MSc Clinical Chemistry
School of Medicine
Trinity College Dublin

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1.0 Introduction

1.1 Background

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 specialised and computerised working environment.

The key to safeguarding the quality of investigations, and hence patient safety and care, is to have a highly educated and motivated workforce with a detailed understanding of the underlying medical science and biochemistry, analytical technology, 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 mono-specialisation within the pathology disciplines and this has led to demand for an MSc Course in Clinical Chemistry at an advanced level. Even with the ongoing development of core blood sciences laboratories, the need for specialist discipline-specific knowledge will continue.

It is also intended that the MSc, which requires four academic terms in a two year cycle, will assist eligible candidates in their subsequent preparation for Fellow of the Royal College of Pathologists in Clinical Biochemistry.

1.2 Clinical Chemistry - 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 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 dyslipidaemia, liver disease, inflammation, endocrine and metabolic disorders, or inborn errors of metabolism. 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 laboratories come from two different streams: medical scientists and clinical biochemists who differ in their mode of entry (both are graduate entry). Medical practitioners in the discipline are known as chemical pathologists. They work closely with endocrinologists and other physicians, and are often clinically responsible for patients with a range of metabolic disorders.

1.3 Clinical Chemistry/Clinical Biochemistry at TCD

An academic Department of Clinical Biochemistry has existed at TCD within the Division of Laboratory Medicine for many years. The present staff consists of four part-time lecturers (Dr Gerard Boran, Dr. Vivion Crowley, Dr Ann Leonard and Professor William Tormey), assisted by 3 clinical tutors. The current MSc Course Director is Dr Gerard Boran. There is an Executive Officer and Dr Ann Leonard is the course coordinator. The Clinical Biochemistry Office is located in Room 1.03 on the first floor of the Trinity Health Science Centre at Tallaght Hospital, Tallaght, Dublin 24.

Further information about TCD biomedical research is available on the course web site www.medicine.tcd.ie/clinical-biochemistry. The postgraduate prospectus can be found at the postgraduate web site www.tcd.ie/Graduate_Studies. Further information about TCD biomedical research is available on the course web site. See Appendix 1 for the current Prospectus entry and Appendix 2 for the current Calendar entry.
1.4 Information about the Institute of Biomedical Science

The Institute of Biomedical Science (IBMS) is the largest professional body for scientists in pathology and laboratory medicine in the United Kingdom, providing support and guidance to students and professionals at every stage of their career.

Working in collaboration with students, the IBMS has developed an eStudent membership to support biomedical science students throughout their studies. Please note however that if a student is already a member of the IBMS in a corporate grade (Licentiate) they would not be eligible for eStudent membership.

IBMS eStudent members will receive benefits including a year e-subscription to the profession’s leading journal, The Biomedical Scientist, a weekly eNewsletter featuring the latest news and developments in the field and access to members-only web content including; eCPD, IBMS forums, and placement and careers guides. A range of bursaries, awards and grants are also available to IBMS eStudent members, as well as access to the IBMS Additions member discount scheme. eStudent membership of the IBMS will connect you to a 20,000 strong network of biomedical science professionals and provide you with additional tools to expand your knowledge and develop your skills.

Please visit the eStudent website for more information (https://www.ibms.org/estudents).

Upon graduation with your MSc you will be eligible for Membership of the Institute if you have two years professional experience. However please note that the MSc is not a suitable qualification for HCPC registration.
2.0 Programme Aims and Overall Objectives

The programme aims are:

- To provide a detailed knowledge and understanding of clinical chemistry in the laboratory investigation of disease, in laboratory management, and in quality assurance
- To provide a full understanding of the pre-analytical, analytical and post analytical issues of biochemical investigations
- To provide up to date knowledge and understanding 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
- To equip graduates with the tools and skills necessary to perform in routine and specialised areas within the clinical biochemistry laboratory
- To provide graduates with the skills necessary to evaluate processes within the laboratory and suggest changes based on current best practice
- To enable graduates to critically evaluate research articles and to design and complete scientific research projects
- To provide core management skills including quality management, audit and method validation
- To enable graduates to communicate effectively with scientific and clinical colleagues and society at large
- To provide learning skills that will enable the graduate to continue with self-directed study

The overall objectives of the course are as follows:

- To offer a high quality postgraduate Master’s course dedicated to Clinical Biochemistry to professional laboratory staff including those from medical science, clinical biochemistry 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, case presentations, and “take-home” assignments 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/medical/Health Sciences background, a comprehensive understanding and sound knowledge of the underlying clinical, 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 quality systems, audit, research and development, and effective information management in the discipline
• To provide the framework for graduates to apply the skills learned on the MSc course to future learning and continuous personal education and development in laboratory medicine and management

3.0 Learning outcomes

Students will develop knowledge and understanding that is informed by the forefront of the field of Clinical Biochemistry and will be capable of applying these to developing new insights and to problem solving using knowledge and creativity. They will be able to demonstrate a range of standard and research skills and to effectively communicate findings and conclusions. They will develop learning skills that will allow them to continue with self-directed study and will have the opportunity for progression to other programmes such as a Doctoral Degree or FRCPath.

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
• Have developed an enduring set of practical, clinical, scientific and research skills for use in their laboratory work.

3.1 Knowledge

Students will develop knowledge and understanding:
• That is informed by the latest developments in Clinical Chemistry and will be capable of applying these to develop new insights and for problem solving using knowledge and creativity
• Of the medical, scientific and technological principles of Clinical Chemistry and its interrelationship with other disciplines
• Of the applications of Clinical Chemistry for the diagnosis and monitoring of human disease and its contribution to biomedical research.
• Of laboratory techniques, instrumentation and informatics
• Of the principles of laboratory management
• Of research methods and biostatistics
• Of new trends including molecular diagnostics, robotics, core laboratory point of care and self testing

Related teaching and learning methods and strategies
The teaching strategy is a mixture of lectures, tutorials, workshops and case discussions. While the format of lectures is conventional; informal interaction is encouraged. Workshops, tutorials and case discussions involve extensive student participation. Short cases relevant to each module will be covered in the teaching sessions and will be complemented at the Clinical Laboratory Interface Workshops. Additional workshops will deal with both advanced laboratory techniques and the clinical laboratory interface.
Assessment
Summative assessment is through a combination of unseen written examinations, objective structured practical examination (OSPE), oral examination, marked assignments and project dissertation. Formative assessment is through presentations to class, practice OSPE’s and class discussions with feedback and peer-evaluation.

3.2 Skills and other attributes

3.2.1 Intellectual skills

- The ability to demonstrate knowledge of key concepts and topics within Clinical Chemistry
- The ability to select and apply appropriate techniques and processes
- The ability to critically evaluate the scientific and medical literature
- The ability to construct and develop logical arguments, with clear identification of assumptions and conclusions and to present arguments and conclusions with clarity and accuracy.

Related teaching and learning methods and strategies
Logical thinking is developed throughout the course. The ability to present arguments, both verbally and written, is developed through class discussions, presentations to class, practical reports and assignments. Problem analysis, formulation and solving are introduced in lectures and further developed through practical exercises. An assignment requires the student to present and review a journal article. Tutorials and practice on presentation skills are provided.

Assessment
Intellectual skills are assessed formatively through classwork and practical exercises and summatively in assignments and dissertation.

3.2.2 Professional skills

- The ability to demonstrate a range of standard and research skills and to effectively communicate findings and conclusions
Learning skills that provide a framework for continuing self-directed study
The ability to assess the effectiveness of individual tests, strategies and protocols for the investigation of disease
The ability to employ management strategies to problems in the laboratory
The ability to analyse data using appropriate statistical methods
The ability to design and apply quality assurance strategies
The ability to debate ethical issues

Related teaching and learning methods and strategies
Professional skills will be developed through lectures, class discussions and demonstrations. A number of assignments allow students to work on practical issues requiring the skills outlined e.g. method evaluation, tendering, producing a business case.

Assessment
Professional skills are assessed formatively through class work and practical exercises and summatively in assignments and dissertation.

3.2.3 Transferable skills

The ability to study and learn independently
The ability to analyse and think critically about problems and their solutions
Effective verbal and written communication and presentation skills including the ability to communicate scientific ideas
Independent time management
The ability to use library and World-Wide-Web resources
Framework for future learning and continuous professional development in clinical biochemistry, quality systems and laboratory management

Related teaching and learning methods and strategies
The learning process requires students to assimilate and integrate material from several sources
Class discussions, presentations, assignment reports and lectures on presentation skills.
There is a requirement to produce substantial amounts of written work to strict deadlines.
The use of library and World-Wide-Web resources is required throughout the course.

Assessment
These skills are tested both formatively in the class work, practical exercises and presentations and summatively in the assignments, case presentations and dissertation.

4.0 Programme Structure

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 7.2). Students who choose to exit with a diploma may return to complete the research component within a five year period. This is only in cases where the student has reached the required standard in the taught component and they must rescind the Diploma to do so. They will need to register and pay fees for another year. The award of a Diploma is graded at either Pass or Distinction level.

Each year’s programme will commence in September and will extend over a period of 2 years for the MSc degree. A separate timetable is provided for each term. Instruction will be class-based, supported by on-line course material.

The course will be run on a part time bases every Friday of term time.

Students for the MSc (which is expected to be the norm) will be required to obtain credit for all of the following activities:

1. Five Instruction Modules consisting of lectures and case presentations delivered over 2 years.
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.

3. Course work

Course work consists of 6 assignments and 10 case reports to be completed over the two years (see Appendix 3 for Course Work Instructions). All course work must be submitted both electronically and in hard copy on the dates provided.

Presentation of Course Work
All course work must be presented in class; each student will be assigned a date and time slot for each presentation. Marks are assigned for the presentation, therefore, to ensure that everyone has an equal opportunity; all students must adhere to the time allocated to them. This time limit will be strictly imposed and the student will be told that time is up and will have to stop their presentation.

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

4.1 Teaching and Learning Strategies

In our course our teaching and learning strategy emphasises the acquisition and development of lasting clinical laboratory skills. It is necessary, of course, to impart a complex detailed and advanced body of knowledge to the students and this is provided through the lectures delivered by a panel of national and international lecturers who are experts in their chosen field. It is widely
acknowledged however that detailed knowledge is not retained for prolonged periods following academic courses. However, we teach our students the skills of presenting and interpreting laboratory data through a series of face to face workshops for both clinical and laboratory techniques. We allow students practice their newly acquired clinical presentation and interpretive skills in real life situations in the class on a regular basis. These skills are enduring and will not be forgotten years later even when the detailed technical knowledge requires revision or updating.

This course has been approved by the TCD Council and validated by the Institute of Biomedical Science (IBMS). Application for validation through the Academy of Clinical Science and Laboratory Medicine will be made in autumn 2016

4.2 Admission Requirements

4.2.1 General Requirements

Application for admission to the course should be made through the TCD Faculty of Health Sciences office (http://www.tcd.ie/courses/postgraduate/), to be received normally not later than 30th June for the proposed year of entry. Late applications (up to the middle of August) 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 or more of the following criteria:

(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 Clinical Science and Laboratory Medicine OR
(c) have two years current or previous work experience in clinical biochemistry or medical scientist posts

Applicants under (b) should provide documentary evidence, such as a letter from the Academy of Clinical Science and Laboratory Medicine, 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 criteria will be required to attend for interview to assess knowledge and aptitude.

4.2.2 Language Policy on admission

TCD requirements apply and stipulate that students whose first language is not English must provide evidence of competency in this language through one of the well-established international standard tests:

<table>
<thead>
<tr>
<th>Examination</th>
<th>Minimum Level Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>International English Testing System (IELTS)</td>
<td>Grade 6.5</td>
</tr>
<tr>
<td>Test of English as a Foreign Language (TOEFL)</td>
<td>230 - computer based</td>
</tr>
<tr>
<td></td>
<td>570 - paper based</td>
</tr>
<tr>
<td></td>
<td>88 - internet based</td>
</tr>
<tr>
<td>Cambridge Certificate of Advanced English</td>
<td>Grade C</td>
</tr>
<tr>
<td>Cambridge Certificate of Proficiency in English</td>
<td>Grade C</td>
</tr>
</tbody>
</table>

4.2.3 Regulations

In addition to course specific regulations described in this document TCD general regulations described in the University Calendar apply (http://www.tcd.ie/calendar/).
4.2.4 Liaison with Employers

Students are normally expected to do their assignments and research project in the hospital laboratory where they are employed. They need to nominate a supervisor in their hospital laboratory. The management team on the course will liaise with nominated supervisors to discuss student progress and obtain feedback on course. Most of our students are placed in clinical laboratories accredited by Irish National Accreditation Board (INAB) and have well established clinical services. From time to time we arrange laboratory placements/secondments to AMNCH Tallaght Hospital or St. James’s teaching hospitals when it is necessary to provide more experiences for case interpretation or performance of clinical projects. Students who are not in full time employment and require a Laboratory placement will be subject to an annual bench fee. Exposure to specialist areas is provided through laboratory visits.

4.2.5 Graduation

Graduations are organised through Trinity College Dublin. Further information is available at http://www.tcd.ie/academicregistry/graduation/. Students are eligible for graduation once they have successfully passed all assessments and examinations and their research project has been passed. A list of student results is prepared and sent to the TCD Examination Office once the students have submitted two copies of the final bound version of their research project.

All registered postgraduate students eligible to be conferred with a higher degree in the current academic year, are annually invited by email, to make application to the Student and Graduate Records Office. The invitation includes provision of all the information necessary to make application.
Students opting for the Diploma exit will be eligible for graduation once they pass all assessments and examinations.

Students will only be able to proceed to graduation once their results are published. Students can only be nominated to proceed to graduation by the Clinical Biochemistry unit.

5.0 Programme Content

5.1 Overview of Curriculum/ Mode of Delivery

The course is offered only for entry via the MSc register. Students on the MSc register can have an exit option via a Postgraduate. Students who choose to exit with a diploma may return to complete the research component within a five year period. This is only in cases where the student has reached the required standard in the taught component and they must rescind the Diploma to do so. They will need to register and pay fees for another year. The award of a Diploma is graded at either Pass or Distinction level.

The programme commences each year in Michaelmas Term and will extend over a period of 2 years for the MSc degree. Instruction will be class-based, supported by on-line course material on TCD Blackboard. Students for the MSc will be required to obtain credit for all of the following activities: - five Instruction Modules delivered over 2 years, a log book of 10 cases of which 5 must be submitted each year, 6 assignments and the project dissertation. There are also regular workshops and presentations throughout the course which includes site visits to specialist clinical services (e.g. ICU, Dialysis Unit, Sweat Test, Newborn Screening) and specialist laboratory services (e.g. molecular diagnostics, tandem MS, atomic absorption and porphyria).

The course is assessed by a written examination and an OSPE at the end of each year and an oral examination at the end of the second year. There are also marks for the assignments and log book of cases. Revision sessions will be provided each year.
The course includes a series of Techniques Workshops and Clinical Laboratory Interface Workshops. The Techniques Workshops will provide practical instruction and demonstrations of selected techniques including research methods and statistical tools. 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 six written assignments on a regular basis 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.

A Research Dissertation is required on a topic relevant to the practice of Clinical Chemistry/Clinical Biochemistry. The project proposal must be submitted by the end of November in Year 1 and must be signed by the head of the laboratory and by the student’s supervisor. This should be submitted no later than 31st August of the final year and ideally it is expected well before then. Students are requested for updates on chosen project through-out the course.

A Diploma exit option is also available in exceptional circumstances. 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 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 MSc 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, and laboratory work. Adequate breaks will be provided.
5.2 Module content

The course will be run on a modular basis, each module consisting of lectures, tutorials/group discussions and laboratory work. Each module will be completed during one term. Programme content will be at an advanced level (at least 75%) in keeping with a Masters course. While each topic will include a brief review of fundamental knowledge (no more than 25%), the major portion of each topic will deal with knowledge at the forefront of the subject and address current problems and developments.

The following table illustrates the schedule of modules for 2016-2018 and their ECTS credits. Detailed descriptors for each Module are in Appendices 4a-e.

<table>
<thead>
<tr>
<th>Module</th>
<th>Module Descriptor</th>
<th>Availability (2014-2016)</th>
<th>ECTS Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH7501</td>
<td>Clinical Chemistry I</td>
<td>Michaelmas Term 2017</td>
<td>15</td>
</tr>
<tr>
<td>CH7502</td>
<td>Clinical Chemistry II and General Paediatric Biochemistry</td>
<td>Hilary Term 2018</td>
<td>15</td>
</tr>
<tr>
<td>CH7503</td>
<td>Endocrinology and Metabolism I</td>
<td>Michaelmas Term 2016</td>
<td>10</td>
</tr>
<tr>
<td>CH7504</td>
<td>Endocrinology and Metabolism II and Inborn Errors of Metabolism</td>
<td>Hilary Term 2017</td>
<td>10</td>
</tr>
<tr>
<td>CH7505</td>
<td>Quality Assurance and Laboratory Management</td>
<td>Michaelmas Term 2016</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>

The course will be delivered over two years with the opportunity for a new intake of students each year.

Given the potential heterogeneity of the intake, it may be necessary to provide additional lectures to bring everyone to the same level. Students will be required to successfully complete all modules to be eligible for the award of the Diploma or MSc. 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.
5.3 Research Project

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. The project proposal must be signed off by the Head of Department and by the Supervisor at the student’s base laboratory (see Appendix 5 for Project Information, Project Proposal Form and Supervisor Nomination Form).

Supervisor:
The supervisor will normally be a senior member of the laboratory scientific or medical staff. The supervisor may be contacted by the MSc team to determine progress on project. Each project submission must be accompanied by a signed letter from supervisor stating they have reviewed thesis submission and the thesis is suitable for submission. Supervisor will be required to participate in the employer liaison group, this will involve no more than three emails a year and completion of survey for continual improvement purposes

Assessing suitability of students’ laboratory:
Students will normally be working in an ISO 15189 accredited laboratory.

A number of meetings will be held throughout the two years of the course, particularly in the first year, 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. All project proposals are assessed internally and then forwarded to the External Examiner for comment in November of the first year.

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 and ready for submission not later than 31st August in the second year in accordance with college requirements.

Each project submission is sent to an Internal Examiner and the External Examiner for grading (see procedure in Appendix 5). Instructions on the preparation of dissertations are available from TCD (see www.tcd.ie). Mentoring will be available for students on the project and other aspects of the course from academic staff whom students may contact for advice. The suggested word count is no longer than approximately 12,000 words.

Two soft-bound copies (e.g. using a ring binder or similar simple binding; must open flat) of the dissertations and an electronic copy should be submitted, not later than the 31st August of the final year. A 1-page abstract should be included in the bound copy. The student must await the decision of the examiners before making the final binding arrangements. Note that any extension beyond 31st August is at the discretion of the Dean of Postgraduate Studies to whom applications for any extension should be made. Applications for extension must include a letter from project supervisor outlining the reasons for extension and support of the same. Applications should be made through the Clinical Biochemistry unit room 1.03 Trinity Health Centre AMNCH. The Department of Clinical Biochemistry will then make a formal application to the Dean of Graduate studies. In order to allow for processing time all applications for extension should be made by July 31st. The Dean may then award a short extension ("Dean’s Grace") to the student. Applications for Dean’s Grace are facilitated through the MSc Clinical Chemistry co-ordinator/EO. Students should ascertain their liability for additional fees for any extension beyond the Dean’s Grace period.
5.4 European Credit Transfer and Accumulation System

European Credit Transfer and Accumulation System (ECTS) credits have been calculated for the various course modules and are shown in the table in the section on Module Content.

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.

6.0 Programme Resources

6.1 Physical Resources

Teaching of modules will take place at the Trinity Centres for Health Sciences at Tallaght Hospital, Tallaght, Dublin 24, St. James’s Hospital, James’s Street, Dublin 8, and at The Children’s University Hospital, Temple Street, Dublin 1.

In the Trinity Centre for Health Sciences at Tallaght four seminar rooms of different sizes, and also various lecture theatres when required, are available. Private rooms are available for individual student discussions. The Dean’s room is available for Committee meetings and the Court of Examiners meeting each year.

On site restaurant and coffee shop facilities are available.
Students will have full access to the online services of the TCD library and facilities at Tallaght Hospital/TCD library located close to the lecture rooms.

6.2 Administration

Course administration is undertaken by an Executive Officer (EO) who is responsible for all aspects of the smooth running of the course. The Course Office is located in Room 1.03 on the first floor of the Trinity Health Science Centre at Tallaght Hospital.

Student records are maintained by Trinity College. A portfolio of course work submissions for each student is kept in the Clinical Biochemistry Unit Office (room 1.03) at Tallaght Hospital.

6.3 Course Website and Blackboard elearning system

The course website for the MSc. in Clinical Chemistry [www.medicine.tcd.ie/clinical_biochemistry/](http://www.medicine.tcd.ie/clinical_biochemistry/) provides a valuable resource to students both current and prospective alike. Those thinking of applying will find essential information and there is also a useful guideline on the application process. For current students the Blackboard elearning system is now the central focal point for course material and latest updates. The website and Blackboard system are updated on a regular weekly basis.

6.4 Teaching Staff

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 Trinity Health Ireland Hospitals and The Children’s University Hospital Temple Street. Other national and international lecturers will be included as required.
6.5 Student Support

Postgraduate student support and services can be found at the following link to the Postgraduate Advisory Service and include Student Counselling, College Chaplaincy, Sports and Recreation, Careers Advice, Disability Services, Graduate Studies, Library, College Health Services and International Students: https://www.tcd.ie/orientation/services/pas.php

The Postgraduate Advisory Service is a unique and confidential service available to all registered postgraduate students in Trinity College. It offers a comprehensive range of academic, pastoral and professional supports dedicated to enhancing your student experience.

The Postgraduate Advisory Service is led by the Postgraduate Support Officer who provides frontline support for all Postgraduate students in Trinity. The Postgrad Support Officer will act as your first point of contact and a source of support and guidance regardless of what stage of your Postgrad you’re at. In addition each Faculty has three members of Academic staff appointed as Postgraduate Advisors who you can be referred to by the Postgrad Support Officer for extra assistance if needed.

Contact details of the Postgrad Support Officer and the Advisory Panel are available on our website: http://www.tcd.ie/Senior_Tutor/postgraduate/

The PAS is located on the second floor of House 27. We’re open from 8.30 – 4.30, Monday to Friday. Appointments are available from 9am to 4pm.

Phone: 8961417
Email: pgsupp@tcd.ie

The PAS exists to ensure that all Postgrad students have a contact point who they can turn to for support and information on college services and academic issues arising. Representation assistance to Postgrad students is offered in the area of discipline and/ or academic appeals arising out of examinations or thesis submissions, supervisory issues, general information on Postgrad student life and many others.
Please also follow this link for a list of useful services for students whilst studying at Trinity. [http://www.tcd.ie/Graduate_Studies/useful_links/index.php](http://www.tcd.ie/Graduate_Studies/useful_links/index.php)

### 6.6 Induction to the programme

There is a half day induction program each year for all students. The new first years and second years are introduced to each other. Students are given an outline of the course requirements and details on course assignments, case log book, deadlines, research projects as well as information on use of library, accessing materials and IT. Students are directed to the TCD website for further information on relevant TCD policy documents.

### 6.7 Student Handbook

A student handbook is issued to all new students. This contains all details on the course that apply to them over the following two years.

### 6.8 Student Support Facilities

Trinity College has pastoral care facilities on the main campus and Tallaght Hospital has its own pastoral care department. Multidenominational pastoral support and prayer rooms are available if required.

Postgraduate student support and services including access to Student Support Officers can be found at the following link to the Postgraduate Advisory Service and include Student Counselling, College Chaplaincy, Sports and Recreation, Careers Advice, Disability Services, Graduate Studies, Library, College Health Services and International Students: [https://www.tcd.ie/orientation/services/pas.php](https://www.tcd.ie/orientation/services/pas.php)
Please also follow this link for a list of useful services for students whilst studying at Trinity. [http://www.tcd.ie/Graduate_Studies/useful_links/index.php](http://www.tcd.ie/Graduate_Studies/useful_links/index.php)

**6.9 Student Placements**

It may be possible to arrange supernumerary attachments for applicants wishing to study in Ireland at accredited clinical laboratories in University Teaching Hospitals. In order to facilitate these arrangements the Clinical Biochemistry Department may be required to charge a bench fee per annum to cover training and research costs.

**7.0 Assessment Strategy**

Students are assessed formatively and summatively

**7.1 Eligibility Criteria for Award of 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 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 Laboratory Interface Workshops

- Each student will be required to submit course work over the 2 years of the course; six short assignments and 10 case reports. Each
assignment may include essays, or a short report on a clinical audit or analytical topic requiring some analysis in their base laboratory. Case reports should be based on topics covered in the specified module.

- 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 by the end of the first term in year 1 of the course. A local project supervisor must be nominated.

Students who are unable to submit a successful dissertation prior to 31st August of the final year, or anyone who submits an ill-prepared dissertation deemed unsuitable for examination by the internal examiners, will be required to register for a Third Year (unless submitted during Dean's Grace) in order to complete the dissertation and be awarded an MSc. A full years fee is payable in these circumstances. Note that, whereas an MSc award is not graded, the award of a Diploma is graded at either Pass or Distinction level.

7.2 Eligibility Criteria for Award of Diploma

Students for the Diploma will only be required to complete the Lecture Modules, the Techniques and Clinical Laboratory Interface Workshops and Course Assignments over 4 terms. The dissertation will not be required. Students wishing to avail of the Diploma exit option 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. Students who choose to exit with a diploma may return to complete the research component within a five year period. This is only in cases where the student has reached the required standard in the taught component and they must rescind the Diploma to do so. The award of a Diploma is graded at either Pass or Distinction level.
### 7.3 Schedule of Assessments

The schedule of Assessments and Examinations, with an indication of their weighting towards the final award, is shown in the table below. All components of both formative and summative assessment will have to be passed at the end of each year. This means achieving an overall pass mark of 50% or greater, with no individual component below 40%. In the case of a student not attaining a pass mark a Supplemental Examination will have to be taken and passed in order to progress to the next academic year or to graduate. The Supplemental Examination will consist of the component causing the failure or, if more than one component is failed, the full end of year examination.

The dissertation must be passed for a student 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</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Marks Assigned (%)</td>
<td>Marks Assigned (%)</td>
</tr>
<tr>
<td>5 Instruction Modules (CH7501, CH7502, CH7503, CH7504, CH7505)</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>Techniques Workshops and Clinical Lab Interface Workshops</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Course Work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Assignments</td>
<td>150 marks (60%)</td>
<td>150 marks (60%)</td>
</tr>
<tr>
<td>10 Case Reports</td>
<td>100 marks (40%)</td>
<td>100 marks (40%)</td>
</tr>
<tr>
<td>Total</td>
<td>500 Marks</td>
<td>500 Marks</td>
</tr>
<tr>
<td>Research Dissertation (MSc Only)</td>
<td>Not applicable to Diploma</td>
<td>Must be passed for award of MSc, but is not marked</td>
</tr>
</tbody>
</table>
7.4 Progression from Year 1 to Year 2

All components of examinations and course work will have to be passed at the end of each year. This means achieving an overall 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 for the component failed, or for the whole examination if more than one component is failed, and passed in order to progress to the next academic year or to graduate.

A student may pass with distinction if they fulfil the criteria outlined in Appendix 12, including 70% or greater pass mark on end of year 1 and year 2 examinations with no component requiring compensation and a Grade 1/2 pass (i.e. minor corrections only) on the research project which must be submitted on time.

7.5 Court of Examiners

The Court of Examiners consists of the Course Committee members and the External Examiner. The Court of Examiners will be chaired by the Head of Department (or nominee). The Court will meet shortly after the final examination to assess the results and award students with a pass or, where appropriate, a distinction. Students requiring a Supplemental Examination will be identified. 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).

7.6 Internal Compensation

Compensation is allowed between marks for the Written/OSPE Examinations and course work components in the event that an individual component is failed providing a mark of at least 40% is obtained in the component for which compensation is required.
7.7 Resubmission of Course Work

Resubmission of Formative Assessment Components: students will be offered one opportunity to complete or resubmit an assignment/case report if they fail the assignment/case report but the maximum marks available in this case is 50%.

7.8 Appeal and Disciplinary Procedures

7.8.1 Appeal and Re-marking of Assessments

The grounds for appeal and re-checks against the decision of the Court of Examiners are specified in the TCD Examinations and General Assessment Regulations as laid out in the University of Dublin, Trinity College Calendar Part 2, Graduate Studies and Higher Degrees for a given academic year. Students will bring their appeal to the Course Committee in the first instance and, where they are not satisfied with the outcome, to the established appeal procedure for taught postgraduate programmes in TCD. All decisions are officially notified to the appropriate authorities.

7.8.2 Breaches of Regulations and Disciplinary Redress Process

All assessments for the MSc in Clinical Chemistry programme will be conducted in accordance with the regulations of the Graduate Studies Office of TCD. Where breaches of the assessment regulations are suspected or alleged they will be subject to the relevant TCD procedures. All decisions are officially notified to the appropriate authorities. TCD plagiarism rules will apply on this course. In the case of research projects TCD guidelines for good scientific practice in research and scholarship will apply.
8.0 Appendices

Appendix 1: Prospectus

Please access page 120 in the PDF on this page on the TCD website for the current 2016 Prospectus.

Draft new entry for 2016 Prospectus:

Clinical Chemistry
(M.Sc. / P.Grad.Dip.)

Duration: 2 Year(s) Part Time
Closing Date: For up to date information please see: www.tcd.ie/courses/postgraduate/az/
Course Director: Dr Gerard Boran
Course Email(s): gradapps.hs@tcd.ie; clinchem@tcd.ie
Course Tel(s): + 353-1-896 3556/3557; + 353-1-896 3721
Course URL: www.medicine.tcd.ie/clinical-biochemistry

Course Details

This M.Sc. programme in Clinical Chemistry is offered on a part-time basis over two years. Medical scientists, clinical biochemists, medical doctors and others 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 and with special attention to current developments in the discipline.

Lectures, case discussions and practical instruction workshops will take place on Fridays over four terms with revision sessions in the Trinity term each year. The course consists of six modules worth 90 ECTS: five of these are taught (60 ECTS) with the sixth module consisting of a research project (30 ECTS). The five taught modules are Clinical Chemistry I (CH7501); Clinical Chemistry II and General Paediatric Biochemistry (CH7502); Endocrinology and Metabolism I (CH7503); Endocrinology and Metabolism II and Inborn Errors of Metabolism (CH7504); and Quality Assurance and Laboratory Management (CH 7505). 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 term.

Each module will include techniques workshops: these 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 project conducted in the candidates’ base laboratory will also form part of the course. Instruction on research methods will be included.
The course is assessed by a combination of continuous assessment and examination. Continuous assessment is based on 6 written assignments and ten cases submitted over the two years. A written examination consisting of one written paper and a practical assessment is held at the end of each year covering the year’s topics. The practical assessment will consist of short questions including clinical observations, practical findings, calculations, and other material in the form of an Objective Structured Pathology Exercise (OSPE). There is a short viva voce at the end of the second year. Students will also need to complete and submit a research dissertation of approximately 12,000 words in their final year.

Admission Requirements

Applications will be considered from those who satisfy one or more of the following criteria:

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 Clinical Science and Laboratory Medicine, 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 Clinical science and Laboratory Medicine, 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 criteria will be required to attend for interview to assess knowledge and aptitude.
Appendix 2: Calendar Entry

Please access this page on the TCD website for the current 2016 calendar.

DRAFT NEW CALENDAR ENTRY for 2016 calendar:

Clinical Chemistry (M.Sc. /P. Grad. Dip.)

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

Course Structure: Lectures, case discussions and practical instruction workshops will take place on Fridays over 4 terms with revision sessions in the Trinity term each year. The course consists of six modules worth 90 ECTS: Clinical Chemistry I (CH7501) has 15 ECTS; Clinical Chemistry II and General Paediatric Biochemistry (CH7502) 15 ECTS; Endocrinology and Metabolism I (CH7503) 10 ECTS; Endocrinology and Metabolism II and Inborn Errors of Metabolism (CH7504) 10 ECTS; Quality Assurance and Laboratory Management (CH 7505) 10 ECTS; Research Project has 30 ECTS. 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 term.

Assessment: Continuous assessment: based on 6 written assignments and ten cases over the two years. Exams: there is an exam at the end of each year covering the year’s topics and consisting of one written paper and a practical assessment with a short viva voce at the end of the second year. 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 31st August 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. Students may however exit with a diploma and return to complete the research component within a five year period. This is only in cases where the student has reached the required standard in the taught component and they must rescind the Diploma to do so.

Course Director: Dr. Gerard Boran
### Appendix 3: Course Work Instructions

**COURSE WORK: ASSIGNMENTS AND LOGBOOK of CASES**

**MSc in Clinical Chemistry (Students 2015-2017)**

<table>
<thead>
<tr>
<th>Assignments (6 assignments in total – 150 marks total, 25 for each assignment)</th>
<th>Instructions to students for the 6 assignments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Note: Allocated times for presentations (usually 10 minutes) must be strictly adhered to. You will be stopped if you exceed your allocation. Make sure you practice your presentations in advance.</td>
<td></td>
</tr>
</tbody>
</table>

| Essay | 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). |

| Audit Report | 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 hospital’s 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

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. Ten PowerPoint Slides is recommended, about 500 words overall in the slides.

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.

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](http://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?

The usual format for the presentation in class is to have a Table (in word or excel) consisting of the above criteria with entries for each of the devices demonstrated. A separate PowerPoint is also required for presentation purposes. You may also read from your Table during the presentation.
## Business Case Report

Submit a business case based on an example from your Laboratory within the past 2 years. You may use Word, Power Point 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 for something you want/your lab or hospital wants using guidance from your own organisation on the assumption that most hospital laboratories are very adept at this. Bear in mind that most successful business cases must be concise – usually the major message should be conveyed in a few pages. If the business case documentation you have been given by your lab to work with 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

Ten PowerPoint Sides is recommended, 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. You may use other software if this is more convenient.

The assessment will be based on both your submitted document and a class presentation/discussion.
| Journal Article – review/presentation | A list of suitable article topics will be pre-circulated. All students should read all articles before the presentations in class.  
You are asked to prepare a Power Point Presentation lasting 10 minutes where you review a journal article of your selection. The Power Point presentation should not be more than 10 slides. 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 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. Study the articles abstract very carefully and note the approach used. This will also help you with your own abstract for your dissertation in due course. |
| --- | --- |
| Method Evaluation | 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 |
<table>
<thead>
<tr>
<th>Logbook of Cases</th>
<th>Instructions to Students for the Logbook of 10 Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10 Cases Reports</strong>&lt;br&gt;<strong>book format (100 marks, 10 marks for each case)</strong></td>
<td><strong>Please submit 5 cases per year no later than 1st April each year</strong>&lt;br&gt;<strong>Case presentation dates are detailed in term timetables. Cases should be submitted via Bla</strong>&lt;br&gt;The preferred format is as Power Point slides as this is the format used by the clinical team in most hospital clinical case meetings</td>
</tr>
</tbody>
</table>

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, acid base 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 one week prior to presentation in class. Late submissions will be deducted 10% of marks

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.

- Note: **under no circumstances** should you attempt to give a lengthy lecture on your chosen topic/case. Instead, give a reference or weblink to a good review of the topic and mention a few key summary points in your presentation.
<table>
<thead>
<tr>
<th><strong>OSPEs</strong></th>
<th>Instructions to Students for OSPEs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OSPE Practice Runs</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Marked OSPEs</strong> (90 marks total, 45 marks for each OSPE)</td>
<td>There are 2 Marked OSPEs on the entire course – one per year. These are held on the same day as the end of year Written Paper each year. Each year’s marked OSPE is part of the end of year examination.</td>
</tr>
</tbody>
</table>
Appendix 4a: Module Descriptors: CH7501

<table>
<thead>
<tr>
<th>Module Title:</th>
<th>Clinical Chemistry I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module Code</td>
<td>CH7501</td>
</tr>
<tr>
<td>Module Coordinator:</td>
<td>Dr. Gerard Boran</td>
</tr>
<tr>
<td>Module Authors:</td>
<td>Dr. Gerard Boran, Dr. Vivion Crowley, Professor Philip Mayne, Dr. Ann Leonard, Dr Gerard O’Connor</td>
</tr>
<tr>
<td>ECTS Credits</td>
<td>15</td>
</tr>
</tbody>
</table>

**Rationale and Aims:**

This module covers a number of core areas in clinical biochemistry and the aims are to provide:

- up to date and in depth knowledge of core areas of clinical biochemistry
- 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.
- A framework for future learning and the ability to apply new learning to routine and specialised laboratory activity

**Methods of Teaching and Student Learning:**

The teaching strategy is a mixture of lectures, tutorials, workshops and case discussions. Workshops, tutorials and case discussions involve extensive student participation.

Lectures will be delivered by national and international clinical practitioners, medical scientists and clinical biochemists who are experts in their subjects. While the format of lectures is conventional; informal interaction is encouraged.

Short cases relevant to each module will be covered in each teaching session and will be complemented at the Clinical Laboratory Interface Workshops. Workshops will deal with both advanced laboratory techniques and the clinical laboratory interface.

The varied teaching methodology ensures an inclusive curriculum that takes account of the diverse learning styles and preferences of the diverse student population that is attracted to this course.
Module Content:

Emphasis will be on current trends and recent developments.

**Fluid and electrolyte homeostasis:**
Physiological control of fluid electrolyte levels from a molecular level. Underlying causes of elevated or lowered levels of different electrolytes, physiological and pathological (e.g. potassium, sodium, magnesium) as well as the pre-analytical, analytical and drug influences on results.
Investigation of fluid collections e.g. pleural effusion, ascites.

**Acid Base:**
Interpretation of acid base disturbance, identification of possible causes and suggested treatment.
Patterns of acid base disturbance expected in common conditions.

**Renal Function:**

**Gastrointestinal Function:**
Gastrointestinal and pancreatic exocrine function.
Investigation of suspected pathological conditions
Immunological aspects of gastrointestinal disease
Biochemical aspects of nutrition, monitoring nutritional status and nutritional support.
Investigation of liver disease. Alcohol.
Colorectal Cancer Screening.
Gut Hormones.

**Cardiovascular disease:**
Cardiovascular risk factors and laboratory assessment, including critical appraisal of available biomarkers. BNP and other markers in heart failure.

**Toxicology:**

**Tumour markers:**
Use of tumour markers in screening and early detection of cancer.
Diagnostic utility and the properties of an ideal marker. Monitoring response to therapy.
**Enzymology:**

Use of enzyme measurements in clinical diagnosis. Isoforms, isoenzymes and macro enzymes.

**Methodology:**

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

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

Critically reviewing available methodology – student exercise/presentation.

Specialist techniques including:

- Faecal Immunochemical Testing in Colorectal Cancer screening.
- Estimating GFR.
- Immunosuppressive drug measurement.
- Tandem Mass Spectroscopy for drug analysis

**Course Work:**

- 1 Case
- 2 Assignments

**Learning Outcomes:**

On successful completion of this module participants will be able to:

- Identify and explain the relationship between normal physiological function and the pathological changes that occur in the different clinical conditions, to a molecular level, covered by the above topics.

- Formulate differential diagnoses based on the biochemical results and clinical information and choose further investigations based on the clinical question being asked and the results currently available

- Interpret laboratory results, taking into account clinical information and the pre-analytical and analytical issues in relation to the different analytes, and discuss results with their laboratory and clinical colleagues

- Demonstrate awareness of the capabilities and limitations of biochemical investigations in identifying the presence or absence of disease states associated with the above topics

- Identify, compare and appraise current and new analytical methods for relevant analytes and
appraise recent advances both within the clinical laboratory and research centres.

- Explain controversial issues in relation to using tumour markers to screen for disease
- Assess advances in the understanding of pathological processes in these areas and the part played by clinical biochemistry and molecular medicine

**Assessment:**

**Summative:**
End of year 1 written paper
End of year 1 Objective Structured Practical Exercise (OSPE)
Course work (case presentations/assignments)
*Viva Voce (4% of total course marks):* a proportion of the final year viva voce marks are assigned to Module 1

This module will account for 25% of overall course marks. 50% pass mark for end of year assessment. Compensation is possible provided >=40% mark is obtained in the area requiring compensation.

**Formative:**
OSPE practice runs during term
Presentations to class
Revision sessions in Trinity Term
Optional: Saturday morning tutorial (1 per month)

**Contact Hours:**
Lectures 45, Tutorials 35, Workshops 2, Clinical Lab Interface workshops 4, OSPE 3.
Indicative hours for self-study and assignments 300.

**ECTS Credits:** 15

**Indicative Resources:**

Students will be directed to reviews and articles in relevant clinical/biochemical journals such as:

- Annals of Clinical Biochemistry
- Clinical Chemistry
- New England Journal of Medicine
- Clinical Chemistry and Laboratory Medicine

Specific articles will be referenced by each lecturer.

**Guidelines**, where relevant, will be referenced, some examples are listed below:

**Cardiology:**

**Nephrology:**
Irish Nephrology Society; Irish CKD Guidelines. AKI Guidelines.

**Oncology:**
NCCP Prostate Cancer GP referral guidelines

**Gastroenterology:**
National cancer screening service ([http://www.cancerscreening.ie](http://www.cancerscreening.ie))

**Clinical and Laboratory Standards Institute (CLSI) Guidelines:**
Access to CLSI Guidelines is available through the Laboratory Medicine Department, Tallaght Hospital. These guidelines are extensively referenced throughout the course.

**Web Portals:**
- [http://www.acbi.ie](http://www.acbi.ie) (Association of Clinical Biochemists in Ireland)
- [http://www.clsi.org](http://www.clsi.org) (Clinical and Laboratory Standards Institute)
- [http://www.aacc.org](http://www.aacc.org) (American Association of Clinical Chemistry; NACB guidelines)
Appendix 4b: Module Descriptors: CH7502

<table>
<thead>
<tr>
<th>Module Title:</th>
<th>Clinical Chemistry II and General Paediatric Biochemistry</th>
</tr>
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<tr>
<td>Module Code</td>
<td>CH7502</td>
</tr>
<tr>
<td>Module Coordinator:</td>
<td>Dr. Gerard Boran</td>
</tr>
<tr>
<td>Module Authors:</td>
<td>Dr. Vivion Crowley, Professor Philip Mayne, Dr. Gerard Boran, Dr. Ann Leonard, Dr. Gerard O’Connor</td>
</tr>
<tr>
<td>ECTS Credits:</td>
<td>15</td>
</tr>
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</table>

**Rationale and Aims:**
This module will provide updates on additional core areas of clinical chemistry as well as neonatal and paediatric biochemistry so as to provide:

- up to date and in depth knowledge of core areas of the topics covered
- 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 results with clinical colleagues.
- A framework for future learning and the ability to apply new learning to routine and specialised laboratory activity

Guest speakers will emphasise current trends and recent developments in neonatal, paediatric and obstetric biochemistry as well as the selected core topics in clinical chemistry including cytokines, immunochemistry, haematological biochemistry, and nutrition.

**Methods of Teaching and Student Learning:**

The teaching strategy is a mixture of lectures, tutorials, workshops and case discussions. Workshops, tutorials and case discussions involve extensive student participation.

Lectures will be delivered by national and international clinical practitioners, medical scientists and clinical biochemists who are experts in their subjects. While the format of lectures is conventional; informal interaction is encouraged.

Short cases relevant to each module will be covered in each teaching session and will be complemented at the Clinical Laboratory Interface Workshops. Workshops will deal with both advanced laboratory techniques and the clinical laboratory interface.
The varied teaching methodology ensures an inclusive curriculum that takes account of the diverse learning styles and preferences of the diverse student population that is attracted to this course.

**Module Content:**

**Neonatal and Paediatric Biochemistry**


**Obstetric Biochemistry**

Physiological changes in pregnancy and how they affect interpretation of results and, how to identify pathological conditions during pregnancy. The role of biochemistry in the diagnosis and management of pre-eclampsia. Human chorionic gonadotropin analytical issues and clinical utility (including hCG heterogeneity).

**Age-related biochemistry**

This area is covered as part of the individual lectures covering the effect of aging on biochemistry results and areas of special interest in the older person.

**Molecular Diagnostics and Genetics**

Molecular diagnostics methods

Molecular Diagnostics of Alpha-1 Antitrypsin Deficiency.

Biochemical Genetics.

**Haematological biochemistry**

Up to date information on vitamin B₁₂ and folate. Pathophysiology of multiple myeloma and paraproteinaemia and the laboratory investigations. Protein electrophoresis (different techniques), immunofixation and light chain analysis. Effect of paraproteins on other biochemical investigations. Haemochromatosis and relevant investigations.

**Imunochemistry**

Biochemistry and clinical aspects of cytokines

Acute phase response and its effect on biochemical tests and their interpretation.

Biochemistry of the Inflammatory Response.
**Immunodeficiency and Allergy**
Immunodeficiency conditions, investigation and monitoring. Allergies and how they are investigated.

**Nutrition and Trace elements (including their toxicology)**
Trace elements, their clinical relevance and analytical methods.
Physiology and pathology of the vitamins.
Identifying and explaining abnormal results. Nutrition including enteral and parenteral requirements.

**Calculations in Clinical Chemistry**
Calculations in clinical chemistry, statistics, buffers, half-life estimation, TmP and other clinically relevant calculations.

**Methodology**
Selected aspects of analytical methods relevant to the module with special emphasis on methodologies not found in all routine laboratories such as electrophoresis, HPLC.
Critical assessment of available biochemical investigations for each topic covered in this module.
Critically reviewing available methodology (student exercise/presentation).

Specialist techniques including:
Atomic Absorption Spectroscopy
Proteomics. SELDI-TOF. MALDI-TOF
Sweat Tests

**Course Work:**
- 4 Cases
- 1 Assignment

**Learning Outcomes:**
On successful completion of this module participants will be able to:

- Identify and explain the relationship between normal physiological function and the pathological changes that occur in the different clinical conditions, to a molecular level, covered by the above topics.

- Formulate differential diagnoses based on the biochemical results and clinical information and choose further investigations based on the clinical question being asked and the results currently available.
- Interpret laboratory results, taking into account clinical information and the pre-analytical and analytical issues in relation to the different analytes and discuss results with their laboratory and clinical colleagues

- Demonstrate awareness of the capabilities and limitations of biochemical investigations in identifying the presence or absence of disease states associated with the above topics

- Identify, compare and appraise current and new analytical methods for analytes covered in the above list of topics and appraise recent advances employed both within the clinical laboratory and research centres.

- Assess advances in the understanding of pathological processes in these areas and the part played by clinical biochemistry and molecular medicine

**Assessment:**

**Summative:**

End of year 1 written paper.

End of year 1 Objective Structured Practical Examination (OSPE)

Course work (case presentations/assignments)

*Viva Voce (4% of total course marks)*: a proportion of the final year viva voce marks are assigned to Module 2

This module will account for 25% of overall course marks. 50% pass mark for end of year assessment. Compensation is possible provided >/=40% mark is obtained in the area requiring compensation.

**Formative:**

OSPE practice runs during term

Presentations to class

Revision sessions in Trinity Term prior to exams

Optional: Saturday morning tutorial (1 per month)

**Contact Hours:**

Lectures 45, Tutorials 15, Workshops 4, Clinical Lab Interface workshops, OSPE 4.

Indicative hours for self-study and assignments 300.

**ECTS Credits:** 15
Indicative Resources:

- *Laboratory Diagnosis of Inherited Metabolic Diseases*, AACC Publication 2012
- Anne Green, Imogen Morgan, Jim Gray. *Neonatology and Laboratory Medicine*, ACB 2003
- Dennis J. Dietzen, Michael J. Bennett and Edward C.C. Wong (Eds). *Biochemical and Molecular Basis of Paediatric Disease* AACC Press 2010

Students will be directed to reviews and articles in relevant clinical/biochemical journals such as:

- Annals of Clinical Biochemistry
- Clinical Chemistry
- New England Journal of Medicine
- Clinical Chemistry and Laboratory Medicine

Guidelines, where relevant, will be referenced, some examples are listed below:

**Trace elements and their toxicology:**


**Clinical and Laboratory Standards Institute (CLSI) Guidelines:**

Access to CLSI Guidelines is available through the Laboratory Medicine Department, Tallaght Hospital. These guidelines are extensively referenced throughout the course.

**Web Portals:**

- [http://www.acbi.ie](http://www.acbi.ie) (Association of Clinical Biochemists in Ireland)
- [http://www.clsi.org](http://www.clsi.org) (Clinical and Laboratory Standards Institute)
- [http://www.aacc.org](http://www.aacc.org) (American Association of Clinical Chemistry; NACB guidelines)
Appendix 4c: Module Descriptors: CH7503

<table>
<thead>
<tr>
<th>Module Title:</th>
<th>Endocrinology and Metabolism I</th>
</tr>
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<tbody>
<tr>
<td>Module Code:</td>
<td>CH7503</td>
</tr>
<tr>
<td>Module Coordinator:</td>
<td>Dr. Gerard Boran</td>
</tr>
<tr>
<td>Module Authors:</td>
<td>Dr. Vivion Crowley, Professor Philip Mayne</td>
</tr>
<tr>
<td>ECTS Credits:</td>
<td>10</td>
</tr>
</tbody>
</table>

**Rationale and Aims:**

This module will provide the students with up to date knowledge of selected metabolic and endocrine disorders: biochemical investigations and their interpretation in conjunction with clinical information.

There will be emphasis on current trends and recent developments. Lectures will be delivered by national and international clinical practitioners who are experts in their subjects.

The aim of this module is to provide:
- up to date and in depth knowledge of the topics included in this module
- an in depth understanding of new procedures and methodologies in endocrinology and metabolism
- the skills to critically assess efficient utilisation of endocrine laboratory services and appropriate laboratory investigations for given clinical conditions
- the ability to interpret biochemical endocrinology results in conjunction with clinical information and to discuss the clinical utility of these results with clinical colleagues.

**Methods of Teaching and Student Learning:**

The teaching strategy is a mixture of lectures, tutorials, workshops and case discussions.

Conventional lectures will be combined with workshops, tutorials and case discussions involving extensive student participation where informal interaction will be encouraged. Short cases relevant to each module will be covered during teaching sessions and will be complemented at the Clinical Laboratory Interface Workshops. Relevant advanced laboratory techniques will also be covered in workshop format.

The varied teaching methodology ensures an inclusive curriculum that takes account of the diverse learning styles and preferences that may arise from the diverse student population that is attracted to this course.

**Module Content:**

**Neuroendocrine regulation and hormone signaling**

Relevant aspects of neuroendocrine regulation as well as end-organ endocrinology will be covered within relevant topics. This will include hormone signaling and hormone receptors to the molecular
level, G-Protein receptor linked signaling, and positive and negative feedback mechanisms. Relevant drugs affecting hormone production will be covered, as well as hormone resistance syndromes e.g. thyroid, androgens.

**Autoimmune mechanisms in endocrinology:**
Autoimmune processes in endocrinology will be covered in the relevant endocrine axes.

**Hypothalamus and pituitary gland:**
Hypothalamic function and pulse generation. Pituitary gland hormone production in health and disease. Investigation of hypothalamic pituitary disease including molecular aspects. Heterogeneity of circulating hormones and their analytical and clinical implications e.g. macrohormones. Prolactinoma. Growth Hormone, laboratory aspects and clinical presentation

**Parathyroid gland:**

**Thyroid function:**
Thyroid disease: guidelines; interpretation of results; discordant results and problem solving. Thyroid cancer and thyroglobulin. Thyroid disease in pregnancy. Thyroid hormone resistance syndrome.

**Adrenal cortex:**
Adrenal Cortex, Hormone Production and Molecular Function. Adrenal steroidogenesis Laboratory Investigation including adrenal steroid profiling Cushing’s and Addison’s – clinical, pathophysiology and investigation;

**The Gonads and Reproductive Endocrinology:**

**Special Areas:**
Endocrinology of hypertension, Carcinoid Syndrome, Multiple Endocrine Neoplasia

**Growth disorders**
Growth Hormone, laboratory aspects and clinical presentation.
GH deficiency or excess in adults; IGF1 and IGF BP3.

**Methodology**

Relevant analytical methods for this module with special emphasis on specialist hormone measurement methodologies not found in all routine laboratories.

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

**Specialist techniques including:**

- Dynamic function tests
- Macro-hormones and their analytical and clinical impact
- Adrenal steroid profiling (urine)

**Course Work:**

- 2 Cases
- 1 Assignment

**Learning Outcomes:**

On successful completion of this module participants will be able to:

- Identify and explain the relationship between normal physiological function and the pathological changes that occur in the different endocrine conditions covered by the above topics to a molecular level.

- Formulate differential diagnoses based on the biochemical results and clinical information and interpret laboratory results and, taking into account clinical information, pre-analytical and analytical issues in relation to the different analytes

- Discuss biochemical results with their laboratory and clinical colleagues including further relevant investigations based on the clinical question being asked and the results currently available

- Demonstrate awareness of the capabilities and limitations of endocrine and other investigations in identifying the presence or absence of disease states associated with the above topics

- Appraise relevant current and new analytical hormone for hormones in the routine and research context
- Assess advances in the understanding of endocrine pathological processes and the part played by molecular endocrinology

**Assessment:**

**Summative:**
End of year 2 Examination
End of year 2 Objective Structured Practical Examination (OSPE)

*Viva Voce (4% of total course marks):* A proportion of the final year viva voce marks are assigned to Module 4

This module will account for 16.67% of overall course marks. 50% pass mark for end of year assessment. Compensation is possible provided >/=40% mark is obtained in the area requiring compensation.

**Formative:**
OSPE practice runs
Presentations to class

**Contact Hours:**
Lectures 30, Tutorials 10, Workshops 8.
Indicative hours for self-study and assignments 220.

**ECTS Credits:** 10

**Indicative Resources:**

**Texts:**

Students will be directed to reviews and articles in relevant clinical/biochemical *journals* such as:

- Annals of Clinical Biochemistry
- Clinical Chemistry
- New England Journal of Medicine
- Clinical Chemistry and Laboratory Medicine

**Guidelines,** where relevant, will be referenced, some examples are listed below:
Irish national guidelines for thyroid function testing in primary care, 2016
UK Guidelines for the Use of Thyroid Function Tests, British Thyroid Association, 2006.

**Clinical and Laboratory Standards Institute (CLSI) Guidelines:**
Access to CLSI Guidelines is available through the Laboratory Medicine Department, Tallaght Hospital. These guidelines are extensively referenced throughout the course.

**Web Portals:**
- [http://www.clsi.org/](http://www.clsi.org/) (Clinical and Laboratory Standards Institute)
- [http://www.aacc.org](http://www.aacc.org) (American Association of Clinical Chemistry; NACB guidelines)

Appendix 4d: Module Descriptors: CH7504

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<tr>
<th>Module:</th>
<th>Endocrinology and Metabolism II and Inborn Errors of Metabolism</th>
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<tr>
<td>Module Code</td>
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<tr>
<td>Module Coordinator:</td>
<td>Dr. Gerard Boran</td>
</tr>
<tr>
<td>Module Authors:</td>
<td>Dr. Gerard Boran, Dr. Vivion Crowley, Professor Philip Mayne</td>
</tr>
<tr>
<td>ECTS Credits</td>
<td>10</td>
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**Rationale and Aims:**
This module will provide the students with up to date knowledge of selected metabolic and endocrine disorders in adults and children: biochemical investigations and their interpretation in conjunction with clinical information including inborn errors of metabolism. The principles of screening and neonatal conditions screened will also be covered.

There will be emphasis on current trends and recent developments. Lectures will include clinically relevant topics by national and international guest speakers who are experts in their subjects.

The aim of this module is to provide:
- up to date and in depth knowledge of these 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 the selected endocrine and IEM clinical conditions
- the ability to interpret biochemical results for endocrine disorders in this module and IEMs in conjunction with clinical information and to discuss the clinical utility of these results with clinical colleagues

**Methods of Teaching and Student Learning:**

The teaching strategy is a mixture of lectures, tutorials, workshops and case discussions. Informal interaction is encouraged during lectures. Workshops, tutorials and case discussions involve extensive student participation.

Short endocrine and IEM cases relevant to this module will be covered in each teaching session and will be complemented at the Clinical Laboratory Interface Workshops. Workshops will deal with both advanced laboratory techniques and the clinical laboratory interface.

The varied teaching methodology ensures an inclusive curriculum that takes account of the diverse learning styles and preferences that may arise from the diverse student population that is attracted to this course.

**Module Content:**

**Neonatal Screening**


**Paediatric Endocrinology**

Congenital adrenal hyperplasia. Short stature and growth hormone dysfunction. Precocious puberty.

**Inborn errors of metabolism (IEM)**

Inborn errors of metabolism: pathogenesis and molecular basis of these conditions, their clinical presentation and investigation and protocols for making a diagnosis. Molecular genetics of inherited metabolic disorders. Conditions covered here include:

- Hyperammonaemia.
- Mitochondrial disorders and lactic acidosis.
- Galactosaemia and related disorders.
- Neurotransmitter disorders.
- Disorders of purine and pyrimidine metabolism.
- Inherited metabolic disorders presenting in adults.
- Lysosomal Storage Disorders.
- Organic Acidaemias.

**Diabetes Mellitus (DM)**
Classification, pathogenesis and molecular basis of the different types of diabetes mellitus.
Clinical management of diabetes. Biochemical investigation, diagnosis and monitoring of DM.
HbA_1c_ methodology including variants, target levels and standardisation. Diabetes and pregnancy.
Point of care testing in DM

**Adrenal Medulla:**
Catecholamines and metanephrines in health and disease; phaeochromocytoma and neuroblastoma.
Renin and aldosterone: clinical and analytical aspects.

**Immunoassays and choosing an Immunoassay Platform:**
Immunoassays and interferences; standardisation of immunoassays; choosing an immunoassay analyser; analysis of steroid hormones, problems and solutions.

**Lipid Metabolism:**
Lipid metabolism and Dyslipidaemia.

**Obesity:**
Obesity: clinical and biochemical aspects.

**Vitamin D and Bone Metabolism:**
Bone Physiology and pathology.
Clinical aspects of Vitamin D metabolism.
Osteoporosis - pathophysiology and management.

**Porphyria:**
Porphyrias: pathogenesis; classification; clinical and analytical aspects and issues.

**Methodology:**
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.
Visit to specialist metabolic laboratories.

Specialist techniques including:
- GC and Tandem Mass Spectrometry
- HPLC
- Amino acid analysis
- Catecholamine and metanephrine analysis
- Steroid Hormone Assays

Other special topics (lipodystrophy) dependent on guest speaker availability.

**Course Work:**
- 3 Cases

**Learning Outcomes:**
On successful completion of this module participants will be able to:
- Describe the current pathophysiological and biochemical aspects of inborn errors of metabolism and endocrine disorders covered in this module
- Formulate differential diagnoses based on the biochemical results and clinical information and choose further investigations based on the clinical question being asked and the results currently available
- Critically assess the investigation strategies and methodologies used to investigate these conditions and discuss findings with laboratory and clinical colleagues
- Assess advances in the understanding of pathological processes in these areas and the part played by clinical biochemistry and molecular medicine
- Identify and appraise specific new analytical methods and recent advances employed both within the clinical laboratory and research centres.

**Assessment:**
Summative:
- End of year 2 Examination
- End of year 2 Objective Structured Practical Examination (OSPE)

*Viva Voce (4% of total course marks):* a proportion of the final year viva voce marks are assigned to Module 5
This module will account for 16.67% of overall course marks. 50% pass mark for end of year assessment. Compensation is possible provided >/=40% mark is obtained in the area requiring compensation.

Formative:
OSPE practice runs
Presentations to class

Contact Hours:
Lectures 55, Tutorials 20, Workshops 3, OSPE 6.
Indicative hours for self-study and assignments 200.

ECTS Credits: 10

Indicative Resources:

Texts:

- Dennis J. Dietzen, Michael J. Bennett and Edward C.C. Wong (Eds). *Biochemical and Molecular Basis of Paediatric Disease* AACC Press 2010
- Laboratory Diagnosis of Inherited Metabolic Diseases, 2012, AACC publication.

Students will be directed to reviews and articles in relevant clinical/biochemical journals such as:

- Annals of Clinical Biochemistry
- Clinical Chemistry
- New England Journal of Medicine
- Clinical Chemistry and Laboratory Medicine

Guidelines, where relevant, will be referenced, some examples are listed below:

- Definition and diagnosis of diabetes mellitus and intermediate hyperglycaemia, 2006, WHO; IDF.


Clinical and Laboratory Standards Institute (CLSI) Guidelines:
Access to CLSI Guidelines is available through the Laboratory Medicine Department, Tallaght Hospital.
These guidelines are extensively referenced throughout the course.

**Web Portals:**
- [http://www.clsi.org/](http://www.clsi.org/) (Clinical and Laboratory Standards Institute)

Appendix 4e: Module Descriptors: CH7505

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<tr>
<th>Module Title:</th>
<th>Quality Assurance and Laboratory Management</th>
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<tbody>
<tr>
<td>Module Code:</td>
<td>CH7505</td>
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<tr>
<td>Module Coordinator:</td>
<td>Dr. Ann Leonard</td>
</tr>
<tr>
<td>Module Authors:</td>
<td>Dr. Gerard Boran, Dr. Vivion Crowley, Prof. Philip Mayne, Dr. Ann Leonard</td>
</tr>
<tr>
<td>ECTS Credits:</td>
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**Rationale and Aims:**
This module will introduce the students to the key principles of laboratory management, health informatics and quality assurance and provide them with the ability to implement this knowledge in the workplace. Students will gain an understanding of management theory, information management and quality management and laboratory systems. Awareness of the legal and ethical requirements of a laboratory.

There will be emphasis on current trends and recent developments. Lectures will be delivered by national and international clinical practitioners who are experts in their subjects.

The aim of this module is to provide:
- an understanding of the principles and requirements of laboratory management and quality assurance
- the skills to critically assess efficient utilisation of laboratory services and to evaluate different workplace scenarios from the management
- An understanding of the role of clinical laboratory informatics and its relationship with other IT systems
- an in depth understanding of new procedures and methodologies
- a strategy and framework for future learning in the area of laboratory management and provision of a quality service.
**Methods of Teaching and Student Learning:**
The teaching strategy is a mixture of lectures, tutorials and workshops.

Informal interaction is encouraged at interactive lectures given in many cases by leading hospital and laboratory managers. Workshops and tutorials involve extensive student participation, and the course assignments require workplace practice on topics relevant to this module such as business cases, audits, method evaluation, and aspects of point of care testing. The varied teaching methodology also allows adaptation to accommodate varying background, skills and experience in our student population.

**Module Content:**

**Quality Assurance**
- Method Evaluation
  Clinical utility and analytical performance

- Method Validation
  Accuracy, precision, bias. Comparison with other assays

- Sources of variation in laboratory results
  Measures of uncertainty. Analytical and biological variation. Multiple analyses.

- Quality Assurance
  Function of internal quality control and external quality assurance. Managing and problem solving internal quality control issues. Managing, understanding results and dealing with problems of EQA.

**Laboratory Management**
- Accreditation
  Requirements for a quality management system including documentation control, policies and standard operating procedures, audits, managing non-conformances and incidents, staff training and development

- Laboratory Management
  Covering business case development, tendering process, demand management, principles of lean six sigma, relevant statistics for laboratory management and research, laboratory automation, health and safety.
  The role of the manager in the laboratory. The management and assessment of a quality system. Service planning, including out of hours cover. Staff management and continuing professional development.
• Laboratory Information Systems and Decision Support
  Understanding use of information management for decision support within the laboratory and throughout the hospital. IT solutions for provision of information to external users and receipt of data from external laboratories

• Human Resource Management/Staff conflict resolution
  Managing staff resources and dealing with work related staff problems

• POCT
  Provision and management of a POCT service

Course Work:
• 2 assignments

Learning Outcomes:
On successful completion of this module participants will be able to:

• Set up a laboratory service based on user requirements including choosing appropriate general chemistry and immunoassay platforms, pre-analytic systems and POCT; staff resources; laboratory information system requirements and other hospital IT systems, and preparing tender and other documents required for managing a laboratory

• Establish a quality management system, including IQC and EQA, and prepare a laboratory for accreditation.

• Describe the procedures and policies involved in staff management and staff complaints

• Describe the statutory requirements for health and safety within the laboratory and the ability to identify safety issues within the laboratory

• Use statistics in the laboratory setting

• Discuss user requirements for laboratory information systems, new developments in electronic patient charts and other hospital IT systems.

• Devise solutions to laboratory based problems in the areas of management, quality assurance (IQC/EQA), provision of quality results, POCT and service provision.
### Assessment:

**Summative:**
- End of year 2 Examination
- End of year 2 Objective Structured Practical Examination (OSPE)

**Viva Voce (4% of total course marks):** A proportion of the final year viva voce marks are assigned to Module 3.

This module will account for 16.67% of overall course marks. 50% pass mark for end of year assessment. Compensation is possible provided \( \geq 40\% \) mark is obtained in the area requiring compensation.

**Formative:**
- OSPE practice runs
- Presentations to class
- Revision

### Contact Hours:

- Lectures 22, Tutorials 10, Workshops 16.
- Indicative hours for self-study and assignments 220.

### ECTS Credits: 10

### Indicative Resources:

**Texts:**
- Alan Deacon. *Calculations in Laboratory Science* ACB 2009
- M. M. Houck and D. Gialamas. *Forensic Science Laboratory Management* CRC Press 2010

Students will be directed to reviews and articles in relevant *journals* such as:

- Annals of Clinical Biochemistry
- Clinical Chemistry
- Clinical Chemistry and Laboratory Medicine
Guidelines, where relevant, will be referenced, some examples are listed below:

Irish Guidelines for Safe and Effective Management and Use of Point of Care Testing.

Irish Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care.

Clinical and Laboratory Standards Institute (CLSI) Guidelines:
Access to CLSI Guidelines is available through the Laboratory Medicine Department, Tallaght Hospital. These guidelines are extensively referenced throughout the course.

Web Portals:
http://www.westgard.com Westgard Web – Westgard QC
http://www.ukneqas.org.uk (UK national external quality control scheme)
http://www.weqas.com (Welsh external quality control scheme)
http://www.ieqas.ie (Irish external quality assurance scheme)
http://www.clsi.org (Clinical and Laboratory Standards Institute)
http://www.aacc.org (American Association of Clinical Chemistry; NACB guidelines)

Appendix 5: Project Information, Project Proposal and Supervisor Nomination Forms

Project Information

- Final Project Proposal must be submitted by the end of November in the first year of the course
- Choose a project that can be achieved ideally within 1 year. This allows you to present and discuss your preliminary results with the course director and get guidance on selection, presentation, and write-up.
Ensure you discuss your project and dissertation with your Project Supervisor on a regular basis throughout. The dissertation must be submitted to the supervisor for corrections and approval well in advance of the submission deadline to allow sufficient time for changes.

Ethical approval must be obtained from the local hospital Ethics Committee as required. A statement of Ethical approval must be included, or an explanation as to why ethical approval was not required if this is the case.

The expected dissertation length is approximately 12,000 words.

Before the main Chapters, you should include the following sections:

- Cover Page with Title
- Table of Contents
- List of Figures, Tables
- Declaration
- Acknowledgements (and any Dedications)
- List of Abbreviations (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.)

An Abstract at the beginning of the thesis should summarise your dissertation, preferably 1 page in length. Please note that a well-written abstract is vital. It is most important to get this right as it sets a good impression for the rest of the dissertation. It is the first thing your internal and external examiner will read.

In your abstract, you should summarise precisely and concisely your entire project including background, aims, methods, results, and conclusion. Read abstracts from key journals to get a feel for what a good abstract contains. Don’t use abbreviations. In your methods, make sure to say how many patient and control subjects (n=) you studied, if appropriate. In your results, make sure that you include your actual findings for your analyte concentration (+/- SD) and measurement units of same for each study group. It is not sufficient to say your results were “significant/not significant” or just to give a percentage change or a statistic. You must give your results concisely and precisely, then give any relevant statistics (e.g. p values) and let the reader make their own mind up about your findings. Of course you must state in your conclusion part of the abstract what you think is the conclusion from your results.
• **Chapter Headings** should include:
  o Introduction
  o Literature review/background
  o Aims (including overall aims as well as specific objectives for the project including hypothesis statement)
  o Materials and methods (including patient group and size; controls; laboratory methods statistics, statement of ethical approval, etc.)
  o Results
  o Discussion
  o Conclusion
  o References

• Font size of 11 or greater

• Spacing of 1.5

• Font and spacing must be consistent throughout the document

• Any reasonable numbering system for 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.)

• Ensure all Tables and Figures are mentioned and properly references in the text throughout. A common mistake in the Results section of the dissertation is to have a large number of complex tables with no text to explain what is in the Tables, finding by finding. Keep your tables and figures as simple and clear as possible and (especially in the results section) describe them carefully in the accompanying text.

• In the discussion section, you need to discuss and compare your results/findings with other peoples work. You will usually have mentioned many of these other workers already in your Introduction

• References use Vancouver style and must be consistent throughout. Make sure your reference list is correct.

• All information provided in the thesis must be properly referenced

Project Assessment

• Two copies of the final version of the project dissertation and an electronic copy must be submitted no later than 31st August of the final year. The submitted document should be simply ring bound at this point (e.g. with a simple spiral binder) so that it opens flat and ideally printed on both sides of the paper.

• The dissertation is examined by an internal examiner and the external examiner using the Grading system below. In cases where the two examiners return different grades, the lowest grade is acted on.

• Before the final document is bound, it must receive a satisfactory grade from the course examiners, including the External Examiner. The Course Director will advise the grade
awarded to the candidate together with any comments when reports are in from both
examiners. Once corrections have been made within the stipulated time, the Course
Director will issue a Pass (Grade 1) letter to the candidate which will include a request to
prepare and submit the final bound hard-copy dissertation.

- The dissertations are Graded as follows:-

**Grade 1 (Pass)**
This passes the dissertation. A very small number of typographical errors or other very minor
effects do not preclude this grade (but may be noted for the candidate)

**Grade 2 (MINOR revisions)**
This grade is given for dissertations which are essentially OK and passable in terms of scientific
content and overall presentation but still require revisions which are MINOR but more than just a
few typographical errors. A list of comments/observations requiring minor revision of the text of
the dissertation should be provided by the internal examiner.

**Grade 3 (MAJOR revisions)**
This grade should be used where the practical work appears satisfactory but extensive redrafting
of the text is required (e.g. sloppy/bad presentation, poor match of stated aims with results
presented, inadequate presentation/analysis of results/discussion, etc). In cases where the
practical work may be unsatisfactory, further practical work may be recommended/required and
this may have the implication of a further fee (e.g. a third year fee).

**Grade 4 is reserved for a bad fail.**

**Re-examination of dissertations**
Any dissertation receiving a Grade other than 1 (PASS) will have to be re-assessed as follows:-

- Grade 2 dissertations will be reviewed by an internal examiner, and a Grade 1 Pass will
  be assigned if the revisions are satisfactory
- Grade 3 dissertations will be reviewed by both internal and external examiners, and a
  Grade 1 Pass will be assigned if the revisions are satisfactory.
SUPERVISOR NOMINATION FORM
Updated 29/07/2016

Student Name: ___________________ TCD Student No: _______________

I wish to confirm that the above named student has my consent and support to undertake the MSc in Clinical Chemistry. This requires supervision of the student’s course work over a two year period including a project, assignments and a logbook of ten cases. Responsibilities of the supervisor are listed below.

Supervisors Name: __________________________________________________

Position/Title & Place of Employment: _________________________________

_________________________________________________________________

Signature: _____________________________

Email Address: _________________________

Tel No: _______________________________

SUPERVISOR RESPONSIBILITIES

• To assist the student in the conduct of their project including access to resources and facilities at their base laboratory.
• To provide assistance to the student for the course work, logbook of ten cases and assignments.
• Supervisors will be expected to participate in the work liaison group, this will involve three emails per year and completion of continual improvement survey.
• Occasionally we may need to contact the supervisor in connection with the students progress.
• Supervisors are also welcome to contact the Course Director or Executive Officer if they wish to discuss any aspect of the course.
**PROJECT PROPOSAL FORM**

*Updated 29/07/2016*

All headings below must be completed however you may expand any section as required.

<table>
<thead>
<tr>
<th>Student Name and TCD Registration Number</th>
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</thead>
<tbody>
<tr>
<td>Supervisor’s Name</td>
</tr>
<tr>
<td>Name and address of Laboratory</td>
</tr>
<tr>
<td>Accreditation Status (where relevant)</td>
</tr>
<tr>
<td>Proposed Title of Project</td>
</tr>
<tr>
<td>You can tweak this as the project develops: perhaps you get results which may lead you down a slightly different path than anticipated.</td>
</tr>
<tr>
<td>Introduction/Literature Review (background)</td>
</tr>
<tr>
<td>Max 300 words: explain your research idea with absolute clarity from the outset so we all know exactly what you are planning to do. Link it with not more than 5 key references to highlight the gap in knowledge that your project addresses. Provide background information in a few key sentences, but no lectures here please on basic concepts.</td>
</tr>
<tr>
<td>Aims and Objectives</td>
</tr>
<tr>
<td>• Overall aims and hypothesis</td>
</tr>
<tr>
<td>• Specific objectives for the project</td>
</tr>
<tr>
<td>Scope your project specifically and precisely for the MSc: itemise your aims and objectives clearly and don’t have too many (3-5 is usual) to avoid your project getting too big. Avoid generalised broad aims/objectives where the scope is unclear. You can have additional aims/objectives related to longer term ongoing projects but if so clearly separate these from your MSc.</td>
</tr>
<tr>
<td>Ethical Approval</td>
</tr>
<tr>
<td>Note: projects cannot be accepted without a satisfactory response to this section.</td>
</tr>
<tr>
<td>Study design</td>
</tr>
<tr>
<td>• Patients and controls</td>
</tr>
<tr>
<td>• Inclusion and exclusion</td>
</tr>
<tr>
<td>Ensure you have thought out your methodology for each of your specific objectives as they usually require different approaches.</td>
</tr>
</tbody>
</table>
### Criteria
- Samples and storage
- Study methods
- Analytical methods
- What you expect to find (expected results)
- Who are your collaborators

**What is your hypothesis? What are you trying to prove/disprove?**

List names (or grades) and say what you require of them (e.g. a registrar to identify patients for you; a phlebotomist to bleed the patient, etc)

### Work Timetable
Note: aim to complete everything within one year. Give specific target dates for key milestones (planning phase, project work – itemise; writing the first draft; final draft after your supervisor has read it and suggested revisions)

### Proposed statistical analysis
State the techniques you will use (and give the name of your software tool). State your null hypothesis where appropriate.

### Up to 5 Key References
List them 1-5
Note: do not list any standard texts such as Tietz here. These are unlikely to be a source of a gap in scientific knowledge. Instead, list no more than 5 key scientific papers that have examined your question or a similar question, or done your study in a different way, different country/population. If your analytical method is unusual, the reference paper should appear here, but not a kit insert.

### Provide details of costs of your project
Your base laboratory will need to know what costs you are likely to incur to successfully complete your project. Itemise these costs here:
- Additional Staffing (note: needing extra staff will usually render your project unfeasible)
- Equipment
- Assay kits
- Consumables
- Any other relevant categories

**TOTAL COSTS:**
LABORATORY APPROVAL OF PROJECT

I CONFIRM APPROVAL OF THIS PROJECT WHICH HAS BEEN DISCUSSED WITH ME

<table>
<thead>
<tr>
<th>PROJECT SUPERVISOR</th>
<th>HOD / CMS / LAB MANAGER</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME: _______________</td>
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