each assignment may include case reports, essays, or a short report on a clinical audit or analytical topic requiring some analysis in their base laboratory. Each student will have to compile a journal of cases (10 cases) as part of their course work.

- Each student will have to compile a log book of 10 cases to be submitted regularly and at least 5 in each year.

- A Research Dissertation which must be passed. It will not be required of Diploma students. Students will be required to submit titles and outline proposals for their project at the end of November in the first year of the course. A local project supervisor must be nominated.

9.2 Diploma exit option

Students for the Diploma will only be required to complete the Lecture Modules and the Techniques and Clinical Laboratory Interface Workshops over 5 terms. The dissertation will not be required. For reasons described in section 7 (Structure of the MSc and the Diploma exit option),
students will be expected to register at the outset for the MSc. Students who have registered for the MSc but who fail to complete the dissertation may elect to be awarded the Diploma, subject to a pass in the Diploma Assessment. This is expected to happen only in exceptional circumstances. Use of the Diploma exit option will prevent the student from returning to the course to register to continue for the MSc option.

Students who find themselves in the predicament of being unable to submit a successful dissertation prior to the final examination (i.e. by 1st April of the final year) would be required to register for a Third Year in order to complete the dissertation and be awarded an MSc. A (third year) continuation fee would be payable in these circumstances rather than the fee applicable in Year 1 or 2. Note that whereas an MSc award is not graded, the award of a Diploma is graded at either Pass or Distinction level.

9.3 Schedule of Assessments and Examinations

The schedule of Assessments and Examinations with an indication of their weighting towards the final award is shown in the table below. Compensation is allowed between marks for the Written/OSPE Examinations and Assignment components in the event that an individual Assignment or Examination is failed providing a mark of at least 40% is obtained in the component for which compensation is required.

All components of exams will have to be passed at the end of each year. This means achieving an average pass mark of 50% with no individual component below 40%. In the case of an examination not being passed a Supplemental Examination will have to be taken and passed in order to progress to the next academic year or to graduate. The dissertation must be passed to be awarded the MSc and no compensation is allowed with any other component.
<table>
<thead>
<tr>
<th>Course Activity</th>
<th>Diploma</th>
<th>MSc^2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Marks Assigned (%)</td>
<td>Marks Assigned (%)</td>
</tr>
<tr>
<td>5 Instruction Modules (CC, CCGPB, EM, EIELM, QAALM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First Year written examination</td>
<td>75 marks (30%)</td>
<td>75 marks (30%)</td>
</tr>
<tr>
<td>Second Year written examination</td>
<td>75 marks (30%)</td>
<td>75 marks (30%)</td>
</tr>
<tr>
<td>First Year OSPE</td>
<td>45 marks (18%)</td>
<td>45 marks (18%)</td>
</tr>
<tr>
<td>Second Year OSPE</td>
<td>45 marks (18%)</td>
<td>45 marks (18%)</td>
</tr>
<tr>
<td>Final Oral Examination (end of year 2)</td>
<td>10 marks (4%)</td>
<td>10 marks (4%)</td>
</tr>
<tr>
<td><strong>Techniques Workshops and Clinical Lab</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Interface Workshops</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Assignments</td>
<td>150 marks (60%)</td>
<td>150 marks (60%)</td>
</tr>
<tr>
<td>Logbook of Cases</td>
<td>100 marks (40%)</td>
<td>100 marks (40%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>500 Marks</td>
<td>500 Marks</td>
</tr>
<tr>
<td><strong>Research Dissertation (MSc Only)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan and execute a research project. Prepare and submit a dissertation based on this project.</td>
<td>Not applicable to Diploma</td>
<td>Must be passed for award of MSc, but is not marked</td>
</tr>
</tbody>
</table>

9.4 Course Assignments

See separate list of Course Assignments *(appendix 1)*

Course work must be submitted electronically and in hard copy and on time. Marks (10% initially and then 5% per week) will be deducted for late submission. Your name, assignment title, and date should be clearly stated on the cover sheet.
Logbook of Cases
See separate course assignment documents for details on course work and logbook of cases.

9.5 Projects

The dissertation must be passed. It will not be required of Diploma students. Students will be required to submit titles and outline proposals for their project at the end of November in the first year of the course. A local project supervisor must be nominated.

A number of meetings will be held throughout the two years of the course, particularly in the first year of the course, to discuss the project requirements and progress with students. Students are required to produce a substantive contribution to the scientific literature and are encouraged to publish their work either during or after the award of the MSc. Projects which assist with local clinical and laboratory research needs in the student’s institution are welcome, but students are advised that routine method comparisons are often insufficient. The following headings should be used when preparing the project proposal.

- Name of Supervisor
- Introduction/Literature review (background)
- Aims and objectives
  - Overall aims
  - Specific objectives for the project
- Ethical approval
- Study design
  - Patients and controls
  - Inclusion and exclusion criteria
  - Samples and storage
  - Study methods
  - Analytical methods

- Work timetable
- Proposed statistical analysis

2 This is expected to be the norm.
• Proposed outcome measures
• Signed Agreement from local laboratory that support for the project is available
  • Laboratory Consultant
  • Chief Medical Scientist/Principal Biochemist

It is particularly important to ascertain that support for the project will be forthcoming from the student’s own institution, including financial resources, access to laboratories, and availability of patient specimens from clinicians. The project plan should be discussed with clinical and laboratory colleagues and this should commence as early as possible to secure timely access to facilities, and patient specimens. A careful literature search should be conducted, and reported in the dissertation. A proposal to the local hospital ethics committee should be prepared and submitted as soon as possible. Statistical advice should be sought at the project planning stage in order to ensure that the study design and statistical power, including patient numbers, are correct. The project planning and ethics approval should be completed as early as possible, but not later than the end of the first term and the work itself should be completed not later than 1st April in the second year. This will allow some time for Examiners, including the External Examiner to mark the dissertation prior to the final examination. Instructions on the preparation of dissertations are available from TCD (see www.tcd.ie) and in appendix 3. Mentoring will be available for students on the project and other aspects of the course from academic staff whom students may contact for advice.

Two soft-bound copies (e.g. using a ring binder or similar simple binding) of the dissertations should be submitted, not later than the 1st April of the final year. A 1-page abstract should be included. The student must await the decision of the examiners before making the final binding arrangements. Note that any extension beyond 1st April is at the discretion of the Dean of Postgraduate Studies to whom applications for any extension should be made. The Dean may then award a short extension beyond 1st April (“Dean’s Grace”). Students should ascertain their liability for additional fees for any extension beyond the Dean’s Grace period.

10. Staffing and Organisation

10.1 Course Director, Co-ordinator, teaching staff and accommodation
The course will be administered through the Faculty of Health Sciences. The current course director is Dr Gerard Boran and the course co-ordinator is Dr. Margaret Sinnott. Teaching staff will be provided from a panel of teachers consisting of Chemical Pathologists and other consultants, together with Medical Scientists and Clinical Biochemists in the Dublin teaching hospitals including Beaumont Hospital, and The Children’s University Hospital Temple Street. Other national and international lecturers will be included as required. Access to facilities, including accommodation for lecturing and teaching, has been arranged at the TCD Health Sciences Complex at AMNCH and St. James’s Hospital. Arrangements will be confirmed when lecture dates are finalised. A number of guest lectures will be organised for specific Techniques and other Workshops.

Some of the staff involved in the course includes:

<table>
<thead>
<tr>
<th>Participant</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Gerard Boran,</td>
<td>Consultant Chemical Pathologist, AMNCH</td>
</tr>
<tr>
<td>Dr Margaret Sinnott</td>
<td>Consultant Chemical Pathologist, AMNCH</td>
</tr>
<tr>
<td>Ms Geraldine Power</td>
<td>Executive Officer, MSc Clinical Chemistry, Trinity College</td>
</tr>
<tr>
<td>Dr James Gibney</td>
<td>Consultant Endocrinologist, AMNCH</td>
</tr>
<tr>
<td>Prof C O’Morain</td>
<td>Professor of Medicine, TCD AMNCH</td>
</tr>
<tr>
<td>Dr Vivion Crowley</td>
<td>Consultant Chemical Pathologist, SJH</td>
</tr>
<tr>
<td>Prof. Martin Crook, External Examiner</td>
<td>Consultant in Clinical Biochemistry and Metabolic Medicine Guy’s, St Thomas' and University Hospital Lewisham Caldicott Guardian University Hospital Lewisham Visiting Professor University of Greenwich BSc, MB BS, MA (medical ethics and law), PhD, FRCPath, FRCPI, FRCP</td>
</tr>
<tr>
<td>Dr. Marie-Louise Healy</td>
<td>Consultant Endocrinologist, SJH</td>
</tr>
<tr>
<td>Prof. Philip Mayne</td>
<td>Consultant Paediatric Chemical Pathologist, CUH Temple Street</td>
</tr>
<tr>
<td>Dr William Tormey</td>
<td>Consultant Chemical Pathologist, Beaumont Hospital</td>
</tr>
<tr>
<td>Dr. Paula O’Shea</td>
<td>Consultant Biochemist, Galway University Hospital</td>
</tr>
<tr>
<td>Dr. Damian Griffin</td>
<td>Consultant Chemical Pathologist, Galway University Hospital</td>
</tr>
<tr>
<td>Dr. Maria Fitzgibbon</td>
<td>Consultant Biochemist, Mater Hospital</td>
</tr>
<tr>
<td>Dr. Mary Stapleton</td>
<td>Principal Biochemist, Cork University Hospital</td>
</tr>
<tr>
<td>Dr. John O’Mullane</td>
<td>Consultant Biochemist, Cork University Hospital</td>
</tr>
<tr>
<td>Mr Peter Gaffney</td>
<td>Chief Medical Scientist, AMNCH</td>
</tr>
<tr>
<td>Mr. Frank Clarke</td>
<td>Lecturer in Clinical Chemistry, DIT</td>
</tr>
<tr>
<td>Dr Gerard O’Connor</td>
<td>Chief Medical Scientist/Lab Manager, AMNCH</td>
</tr>
<tr>
<td>Dr. Ophelia Blake</td>
<td>Principal Biochemist, St. James’s Hospital</td>
</tr>
<tr>
<td>Dr. Martin Healy</td>
<td>Principal Biochemist, St. James’s Hospital</td>
</tr>
<tr>
<td>Ms. Geraldine Collier</td>
<td>Principal Biochemist</td>
</tr>
<tr>
<td>Mr. John Gibbons</td>
<td>Laboratory Manager, St. James’s Hospital</td>
</tr>
</tbody>
</table>
10.2 Course Committee

A Course Committee has been constituted and will manage any issues arising in connection with the course. The Course Director will be in the chair. Members include: Dr. Gerard Boran, Course Director; Dr. Margaret Sinnott, Course Co-Coordinator; Dr. Vivion Crowley, Consultant Chemical Pathologist, St. James’s Hospital, Dublin 8; Professor Philip Mayne, Consultant Chemical Pathologist, Children’s University Hospital, Temple Street, Dublin 1; Dr. Gerard O’Connor, Laboratory Manager, AMNCH, Tallaght, Dublin 24; Paula O’Shea, Consultant Clinical Biochemist, UCH, Galway; Frank Clarke, Lecturer, DIT, Kevin St., Dublin 2. The quorum shall be 3.
10.3 Court of Examiners

The Court of Examiners will consist of all lecturers on the MSc course together with the Course Committee members and the External Examiner. The Court will be chaired by the Head of Department (or his nominee). The Court may meet shortly after the final examination to assess the results of the Final Written Examinations and Assignments and decide whether a Supplemental Examination is required. It will also recommend the award of the Diploma for Diplomate students (i.e. those who have indicated they will not be submitting a dissertation).

Appendix 1
Module Descriptors/Learning Outcomes

MSc in Clinical Chemistry:

On completion of the MSc in Clinical chemistry the graduate is expected to have a detailed knowledge and understanding of clinical biochemistry in the areas of laboratory investigation of medical conditions, laboratory management, and quality assurance. Graduates should have a full understanding of the preanalytical, analytical and post analytical issues of biochemical investigations. They should have up to date knowledge and understand of the underlying pathophysiology and clinical utility of these investigations and be able to critically discuss the interpretation of biochemical results with clinical and scientific colleagues.

At the end of this programme the graduates should have the tools and skills to perform in routine and specialised areas within the clinical biochemistry laboratory. Graduates should be capable of identifying and evaluating problems and providing solutions. They should be able to critically evaluate research articles and be capable of designing and completing scientific research projects.

Graduates who complete this MSc programme should be capable of evaluating processes within the laboratory and suggest changes based on current best practice.

The MSc in Clinical Biochemistry consists of five Modules designed to cover a wide syllabus i.e. general and specialised biochemistry, endocrinology and metabolism, genetics and molecular medicine, paediatrics and pregnancy. This will be achieved through lectures, interactive sessions, case presentations, course work and reading of appropriate books and journal.

Modules:

- Clinical Chemistry Module

Topics

Fluid and Electrolyte Homoeostasis and Disturbance
Acid-Base Balance and Disturbance
Renal Function and Disease
Gastrointestinal and Exocrine Pancreatic Function and Disease
Liver Function and its Disorders
Enzymology
Cardiovascular Biomarkers in Relation to Cardiovascular Disease
Toxicology and Drugs of Abuse
Biochemical Aspects of Nutrition and Nutritional Support
Tumour Markers

Aims

The aims of this module are to provide:
• up to date and in depth knowledge of the topics listed on the timetable (see above list of Topics)
• An in depth understanding of new procedures and methodologies
• the skills to critically assess efficient utilisation of laboratory services and appropriate laboratory investigations for given clinical conditions
• the ability to interpret biochemical results in conjunction with clinical information and to discuss the clinical utility of these results with clinical colleagues.

Learning Outcomes of this Module

At the end of this module participants will:
• Understand the current physiological and biochemical aspects of each topic to a molecular level
• Be able to identify and explain the relationship between normal physiological function and the pathological changes that occur in the different clinical conditions covered by the above topics.
• Formulate differential diagnoses based on the biochemical results and clinical information
• Be able to interpret laboratory results, taking into account clinical information and the preanalytical and analytical issues in relation to the different analytes
• Suggest further investigations based on the clinical question being asked and the results currently available
• Demonstrate awareness of the capabilities and limitations of biochemical investigations in identifying the presence or absence of disease states associated with the above topics
• Be able to discuss biochemical results with their laboratory and clinical colleagues
• Critically compare analytical methods for analytes covered in the above list of topics
• Debate controversial issues in relation to using tumour markers to screen for disease
• Be able to independently review advances in the understanding pathological processes in these areas and the part played by clinical biochemistry and molecular medicine
• Identify and review specific new analytical methods and recent advances employed within the clinical laboratory as well as in use in research centres.

Syllabus

Fluid and electrolyte homeostasis. Physiological control of electrolyte levels from a molecular level. Underlying causes of elevated or lowered levels of different electrolytes (e.g. potassium, sodium, magnesium etc) and the preanalytical, analytical and drug influences on results. Interpretation of acid base disturbance, identification of possible causes and suggested treatment. Patterns of acid base disturbance expected in common conditions. Acute and chronic renal failure and renal tubular defects. Renal dialysis. Gastrointestinal and pancreatic exocrine function and investigation of suspected pathological conditions. Immunological aspects of gastrointestinal disease. Biochemical aspects of nutrition, monitoring nutritional status and nutritional support. Investigation of liver disease and general enzymology. Cardiovascular disease, cardiovascular risk factors and laboratory assessment, including critical appraisal of available biomarkers. Toxicology, metabolic aspects of prescribed drugs, drugs of abuse and poisons, investigation of the poisoned patient. Tumour markers for screening, early detection of cancer, diagnostic utility, monitoring response to therapy and the properties of an ideal marker. Methods available for analysis of the analytes covered in the module with special emphasis methodologies not found in all routine laboratories. Critical assessment of available biochemical investigations for each topic covered in this module. Molecular basis of pathological conditions in the topics covered.

Source of Material

Lectures from experts in the topics covered in this module. Demonstrations in local laboratories and workshops, where appropriate. Case discussions with clinicians who have detailed knowledge of and expertise in the topics covered. Personal reading of articles and reviews in suitable medical/biochemical books and journals e.g. Clinical Chemistry by Marshall, New England Journal of Medicine, Annals of Clinical Biochemistry, Clinical Chemistry.

• Clinical Chemistry Module and General Paediatric Biochemistry Module (CCGPB)

Topics

General Paediatric Biochemistry e.g. calcium metabolism, glucose and hypoglycaemia. Prenatal and Postnatal Diagnosis and Screening Cystic Fibrosis and Sweat Tests Pregnancy and Pre-eclampsia Therapeutic Drug Monitoring and Pharmacogenetics Calculations in Clinical Chemistry Molecular Diagnostics and Genetics Proteomics Trace Elements Vitamin B12 and Folate
Cytokines and the Inflammatory Response.
Immunodeficiency and Allergy
Multiple Myeloma and Paraproteinaemia

Aims

The aims of this module are to provide:
• up to date and in depth knowledge of the topics listed on the timetable (see above list of Topics)
• An in depth understanding of new procedures and methodologies
• the skills to critically assess efficient utilisation of laboratory services and appropriate laboratory investigations for given clinical conditions
• the ability to interpret biochemical results in conjunction with clinical information and to discuss the clinical utility of these results with clinical colleagues.

Learning Outcomes of this Module

At the end of this module participants will:
• Understand the current physiological and biochemical aspects of each topic to a molecular level
• Be able to identify and explain the relationship between normal physiological function and the pathological changes that occur in the different clinical conditions covered by the above topics.
• Formulate differential diagnoses based on the biochemical results and clinical information
• Be able to interpret laboratory results, taking into account clinical information and the preanalytical and analytical issues in relation to the different analytes
• Suggest further investigations based on the clinical question being asked and the results currently available
• Demonstrate awareness of the capabilities and limitations of biochemical investigations in identifying the presence or absence of disease states associated with the above topics
• Be able to discuss biochemical results with their laboratory and clinical colleagues
• Critically compare analytical methods for analytes covered in the above list of topics
• Have an understanding and appreciation of the possible routine applications for micro-array technology and proteomics
• Be fully aware of the technologies utilised in molecular medicine and genetics, its capabilities and limitations
• Be cognisant of the changes that occur during pregnancy and how these changes affect biochemical investigations normally and in pathological conditions
• Full understanding of the issues involved in analysing hCG and what the different methodologies have to offer

• Understand the principles of neonatal screening and the issues involved in providing a National Neonatal Screening service

• Competently perform calculations relevant to clinical chemistry

• Be able to independently review advances in the understanding pathological processes in these areas and the part played by clinical biochemistry and molecular medicine

• Identify and review specific new analytical methods and resent advances employed within the clinical laboratory as well as in use in research centres

**Syllabus**

General Paediatric biochemistry covering electrolytes, calcium, glucose, renal and liver function and the associated pathological conditions and relevant biochemical investigations.

Neonatal screening, conditions screened for, incidence and prevalence in the Irish population.

Criteria for screening and suggested expanded screening panel. Analytical methodologies used in screening. Cystic fibrosis, molecular pathology and screening. Monitoring patients with cystic fibrosis. Physiological changes in pregnancy and how they effect interpretation of results and, how to identify pathological conditions during pregnancy. The role of biochemistry in the diagnosis and management of pre-eclampsia.

Therapeutic drug monitoring, what and why. Pharmacogenetics, emerging clinical uses.

Calculations in clinical biochemistry, statistics, buffers, half-life estimation, TmP etc.

Molecular diagnostics and genetics covering technologies and methodologies, clinical utility.

Proteomics and its clinical application

Trace elements, their clinical relevance and analytical methods. Identifying and explaining abnormal results. Up to date information on B12 and Folate


Immunodeficiency conditions, investigation and monitoring. Allergies and how they are investigated.

The pathophysiology of multiple Myeloma and Paraproteinaemia and the laboratory investigations.

Protein electrophoresis (different types), immunofixation and light chain analysis. Effect of paraproteins on other biochemical investigations.

**Source of Material**

Lectures from experts in the topics covered in this module. Demonstrations in local laboratories and workshops, where appropriate. Case discussions with clinicians who have detailed knowledge of and expertise in the topics covered. Personal reading of articles and reviews in suitable medical/biochemical books and journals e.g. Clinical Chemistry by Marshall, New England Journal of Medicine, Annals of Clinical Biochemistry, Clinical Chemistry, Paediatric Journal etc.
• **Quality Assurance & Laboratory Management Module**

Topics

Laboratory management  
Audit  
Accreditation  
Statistics  
Health and Safety  
Business Case and Tendering  
Predictive Values of Tests and Screening  
External and Internal Quality Control  
Human Resources and Staffing Issues  
Laboratory Information Systems, Informatics and Decision Support  
Automation  
Ethics  
Method Evaluation  
Point of Care Tests (POCT)  
Data Interpretation

Aims

The aims of this module are to provide:

- Understand the requirements of laboratory management and quality assurance  
- up to date and in depth knowledge of the topics listed on the timetable (see above list of Topics)  
- An in depth understanding of new procedures and methodologies  
- the skills to critically assess efficient utilisation of laboratory services and appropriate laboratory investigations for given clinical conditions  
- The ability to interpret biochemical results in conjunction with clinical information and to discuss the clinical utility of these results with clinical colleagues.

**Learning Outcomes of this Module**

At the end of this module participants will have:

- An understanding of the procedures and policies involved in staff management and staff complaints  
- The skills to carry out audits and play and informed part in preparing a laboratory for accreditation.  
- The ability to prepare business plans, tendering documents and other documents required for managing a laboratory
• Knowledge of the statutory requirements for health and safety within the laboratory and the ability to identify safety issues within the laboratory

• An understanding of statistics and their use in the laboratory setting

• The ability to critically evaluate laboratory methods and utility of biochemical tests

• An understanding of the structures, guidelines, staffing requirements, IT and other issues involved in providing a POCT service throughout the hospital

• The ability to assess POCT devices

• Current knowledge on new developments in automation and preanalytic systems and the ability to describe and critique the capabilities and limitations of new developments in this area

• Knowledge of user requirements for laboratory information systems, new developments in electronic patient charts and other hospital IT systems and the ability to identify utility and limitations of these systems.

• An understanding of the external quality systems available, their reports and the ability to problem solve

• The ability to manage internal quality control and problem solve

Syllabus

External quality control, why and how, identifying and dealing with problems.
Internal quality control, why and how, identifying and dealing with problems.
General quality assurance
Statistics in laboratory medicine.
Utility of biochemical tests in the investigation, management and monitoring of patients.
Audits – different types of audit and how they should be carried out
Accreditation – what is required and how to approach preparing your laboratory for accreditation
Health and Safety within the laboratory – statutory and local requirements.
Staff management – staff required to run the service, dealing with complaints from staff and laboratory users, disciplinary issues
Preparing business cases and tender documents, replacing a major analyser, setting up a new service.
Laboratory Information Systems, other IT systems within a hospital, electronic patient charts,
Informatics and Decision Support
Laboratory automation
Providing a POCT service

Source of Material

Lectures from experts in the topics covered in this module. Demonstrations in local laboratories and, workshops where appropriate. Discussions with laboratory and hospital personnel who have detailed knowledge of and expertise in the topics covered. Personal reading of articles and reviews
in suitable laboratory management/medical/biochemical books and journals e.g. Accreditation by Burnett, New England Journal of Medicine, Annals of Clinical Biochemistry, Clinical Chemistry.

- **Endocrinology and Metabolism Module**

Topics

- Neuroendocrine regulation and hormone signalling
- Autoimmune mechanisms in Endocrinology
- The Pituitary in Health and disease
- Update on thyroid dysfunction and disease
- Pathophysiology of the Parathyroid Glands
- Adrenal Cortex and Medulla
- Growth Hormone
- The Gonads and Reproductive Endocrinology
- Paediatric Endocrinology
- Immunoassays and choosing an Immunoassay Platform
- Steroid Hormone Assays
- Catecholamine analysis
- Case discussions

Aims

The aims of this module are to provide:
- Up to date and in depth knowledge of the topics listed on the timetable (see above list of Topics)
- An in depth understanding of new procedures and methodologies
- The skills to critically assess efficient utilisation of laboratory services and appropriate laboratory investigations for given clinical conditions
- The ability to interpret biochemical results in conjunction with clinical information and to discuss the clinical utility of these results with clinical colleagues.

**Learning Outcomes of this Module**

At the end of this module participants will:
- Understand the current physiological and biochemical aspects of each topic to a molecular level
- Be able to identify and explain the relationship between normal physiological function and the pathological changes that occur in the different clinical conditions covered by the above topics.
- Have an understanding of circadian rhythm of each hormone, biological and analytical variation and the effect on the interpretation of laboratory results
- Have current evidence based (if available) knowledge of dynamic function tests for the investigation of endocrine disorders, protocols for performing these investigations and normal cut-offs and associated problems
• Have up to date knowledge of the heterogeneity of individual hormones and the effects this has on the analysis of these hormones and on their interpretation in given clinical conditions e.g. PTH in renal disease, Macroprolactin, growth hormone etc

• Have an in depth understanding of puberty from the physiological and pathological point of view and the ability to advise on appropriate biochemical investigations and interpretation of results

• Have an understanding of standardisation of hormone assays and the ability to critically assess the issues involved

• Be able to critically assess immunoassay systems

• Be able to formulate differential diagnoses based on the biochemical results and clinical information

• Be able to interpret laboratory results, taking into account clinical information and the preanalytical and analytical issues

• Be capable of suggesting further investigations based on the clinical question being asked and the results currently available

• Be able to demonstrate awareness of the capabilities and limitations of biochemical investigations in identifying the presence or absence of disease states associated with the above topics

• Be able to discuss biochemical results with their laboratory and clinical colleagues

• Have the ability to critically compare analytical methods for analytes covered in the above list of topics

• Be able to independently review advances in the understanding pathological processes in these areas and the part played by clinical biochemistry and molecular medicine

• Identify and review specific new analytical methods and resent advances employed within the clinical laboratory as well as in use in research centres.

Syllabus

Neuroendocrinology and control of the endocrine system by higher centres within the brain. Hypothalamic function and pulse generation
Hormone signallning and hormone receptors to the molecular level
Positive and negative feedback mechanisms
Drugs that effect hormone production – increase or decrease
Hormone resistance e.g. thyroid, androgen
Autoimmune processes in endocrinology – what antibodies and when
The Pituitary gland, hormone production in health and disease
Thyroid disease – guidelines, interpretation of results, discordant results and problem solving
Prolactin and Macroprolactin
Growth hormone analysis and standardisation, GH deficiency or excess in adults and children, IGF1
PTH what are we measuring, especially in renal disease, hyper- and hypo-parathyroidism in adults
and in children, Pseudohypoparathyroidism
Cushing’s and Addison’s – clinical, pathophysiology and investigation
Assessing adrenal cortex function
Puberty – normal and pathological
Catecholamines and metanephrines in health and disease – phaeochromocytoma, neurobalstoma
Reproductive endocrinology and assisted reproduction
Case discussions, with experienced clinicians, covering the areas of endocrinology mentioned under
“Topics”
Immuoassay systems and their associated problems, particularly standardisation of assays and
steroid assays. Choosing an immunoassay system.
Critical assessment of available biochemical investigations for each topic covered in this module.
Molecular basis of pathological conditions in the topics covered.

Source of Material
Lectures from experts in the topics covered in this module. Demonstrations in local laboratories and
workshops, where appropriate. Case discussions with clinicians who have detailed knowledge of
and expertise in the topics covered. Personal reading of articles and reviews in suitable
medical/biochemical books and journals e.g. Clinical Chemistry by Marshall, New England Journal
of Medicine, Annals of Clinical Biochemistry, Clinical Chemistry, Journal of Endocrinology and
Metabolism, Endocrinology etc.

- Endocrinology and Inborn Errors of Metabolism Module (EIEM)

Topics
Paediatric Metabolic Medicine and Inborn Errors of Metabolism
Short Stature
Hypoglycaemia
Diabetes (DM) and Obesity
Porphyria
Bone, Osteoporosis, Vitamin D and Bone Markers
Lipid Metabolism and Markers of Cardiovascular Risk (also covered in an additional lecture in
April 2007)
Gut Hormones (covered in an additional lecture in April 2007)

Aims
The aims of this module are to provide:
- Up to date and in depth knowledge of the topics listed on the timetable (see above list of Topics)
- An in depth understanding of new procedures and methodologies
The skills to critically assess efficient utilisation of laboratory services and appropriate laboratory investigations for given clinical conditions

The ability to interpret biochemical results in conjunction with clinical information and to discuss the clinical utility of these results with clinical colleagues.

**Learning Outcomes of this Module**

At the end of this module participants will:

- Understand the current physiological and biochemical aspects of each topic to a molecular level
- Be able to identify and explain the relationship between normal physiological function and the pathological changes that occur in the different clinical conditions covered by the above topics.
- Formulate differential diagnoses based on the biochemical results and clinical information
- Be able to interpret laboratory results, taking into account clinical information and the preanalytical and analytical issues in relation to the different analytes
- Suggest further investigations based on the clinical question being asked and the results currently available
- Demonstrate awareness of the capabilities and limitations of biochemical investigations in identifying the presence or absence of disease states associated with the above topics
- Be able to discuss biochemical results with their laboratory and clinical colleagues
- Critically compare analytical methods for analytes covered in the above list of topics
- Have a detailed understanding of the pathophysiology of diabetes mellitus, including the different types of DM, molecular basis of the disease process, the potential complications of long term DM, diagnosis, assessment and monitoring of DM control, home glucose monitoring, oral glucose tolerance test, microalbuminuria and DM during pregnancy.
- Understand the underlying causes of hypoglycaemia in adults and children and how this condition should be investigated and results interpreted
- Understand and be able to apply the principles of paediatric screening and neonatal screening in the clinical environment
- Demonstrate knowledge of the various methodologies and investigation protocols used to identify inborn errors of metabolism
- Understand the molecular basis of inborn errors of metabolism
- Have a very good understanding of the pathophysiology of inborn errors for which there is national screening
• Demonstrate knowledge of the molecular and pathological basis of inborn errors of amino acid metabolism, fatty acid oxidation defects, mitochondrial/respiratory chain disorders, organic acidaemias, lysosomal and peroxisomal disease

• Have a detailed understanding of the molecular and pathophysiology of obesity

• Understand the underlying pathophysiology and be able to identify the different porphyrin disorders

• Be able to critically assess the available bone markers for diagnosis and monitoring of osteoporosis and bone disorders

• Have an in depth knowledge of lipid metabolism, lipid disorders and biochemical investigations required to diagnose and monitor lipid abnormalities

• Have an in depth knowledge of current and novel markers available for the assessment of cardiovascular risk

• Know how to investigate the biochemical/endocrine causes of hypertension and critically discuss the utility and limitations of the available investigations

• Full understanding of the current status of vitamin D analysis and its utility in the assessment of calcium metabolism and bone disease.

• Be able to independently review advances in the understanding pathological processes in these areas and the part played by clinical biochemistry and molecular medicine

• Identify and review specific new analytical methods and resent advances employed within the clinical laboratory as well as in use in research centres.

**Syllabus**

Classification, pathogenesis and molecular basis of diabetes mellitus. Biochemical investigation, diagnosis and monitoring of DM. HbA1c – methodology, Hb variants, target levels and standardisation. DM and pregnancy. POCT in DM.

Inborn errors of metabolism – pathogenesis molecular basis of these conditions, clinical presentation, investigations and protocols for making a diagnosis, national screening. Conditions: inborn errors of amino acid metabolism, glycogen storage disease, fatty acid oxidation defects, mitochondrial/respiratory chain disorders, organic acidaemias, galactosaemia, lysosomal disease and peroxisomal disease. Hypoglycaemia, hyperammonaemia and lactic acidosis.

Methods available for analysis of the analytes covered in the module with special emphasis methodologies not found in all routine laboratories.

Critical assessment of available biochemical investigations for each topic covered in this module.

Molecular basis of pathological conditions in the topics covered.

Porphyria – pathogenesis, classification, clinical aspects, acute porphyries and methodologies.

Biochemical aspects of hypertension and cardiovascular disease, current and novel markers of cardiovascular risk. Lipid metabolism, pathophysiology and mechanism of action of lipid lowering drugs.

Methodologies – particularly tandem mass spectroscopy, HPLC, amino acid analysis
Case discussions, with experienced clinicians, covering the areas of endocrinology mentioned under “Topics”

**Source of Material**

Lectures from experts in the topics covered in this module. Demonstrations in local laboratories and workshops, where appropriate. Case discussions with clinicians who have detailed knowledge of and expertise in the topics covered. Personal reading of articles and reviews in suitable medical/biochemical books and journals e.g. Clinical Chemistry by Marshall, New England Journal of Medicine, Annals of Clinical Biochemistry, Clinical Chemistry, Paediatric Journal, Journal of Endocrinology and Metabolism, Endocrinology etc.

**Appendix 2**

**COURSE ASSIGNMENTS, LOGBOOK of CASES, and ASSESSMENTS**

**MSc in Clinical Chemistry (Students 2011 – 2013)**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>MARK</th>
<th>DESCRIPTION</th>
<th>DATE DUE</th>
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<tbody>
<tr>
<td>Assignment 1</td>
<td>25</td>
<td>Journal article – review/presentation</td>
<td>04/11/2011</td>
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<tr>
<td>Assignment 2</td>
<td>25</td>
<td>Method Evaluation</td>
<td>30/01/2012</td>
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<tr>
<td>Assignment 3</td>
<td>25</td>
<td>Essay</td>
<td>13/04/2012</td>
</tr>
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<td>Assignment 4</td>
<td>25</td>
<td>Audit Report (QAALM)</td>
<td>12/10/2012</td>
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<td>Assignment 5</td>
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<td>POCT Workshop Report (QAALM)</td>
<td>07/12/2012</td>
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<tr>
<td>Assignment 6</td>
<td>25</td>
<td>Business Case Report (QAALM)</td>
<td>08/02/2013</td>
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<tr>
<td>Logbook of Cases</td>
<td>100</td>
<td>10 Cases presented in log book format</td>
<td>5 per year (not later than 1st April each year)</td>
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<tr>
<td>1st Year OSPE</td>
<td>45</td>
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<tr>
<td>2nd Year OSPE</td>
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<tr>
<td>1st Year Exam (one paper)</td>
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<td>2nd Year Exam (one paper)</td>
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<td>Viva Voce (end of Yr 2)</td>
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<tr>
<td><strong>TOTAL MARKS</strong></td>
<td><strong>500</strong></td>
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<tr>
<td>Assignments (6 assignments in total – 150 marks total, 25 for each assignment)</td>
<td>Instructions to Students for the 6 Assignments</td>
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<td><strong>Essay</strong></td>
<td>Please submit ONE essay from the advised list of topics. You are asked to submit in handwriting, using an official TCD answer book. The length of the essay will normally be what is achievable for you in the usual 45 minute period available to answer most essay questions under examination conditions. In any event, the essay length should not exceed handwritten 8 pages. You are advised to read the topic in detail before attempting the essay, but you may refer to textbooks and notes while writing. One of the objectives of this essay assignment is to practice essay handwriting skills which will be required for the final examination papers. Ensure your essay is properly planned with logical sections (introduction stating what you will cover or focus on, main body with headings where appropriate, and a conclusion). You may include 2-3 key references to assist with your future revision (though references with citations are not a requirement of a well-written essay and full citations are of course rare under exam conditions).</td>
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<tr>
<td><strong>Audit Report</strong> (this is linked with QAALM module)</td>
<td>Using data from your own hospital Laboratory you are required to submit a horizontal, vertical, witness, or clinical audit of your choice. Use any appropriate format to present the audit e.g. forms in use in your base laboratory. For clinical audits follow a defined format - find out how audit is done in your laboratory and hospital and use this format. Speak to your laboratory's quality officer, and your hospitals clinical audit department. However, ensure that you have included clear CONCISE sections describing what you did, e.g. • Title of audit • Introduction/Aim of audit • Background to the Audit • Standard that you audited against (and its source, what kind of standard is it?) • Your Audit methodology • Results/Findings and Conclusions from the Audit • Recommendations for improvements • Plans for re-audit and concluding remarks</td>
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</table>
Try to keep to approximately 500 words plus any supporting proformas etc. Do not include any identifiable patient details. Ensure any attached proformas used during the audit are adequately explained if they are not self-explanatory.

You will be asked to make a presentation of your audit in class, as this is how most hospital audits done by clinical teams are disseminated. Powerpoint or Word or another software tool are all suitable, but please ensure that your format and layout is good for presentation to save yourself the trouble of having to do a separate Powerpoint for the class presentation.

You will be assessed on the submitted document and on the class presentation/discussion. Refer to lecture material for more information. Make sure you understand the audit cycle and the difference between audit and research. Also check the RCPath website which has a useful section on clinical audit (www.rcpath.org).

POCT Workshop Report

(this is linked with the POCT demonstration/technique workshop)

POCT Device Comparison Guideline

When writing up the assignment based on your assessment/comparison of the POCT Glucose devices reviewed at the POCT workshop you may choose to include the following headings for consideration:

1. **Compliance with regulatory requirements**
   a. CE Marking
   b. Is there reference to any Standards in the material provided?
   c. Health and Safety considerations
      i. Is the unit of measurement interchangeable?
      ii. Have sufficient instructions been provided for obtaining samples?
   d. Has information on the safe disposal of waste materials been included?

2. **Ease of use**
   a. Clarity of instruction materials in relation to the Glucometer itself and/or the finger-prick device
   b. Is there a simple Quick-start guide
   c. Access to help-desk functions
   d. System navigation
   e. Data display screen i.e. has consideration been given to those with visual impairments or could the result be read upside-down e.g. 6.9 or 9.6

3. **Reliability of results**
   a. Does the instrument require calibration – is the information provided sufficient?
   b. What advice is given relating to Quality Control and is QC material provided?
   c. Is reagent coding required and is it possible to use a non-coded strip to obtain a result?
   d. Did you achieve the same results with each device type?
      i. If not could the difference observed have been clinically significant i.e. might it have altered the course of treatment?
   e. What was the reportable range and was information on interference levels provided?
Please aim to submit about 3-4 pages of Word or any other suitable software tool. Assessment will be based on the submitted document.

| Business Case Report | Submit a business case based on an example from your Laboratory within the past 2 years. You may use Word, Powerpoint or any other suitable software tool. It may be appropriate in some cases to include an Excel spreadsheet if it is necessary to present financial or workload information. Please ensure any information you divulge is not proprietary – check with your Manager first!
Please speak to relevant staff in your Laboratory about how they would go about it, e.g., the laboratory manager, chief medical scientist, principal biochemist, or consultant. You are also recommended to study the lecture that was given on this topic. The main purpose of this assignment is to get you writing a business case using guidance from your own organisation on the assumption that most hospital laboratories are very adept at this. Bear in mind that most business cases need to be reasonably concise – usually the major message should be conveyed in a few pages. If the business case documentation is more extensive, you should aim to summarise it for the purposes of this assignment in about 3 pages. The bottom line should also appear within these parameters (i.e. costs summary and benefits). If your business cases offers a number of options (e.g. often a do-nothing option, and then various development options including your recommended option), you should summarise the costs and benefits, pros and cons for each of these options.

- Title
- Introduction
- Background to the present case
- Options appraised, including costs, benefits, pros/cons of each option (if appropriate)
- Recommendation (or recommended option)
- Conclusion

Try to keep it to not more than 3 typed A4 pages, plus (if you have to) any absolutely essential supplementary spreadsheets or supporting documents. Any attached documents must be explained if they are not self-explanatory.

The assessment will be based on both your submitted document and a class presentation/discussion. Try to ensure that your format and layout is good for presentation to save yourself the trouble of having to do a separate Powerpoint for the class presentation - in most cases, you should be able to use a Word and/or Excel document for presentation unless you are very good at linking everything into powerpoint.

| Journal Article – review/presentation | We have changed from an essay of 2000 words to the following format:-
You are asked to prepare a Power Point Presentation lasting approx 15mins where you review a journal article of your selection. The Power Point should ideally not be more than 15 slides in length. You will be asked to give a class presentation of your journal article.

You may select any article relevant to laboratory medicine/clinical chemistry. This may be a review article, or an original scientific paper selected from a major scientific journal. It is better to focus the presentation on one major article, though you may refer to other articles, reviews or even newsletter/press articles on the same topic if this is relevant. In general, you can use the headings in the journal article for your presentation, and you can also project figures or tables from the journal article itself. |
V1Revised09Sept2011

if this helps in the presentation.

The Power Point will need to be submitted electronically by the deadline and the assessment will be based on the submitted PP and the class presentation.

Please also attach an electronic copy of your chosen review article with the PP presentation assignment. We will aim to circulate these to the class in advance of the presentation.

Method Evaluation
(this is linked with QAALM module)

Each student should compare two methods in their own laboratory.

e.g.
1. If your laboratory is introducing a new method
2. If your laboratory has two analysers capable of measuring the same analyte e.g. sodium on main analyser and blood gas analyser

Headings:
• Brief introduction
• Practical Requirements: includes specimen size and type, sample handling, workload, IQC, EQA, method robustness, waste disposal, hazards, health and safety issues etc.
• Performance characteristics: includes accuracy, analytical range, analytical specificity and sensitivity, decision limits, interference etc.
• Precision studies
• Detection limit
• Reference ranges
• Acceptability – CLIA, percent of biological variation
• Conclusion

A written report is required and should include Excl spreadsheets of your precision and patient data plus appropriate graphs. The assessment will be based on both your submitted document and a class presentation/discussion. Try to ensure that your format and layout is good for presentation to save yourself the trouble of having to do a separate Powerpoint for the class presentation - in most cases, you should be able to use a Word and/or Excel document for presentation unless you are very good at linking everything into powerpoint.

Logbook of Cases
Instructions to Students for the Logbook of 10 Cases

10 Cases presented in log book format (100 marks, 10 marks for each case)

Please submit 5 cases per year regularly throughout the term.

The preferred format is as Powerpoint slides as this is the format used by the clinical team in most hospital clinical case meetings

At least 5 cases should be submitted during each academic year. You are encouraged to discuss cases with appropriate clinical and laboratory team members and perhaps review the patients chart where possible. Ensure all cases submitted are anonymous (in this regard do not even include patient initials; also you may state the age but not exact dates of birth). You may submit any case, but particularly for common biochemical problems regularly seen in your laboratory (i.e. you might wish to include any of sodium potassium, calcium, phosphate, thyroid, gonadal, renal, acidbase cases). You may submit but are NOT required to find rare or very unusual cases and hence should have no difficulty in selecting
suitable cases on a weekly basis from your standard laboratory workload. Try to submit on 10 different biochemical problems if possible. Exotic cases will not score any better than a well-presented “common gardener” problem.

Assessment consists of the submitted cases, and presentation/discussion at Case Presentation sessions arranged each term.

Each case should be submitted electronically and in paper copy.

Suggested Case report Headings (note these are not obligatory and may be adjusted to suit the type of case):-

- Case title Slide (please use a descriptive title). Include your name, date and case number (case 1 of 10 etc)
- Presenting Complaint – to include history of the presenting complaint
- Brief Mention of relevant aspects of Past History, Family History, Social History, Systems Review
- Examination Findings – relevant. Don’t forget to include relevant units and reference ranges
- Results with interpretation
- You may want to ask a question at a suitable point – e.g. what is the diagnosis?
- Differential Diagnosis with discussion
- Diagnosis and information on the pathogenesis and treatment of the condition
- Brief Account of the patient’s Progress, Monitoring (including cumulative laboratory findings). Response to treatment may be included where relevant (or you may focus on initial diagnosis if you wish)
- Background information on the condition
- Summary/Conclusions and references (where appropriate)
- Note: it may be useful to include a few keywords for indexing purpose on a final slide (e.g. especially if your Case title attempts to create a bit of mystery by concealing the nature of the case). Just include some keywords on the end slide, e.g. hyperthyroidism, Graves’ disease. This will help us index them for future reference.

OSPEs

Instructions to Students for OSPEs

OSPE Practice Runs

A number of practice run OSPEs are held in order to familiarise students with the OSPE format (approximately one per term). The practice OSPEs will aim to cover material from that term. A feedback session will follow each practice run.

The next OSPE practice run is in December 2011.

Marked OSPEs (90 marks total, 45 marks for each OSPE)

There are 2 Marked OSPEs on the entire course – one per year. These will now be held on the same day as the First Year or Second Year Written Paper. Each years’ marked OSPE is part of the end of year examination.

Hence from May 2011 onwards, all students regardless of year of entry will be doing the same OSPE at the same time (i.e. all students will either be doing Practice-Runs or a Marked OSPE at any one sitting, and the marked OSPEs will always be on the same day as the end of year Written Paper). This will simplify administration of the OSPEs.
Appendix 3
Project Information

- Final Project Proposal must be submitted by the end of November in the first year of the course
- Ethical approval must be obtained from the local hospital as required
- Abstract/summary at the beginning of the thesis
- 12 000 words
- Chapter Headings:
  - Introduction
  - Literature review/background
  - Aims - overall aims and specific objectives for the project
  - Materials and methods (including patient group and size; controls; laboratory methods; statistics, etc)
  - Results
  - Discussion
  - Conclusion
  - References
- Do not forget the declaration that your work has not been published elsewhere and the acknowledgement
- Font size of 11 or greater
- Spacing of 1.5
- Font and spacing must be consistent throughout the document
- Numbering of chapters, sections and subsections is required e.g. 1.0 Literature Review; sub-headings will be 1.1, 1.2, 1.3 etc; subsections within a sub-heading should be numbered 1.1.1, 1.1.2 etc or 1.2.1, 1.2.2 etc.
- References use Vancouver style
- All information provided in the thesis must be properly referenced
• Abbreviations must all be listed at the front of the thesis. The full term, followed by the abbreviation in brackets, must be used the first time the abbreviation is introduced in the text. Thereafter, the abbreviation should be used consistently. ALL abbreviations, including units, must be explained and listed.
• The must be a list of figures and a list of tables at the beginning of the thesis.
• The project must by submitted to the supervisor for corrections and approval prior to submission to the Examiners’ Committee

The final version of the project must be submitted by April 1st of the second year. The document may be ring bound at this point. Before the final document is bound, it must receive a pass mark from the MSc course examiners, including the External Examiner

Appendix 4
Summary Syllabus

Coverage of methodologies and diagnostics will be integrated with the clinical material in all of the Modules and will be complemented by the Techniques Workshops. Likewise, short cases relevant to each module will be covered in each teaching session but will be complemented at the Clinical Laboratory Interface Workshops. All topics or aspects of each topic cannot be covered in lectures/workshops so it is very important that you read the relevant journals covering clinical biochemistry e.g. Annals of Clinical Biochemistry, Clinical Chemistry, New England Journal of Medicine etc.

CC  Clinical Chemistry Module
This module will introduce the discipline of clinical biochemistry and will cover clinical enzymology, therapeutic drug monitoring and toxicology, fluids and electrolytes, biochemical aspects of nutrition, renal function and renal stones, blood gases and lung disease, liver function and gallstones, pancreatic and gastrointestinal function, cardiovascular biomarkers, and tumour markers.

CCGPB  Clinical Chemistry and General Paediatric Biochemistry
This module will cover neonatal and paediatric biochemistry, obstetric and age-related biochemistry, nucleic acid biochemistry, haematological biochemistry, vitamins, immunochemistry and transplantation, and trace elements and their toxicology.
EM  Endocrinology and Metabolism
This module will introduce the course on biochemical aspects of endocrinology and metabolism and will cover the hypothalamus and pituitary gland, disorders of thyroid function, and the adrenal cortex and medulla. Diabetes Mellitus will be covered in several sessions, together with obesity and the metabolic syndrome and hypoglycaemia. Hypertension, especially endocrine hypertension, and hyperlipidaemia will be covered. There will be sessions on calcium and bone metabolism, gastrointestinal tract hormones, carcinoid and multiple endocrine neoplasia and sessions on disorders of growth in adults.

EIEM  Endocrinology and Inborn Errors of Metabolism
This module will develop on the earlier endocrinology and metabolism module and will cover biochemical aspects of reproductive endocrinology over several sessions. Paediatric endocrine biochemistry including disorders of growth in children will be covered. Metabolic topics will include a thorough review of inborn errors of metabolism in children and adults, porphyrias, hyperuricaemia and gout.

QAALM  Quality Assurance and Laboratory Management Module
This module will introduce the concepts of quality assurance and effective laboratory management. Topics covered will include sources of variation in laboratory results, determination of reference values, evaluation of laboratory methods, the predictive value of tests, principles of screening for disease using biochemical investigations, and quality standards for point of care testing. The principles and practice of internal and external quality assurance and available schemes will be covered. Clinical audit and accreditation schemes will be reviewed. Sessions on laboratory organisation, human resources management in the laboratory, health and safety in the clinical laboratory, financial management and budgeting will be included. Automation and laboratory information systems will be covered.

TW  Techniques Workshops
These workshops will take place throughout the course and are designed to offer exposure to common and important techniques especially those, which are not represented in every clinical laboratory. The syllabus for these workshops will cover techniques such as spectrophotometry, fluorometry, nephelometry, turbidimetry, radioactivity and its measurement, electrochemistry, electrophoretic techniques, chromatography, mass spectrometry, proteins and immunochemical
techniques, molecular diagnostics, immunoassay, automation including preanalytical robotics. Research methods and statistical tools will also be covered. The workshops will be arranged in suitable clinical or demonstration laboratories. Practical exercises to be carried out in the student’s home laboratory will be set and reviewed at these workshops

**CLI Clinical Lab Interface Workshops**

These workshops are designed to develop the students’ ability to discuss, present and report on clinical laboratory data, clinical audit and other situations where laboratory staff are required to discuss the service with its users. Hence exercises will be set dealing with clinical case presentations, presentation of laboratory workload and financial data for business cases/cases of need, research methods, and extraction of epidemiological data.
Appendix 5
Calendar Entry (2011)

Clinical Chemistry (MSc/P.Grad.Dip)

Course No. 736:

Changes to Calendar, Part II, for Academic year 2011

1. *Introduction:* This M.Sc. programme in Clinical Chemistry is offered on a part-time basis over 2 years. All students regardless of background will gain a comprehensive understanding of the principles of Clinical Biochemistry to an advanced level.

2. *Course Structure:* Lectures, case discussions and practical instruction workshops will take place on Fridays over five terms with revision in the sixth term. The course consists of five modules worth 90 ECTS:
   - 1 Clinical Chemistry 10 ECTS
   - 2 Clinical Chemistry and General Paediatric Biochemistry 15 ECTS
   - 3 Endocrinology and Metabolism 10 ECTS
   - 4 Endocrinology and Inborn Errors of Metabolism 15 ECTS
   - 5 Quality Assurance and Laboratory Management 10 ECTS
   - Research Project 30 ECTS

Revision sessions will be provided over three Fridays prior to the final examination. Students will carry out research in their base laboratory for the dissertation throughout the course and will be required to submit an outline proposal for the subject of their dissertation by the end of the first month of the course.

3. *Assessment:* Continuous assessment will be based on ten written assignments over the two years and a written exam at the end of year 1 (one paper). A final written examination consisting of two written papers, a practical assessment and a *viva voce* will be held in the fifth term. The practical assessment will consist of short questions including clinical observations, practical findings, calculations, and other material in the format known as an Objective Structured Pathology Exercise (OSPE). Students will also need to complete and submit a research dissertation of approximately 12,000 words by the 1st April of their final year. A pass must be obtained in the dissertation in order to be awarded the M.Sc. (no compensation is allowed). The written components must also be passed, though compensation is allowed between the components, provided a minimum mark of 40% is obtained in the failed component. Students who pass all components of the assessments but who do not submit a successful dissertation may be awarded a Diploma but not the M.Sc. Use of the Diploma exit option will prevent the student from returning to the course to register to continue for the M.Sc. option at any later stage.

4. *Course Director:* Dr Gerard Boran  
   *Course Co-ordinator:* Dr Margaret Sinnott
Appendix 6
Prospectus Entry (2011)

CLINICAL CHEMISTRY (M.Sc./P.Grad.Dip.)

COURSE CODE 736

Course Director: Dr Gerard Boran
Course Co-Ordinator: Dr Margaret Sinnott
Duration: Two years, part-time
Closing Date: 30 July of each year. Applications should be addressed directly to Ms Dara O’Mahony, School of Research and Postgraduate Education, Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8.
Telephone: + 353-1-896 3556/3557

Geraldine Power, Executive Officer, MSc Clinical Chemistry Tel: 01 896 3721
Email: geraldine.power@tcd.ie
Email for Application Forms: gradapps.hs@tcd.ie
Course Telephone: +353 1 414 3911
Course Email: clinicalbiochemistry@tcd.ie
Internet: www.medicine.tcd.ie/clinical_biochemistry/courses

This M.Sc. programme in Clinical Chemistry is offered on a part-time basis over 2 years. Candidates employed as medical scientists, clinical biochemists or medical doctors who wish to develop a special interest in Clinical Biochemistry are particularly invited to apply. All students, regardless of background, will gain a comprehensive understanding of the principles of Clinical Biochemistry to an advanced level, including clinical and research aspects. Special attention will be given to current developments in the discipline.

A comprehensive lecture programme will be delivered on Fridays over five terms. This will consist of five Modules (Clinical Chemistry, Clinical Chemistry and General Paediatric Biochemistry, Endocrinology and Metabolism, Endocrinology, Metabolic Disease and Inborn Errors of Metabolism and Quality Assurance and Laboratory Management). Each module will include Techniques Workshops: these will focus on developing practical skills through demonstrations and assignments in the candidates’ base laboratory. A series of Clinical Laboratory Interface Workshops will foster clinical reasoning and data presentation skills. A research dissertation conducted in the candidates’ base laboratory will also form part of the course. Instruction on research methods will be included. Revision sessions will be provided over three Fridays at the beginning of the Trinity Term of the second year.

The course is assessed by means of course work, a final examination and a dissertation. Course work consists of eight written assignments over the two years and a written paper at the end of year 1. The final examination at the end of year 2 is made up of two written papers, a practical assessment (Objective Structured Practical Examination (OSPE) which will include short questions with clinical observations, practical findings, calculations and other material) and a viva voce. A dissertation of approximately 12 000 words, based on a research project, must be submitted by April 1st of year 2. A pass must be obtained in the dissertation in order to be awarded the M.Sc. (no compensation is allowed). The written components of the course must also be passes but compensation is allowed here so long as a minimum mark of 40% is obtained in the component for which compensation is required. Students who pass all components of the assessment but who do not submit a successful dissertation may be awarded a Diploma but not the M.Sc. Use of the Diploma exit option prohibits the student from returning to the course to register to continue for the M.Sc. option at any later stage.