



The Academy of
Clinical Science and
Laboratory Medicine



NEW HORIZONS



**ADVANCED PRACTICE AND EXTENDED SCOPE OF
PRACTICE FOR MEDICAL SCIENTISTS IN IRELAND**





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FOREWORD

- The Academy of Clinical Science and Laboratory Medicine (ACSLM) and the Medical Laboratory Scientists Association (MLSA) recognises the need for radical innovation in the delivery of Pathology services. The profession is anxious to enter into discussions with relevant organisations to pursue the agenda of advanced practice and extension of scope. This offers the prospect of improved patient services, optimal use of existing staff and increased efficiency.
- The HSE clinical strategy has 3 main objectives: to improve the quality of care that is delivered (clinical-effectiveness), to improve access to all services (improve patient-flow) and to improve cost-effectiveness. Many innovative strategies have been proposed and implemented.
- Health services in all developed countries are facing similar challenges to the Irish Healthcare service as demands increase and projected funding required is unsustainable.
- One strategy that is being widely adopted internationally is to expand the scope of practice of existing practitioners. Building on the education and experience of such staff, upskilling them in a structured programme can release other staff, such as doctors, to focus their skills on more complex issues commensurate with their training.
- Some Medical Scientists in Ireland have expanded their roles beyond the traditional one, but the development is unstructured.
- Medical Scientists in other countries, such as the UK, have expanded roles in defined areas, and have expanded their practice or have become Consultant Scientists.
- There are several similar examples of Health and Social Care Professions taking on new roles in Medicine, Nursing, Pharmacy and Radiology in Ireland and in other countries.
- Advanced Practice along with having clear measurable benefits to the patient care pathway also has benefits to the profession in having a highly skilled motivated workforce that results in retention of staff.

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ADVANCED PRACTICE AND EXTENDED SCOPE OF PRACTICE FOR MEDICAL SCIENTISTS IN IRELAND

Medical Scientists are key decision makers in the delivery of Pathology diagnostic services to patients. Within Clinical and Laboratory Medicine, they operate services in: Cellular Pathology (Histopathology), Clinical Chemistry, Haematology, Immunology, Medical Genetics, Medical Microbiology, Molecular Diagnostics, Point-of-Care-Testing, Transfusion and Transplantation Science and Virology. They form the largest part of the workforce collaborating with and supporting Consultant doctors in the delivery of crucial services in these areas.

While the final diagnosis has traditionally been the role of Medical Consultants, developments driven by a combination of the advances in technology, changing workforce demographics, advanced education, expanded competencies and increased demands on the Health Services in general have led to an increase in clinical and diagnostic input by Medical Scientists. Up to 80% of diagnoses rely on the work of Laboratory Medicine.

Medical Scientists in the public service number about 2,000 and represent a dynamic and efficient, constantly evolving profession which has adapted to its changing environment by showing a keen appetite to research, learn, and innovate. As the prevalence of certain diseases such as cancer and diabetes increase, the demands on the Pathology services have risen and this has increased the reliance on the knowledge, skills and competencies of Medical Scientists.

The shortage of Medical Consultants in the specialities represented by Clinical and Laboratory Medicine has created a situation in which highly trained, highly skilled Medical Scientists have been called upon to fill the gap in services and this will be discussed later in the paper. An example of where Scientists are working at a Consultant level already exists in the Irish Healthcare system where Consultant Clinical Biochemists deliver services at the Consultant level and are recognised as diagnostic partners at that level. In the UK, Consultant Clinical and Medical Scientists lead the pathology services in many centres including all the Regional Genetics Centres.



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In response to the environment of increasing complexity and demand, the Government published *Future Health. A Strategic Framework for Reform of the Health Service 2012 – 2015*, (2012). At Action 46 the plan states:

‘The Department of Health will work with the HSE from 2012 to implement an approach to workforce planning and development that includes recruiting and retaining the right mix of staff, training and up-skilling the workforce, providing for professional and career development and creating supportive and healthy workplaces’.

The HSE has begun implementing this action through the Advanced Practice Programme by which it seeks to raise the skills and increase the responsibilities of clinical and care professionals in the Health Service.

Medical Scientists have responded to these drivers within the Health Service by increasing their knowledge, skills and competencies and taking on new clinical leadership responsibilities. The Academy of Clinical Science and Laboratory Medicine and the Medical Laboratory Scientists Association believe that there are many Medical Scientists, respected as experts in their field, ideally positioned to move to a higher level of practice and to develop their knowledge, skills and competencies further in order to improve the patient journey.

The development of recognised advanced practice for Medical Scientists will bring benefits to service users and providers, including timely access to healthcare, reduced waiting times, reductions in unnecessary clinical costs, and freeing other healthcare professionals to focus on patient care. An example of the value-added benefit of such positions has been outlined in the HSE position paper on the development of Advanced Practice for allied health professionals in Ireland (2014)¹.

¹*Progressing Advanced Practice – In the Health & Social Care Professions (2014)*, p.8 - HSE www.hseland.ie

Recommendations for Advanced Practice

Medical Scientists provide laboratory and clinical services in hospitals both public and private across the state. The entry level standard for the profession is a QQI level 8 Bachelor of Science degree offered by Cork Institute of Technology/University College Cork, Dublin Institute of Technology and Galway-Mayo Institute of Technology. Each has an ECTS requirement of 240 credits which far exceeds the International Federation of Biomedical Laboratory Sciences recommended basic level of 180 ECTS. Approximately 80% of the profession are educated to MSc level and beyond. Irish Medical Scientists are seen as exemplars in Europe.

The 2001 Report of the Expert Group on Medical Technician / Technologist Grades recommended that “formal consideration needs to be given to the possible role of consultant level scientists in disciplines other than clinical biochemistry” and reported that the role of Medical Scientist must develop to meet the increasing needs of patients and the increasing knowledge and sophistication within the field of Pathology².

The future needs for Medical Scientists within the Pathology Service were reviewed in 2007 in *Implementing a New System of Service Delivery for Laboratory Medicine* and the report recommended ‘a national framework of a uniform approach to post-graduate continuous professional development, appropriately funded and specifically targeted at enhancing the individual’s skills, competencies, to the benefit of the quality and range of service delivery’³.

The National Histopathology Quality Assurance Programme Implementations 2014, published by the Faculty of Pathology of the Royal College of Physicians of Ireland, emphasises the crucial role that Medical Scientists play in the delivery of quality assurance programmes. In a survey completed in 2011, of all hospitals surveyed (24 hospitals) the Medical Scientist had primary responsibility for managing and monitoring coding of laboratory results in 52% of cases whereas the pathologist led in 39% of cases⁴. The report indicated that quality guidelines are used by both Consultant Histopathologists and Medical Scientists⁵. The Report explained that the key to success lay in clinical leadership and participation stating ‘the involvement and work of Medical Scientists was integral to the success of this programme’s implementation’⁶.

The Royal College of Pathologists (UK) recommended in 2007 an ‘extended role for suitably trained and qualified biomedical scientists in the reporting of cytopathology specimens’⁷.

²Report of the Expert Group on Medical Laboratory Technician / Technologist Grades, (2001), p.6

³Implementing a New System of Service Delivery for Laboratory Medicine, (2007), p.67

⁴The National Histopathology Quality Assurance Programme Implementations (2014), pp.18-20

⁵ibid. p.21

⁶ibid. p.29

⁷Extended Role for Biomedical Scientists in the Reporting of Diagnostic Cytopathology Specimens, (2007)

<http://www.rcpath.org/committees/specialty-advisory-committees/cytopathology/extended-role-for-biomedical-scientists-in-the-reporting-of-diagnostic-cytopathology-specimens/extended-role-for-biomedical-scientists-in-the-reporting-of-diagnostic-cytopathology-specimens>



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Advanced Practice

Within the context of the need to plan for the future development of services to meet increasing complexity in patients' needs, the HSE published a paper entitled *Progressing Advanced Practice*. It highlighted the 'rapid continuous developments in knowledge, skills and technologies to diagnose, treat, manage and prevent ill-health'⁸. Advanced practice yielded both improved patient and financial outcomes. Advanced practice was defined by the principles of autonomy, expert clinical practice, clinical leadership and research. The paper found that:

*"Many HSCPs employed at the grade of clinical specialist are often working at a level more substantive than the descriptors for this grade.... There are many professionals, respected as experts in their field, ideally positioned to move to a higher level of practice, and further develop their knowledge, skills and competences to improve the patient / client journey"*⁹.

The National Leadership and Innovation Agency for Healthcare, in 2010, defined Advanced Practitioners as experts in practice who combined their expert practice with some of the following: team leadership, a role as an educator, researcher or service development. Advanced practitioners must have expert knowledge and skills in their field of Laboratory Medicine, work in inter-disciplinary teams and may have further expertise in research skills, education, management or leadership.

The ACSLM and MLSA recommend that Advanced Practice on the pathway to Consultant Grade should be distinguished from the separate concept of extended scope of practice. Extended scope of practice extends the scope of practice of the professional without requiring the higher competencies of the Consultant Scientist. Both concepts are necessary to benefit the patient care pathway and to the development of the profession in an efficient and productive manner.

⁸*Progressing Advanced Practice* (2014), p.3

⁹*ibid*.pp.5-6

Advanced Practice and Extended Scope in Operation in Clinical and Laboratory Medicine

Below are some concrete examples of roles in the Irish Healthcare System where Medical Scientists in Ireland are displaying Advanced Practice and Extended Scope of Practice.

Examples of Advanced Practice:

1. **Chief Medical Scientists lead the Irish Mycobacterial Reference Laboratory for Tuberculosis and the National MRSA Reference Laboratory** (Fellows of the Academy of Clinical Science and Laboratory Medicine, PhDs)
 - i. Advice to doctors and other scientific service users.
 - ii. Interpretation of molecular typing data in conjunction with patient epidemiological details in outbreak investigations.
 - iii. Interpretation of unusual resistance patterns and identification of possible genes associated with resistance.
 - iv. Leading on scientific research and development.
 - v. Key role in Multi-Disciplinary Team.
 - vi. Implementing relevant new research findings into the service.
 - vii. Collaboration with Dublin Dental Hospital, UCD Veterinary Hospital, University College Hospital Galway, Beaumont Hospital, the Health Protection Surveillance Centre, UK MRSA Reference Laboratory (Scotland).
 - viii. Collaborating on European Antimicrobial Resistance Surveillance Network (EARS-Net) Committee, with the European Centre for Disease Control and the European Staphylococcal Reference Laboratory Working Group.
 - ix. Management of the laboratory aspect of the EARS-Net scheme for MRSA in Ireland in conjunction with the HPSC.
 - x. Key role in European TB reference laboratories expert network.
 - xi. Advice to developing countries on laboratory set up.
2. **Scientific Lead of Molecular Pathology Laboratory (Neuropathology) in Beaumont Hospital, Dublin** (Fellow of the Academy of Clinical Science and Laboratory Medicine, PhD)
 - i. Molecular diagnostic analysis for diagnosis, prognosis and monitoring of brain and spinal tumours.
 - ii. Research and development, publication (40 papers in human genetics).



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- iv. National and International committees including the Irish Molecular Diagnostics Network (IMDN) and CEQAS schemes
- v. Lecturing.
- vi. Commercial collaborations for validation and development of CE-IVD marked tests.
- vii. Development of future training schemes for medical and biomedical science graduates in the area of molecular pathology through the Faculty of Pathology, RCPI.

3. **Scientific Lead of Cancer Molecular Diagnostics in St. James's Hospital Dublin** (Fellow of the Academy of Clinical Science and Laboratory Medicine, PhD)

- i. Advice to doctors and other scientific service users
- ii. Molecular diagnostic analysis for prognosis and monitoring of cancer.
- iii. Research and development, publications, externally funded related research work.
- iv. Multi-disciplinary team input.
- v. National and international committee work.
- vi. Lecturing and supervision of undergraduate and postgraduate research projects.
- vii. Reviewer for international journals.
- viii. Part of local pilot programme for F.R.C.Path in Molecular Pathology.

4. **Scientific Lead of Coagulation in Our Lady's Children's Hospital Crumlin, Dublin** (Fellow of the Academy of Clinical Science and Laboratory Medicine, F.R.C. Path in Haematology)

- i. Advice to doctors and other scientific service users.
- ii. Member of multi-disciplinary team.
- iii. Training and education of Medical Scientists, Specialist Registrars, nurses, and patients.
- iv. Research and development, clinical trials and collaborations.
- v. National and international committee work including membership of the Scientific and Standardisation Committee of ISTH.
- vi. Lecturing and supervision of undergraduate and postgraduate research projects.
- vii. Reviewer for international journals.

5. Scientific Lead the National Histocompatibility and Immunogenetics Service for Solid Organ Transplantation (NHISSOT), Beaumont Hospital, Dublin (Fellow of the Academy of Clinical Science and Laboratory Medicine)

- i. Expert in tissue typing for the National Transplant Unit.
- ii. National Service for renal, pancreatic, liver, cardiac, and lung transplant.
- iii. Advice to doctors and other scientific service users; interpretation of crossmatch and antibody screening results to determine if transplants should proceed.
- iv. Training and education for Medical Scientists, Specialist Registrars, nurses, and patients.
- v. Research and development, clinical trials and collaborations.

6. Clinical Scientist at the Department of Clinical Genetics, Our Lady's Children's Hospital, Crumlin, Dublin

- i. Molecular genetic, cytogenetic and molecular cytogenetic service development to meet population requirements.
- ii. Advice to medical staff and scientific service users.
- iii. Development of best practice guidelines (EMQN, Eurogentest, OECD).
- iv. EQA (EMQN, UKNEQAS & CEQAS) Scheme Assessors & Organisers
- v. Development of reference materials.
- vi. Research and development, grant procurement, publishing.
- vii. National committee work – (GRDO, IMDN, ISHG, ACSLM, HMI).
- viii. International committee work (as per iii & iv above; also IVD Regulation, AMP's International Affairs Committee, CLSI).
- ix. Lecturing medical and science students.
- x. Supervision of undergraduate and postgraduate research projects.
- xi. Reviewers for international journals and textbooks.

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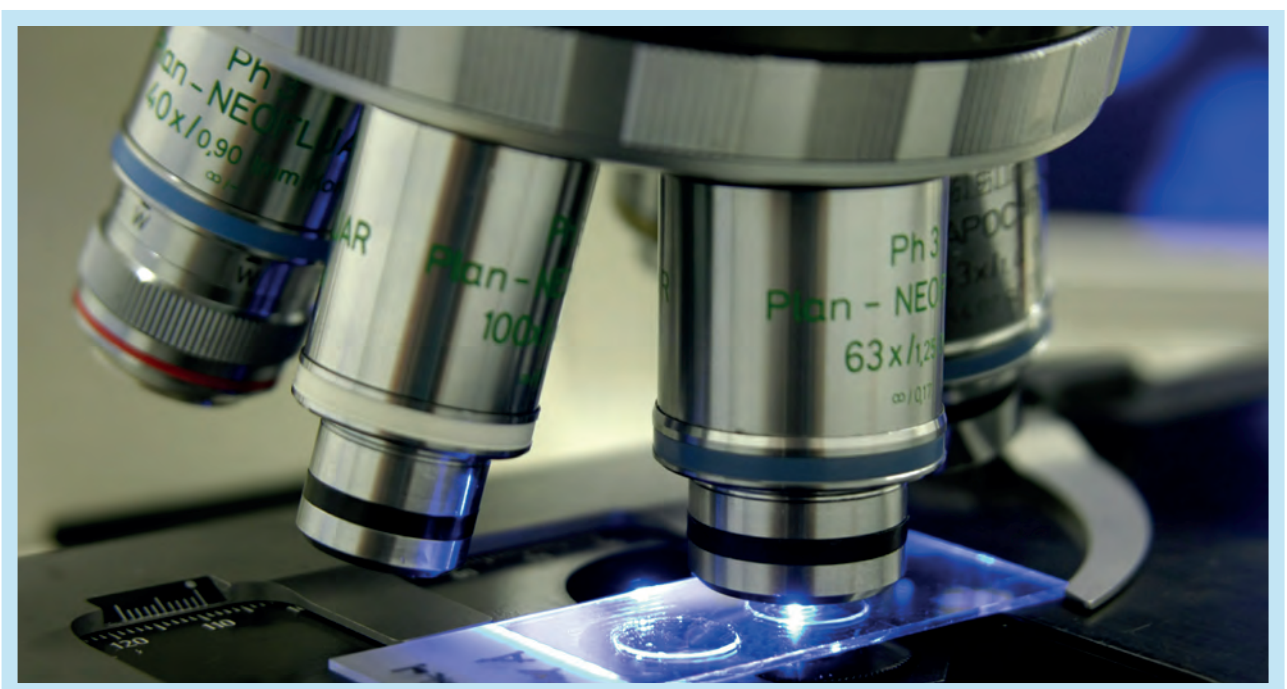
Examples of Extended Scope of Practice:

1. Blood Transfusion
 - a. Rhesus disease tracking.
 - b. RAADP Anti-D programmes co-ordination.
 - c. Pharmaco-vigilance.
 - d. Haemo-vigilance.
2. Cellular Pathology (Histopathology) and Clinical Cytopathology
 - a. Dissecting complex tumours.
 - b. Assisting in diagnosing tumours, biomarker analysis and clinical staging.
 - c. Breast, skin, placenta, and products of conception histo-dissection.
 - d. Cytology needle aspiration cytology.
 - e. Human Papillomavirus testing and typing.
 - f. Cervical smear diagnostic algorithms for cervical cancer diagnosis.
3. Haematology
 - a. National experts in Adult and Paediatric Flow Cytometry.
 - b. National experts in Haemoglobinopathies and other haematological diseases.
 - c. Haematopoietic Stem Cell transplantation.
 - d. Clinical trial co-ordination.
 - e. Bone marrow sampling and reporting.
 - f. Anti-coagulant clinic management.
 - g. Bleeding and thrombotic disease diagnosis and monitoring.
 - h. Molecular diagnostics.
4. Molecular Diagnostics and Genetics (may also be part of routine service depending on expertise)
 - a. Molecular diagnostic analysis for prognosis and monitoring of disease.
 - b. Cancer mutation testing for targeted therapies on colon, lung, and gastric cancers, melanomas and lymphomas.
 - c. Population screening e.g. Cystic Fibrosis Newborn Screening Programme.

5. Other key roles which may be considered to exhibit extended practice

- a. Examiner for the Royal College of Pathologists.
- b. Tutoring and lecturing at third level colleges.
- c. Acting as assessors / auditors in UK NEQAS, CEQAS, European Molecular Genetics Quality Network, ISO 15189, JACIE and other accreditation programmes.
- d. Validation of educational programmes.
- e. Input into policy statements and guidelines such as Clinical Care Programmes.
- f. Leading and advising on accreditation, quality, and 'Lean Healthcare.'
- g. Point-of-Care Testing co-ordinators.
- h. Committee work
- i. Editorial and peer reviewing roles.

While it is agreed that Extended Scope of Practice in the areas of Clinical Science and Laboratory Medicine are recognised to a certain extent through the grade of Specialist Scientist, it is clear from earlier examples that Medical Scientists have already reached a point in their professional development where the role of Advanced Practitioner, as distinct from Extended Practice, needs to be recognised. The role of Advanced Practitioner will allow the profession to contribute even more fully to healthcare into the future and the role of Consultant Scientist may become relevant just as it has in the United Kingdom.





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Where We Want to Go?

Advanced Practice in Allied Professions

There is ample evidence of the value of Advanced Practice in allied health professions. Fellowship of The Royal College of Pathologists (F.R.C.Path) by examination 'for non-medical candidates indicates they have reached the standard appropriate for unsupervised practice'¹⁰. This fellowship pathway is followed by Biochemists working in Ireland and UK. In 2002 Ireland had 90 Clinical Biochemists of which 15 were eligible for recognition at Higher Specialist Level¹¹. Increasingly more Medical Scientists and Clinical Scientists in Ireland (in areas other than Biochemistry) are achieving the qualification of FRC Path but are not given the same recognition as those with the same qualification in the UK.

In *A Guide to Defining the Competences Required of a Consultant in Clinical Chemistry and Laboratory Medicine* a clear vision of the role of the Consultant Scientist was set forth for Clinical Biochemists:

"A consultant is defined as a senior professional with responsibility for the design, development, delivery, and direction of a clinical and / or scientific service in the area of Clinical Chemistry Laboratory Medicine. A consultant functions as an autonomous practitioner within a clinical team and within the overall strategic plan of his / her employing authority and is accountable for service quality, including data interpretation and clinical liaison"¹².

The Society of Radiographers has developed two senior roles: the Advanced Practitioner and the Consultant Radiographer. The Society define the Advanced Practitioner as an expert in clinical practice combined with some of the following: team leadership, an educational role, a research role, and a role in service development. Advanced Practitioners must have expert knowledge and skills in diagnostic imaging and radiotherapy and oncology. Advanced Practitioners also work in multi-disciplinary teams¹³. Consultant Radiographers 'practice at the leading edge of the profession, with the ability to create and interpret knowledge that extends the forefront of the profession. They provide leadership in relation to clinical practice and the delivery of clinical services'¹⁴.

¹⁰College Examinations for Fellowship, Diplomas, and Certificates, Regulations and Guidelines for 2014, Section 2
<http://www.rcpath.org>

¹¹European Communities Confederation of Clinical Chemistry (EC4) *The Practice of Clinical Chemistry in the European Union* (2002), p.199

¹²*A Guide to Defining the Competences Required of a Consultant in Clinical Chemistry and Laboratory Medicine*, in Clin. Chem. Lab. Med, (2005), p.665

¹³The Society of Radiographers, <http://www.sor.org/career-progression/advanced-practitioners>

¹⁴The Society of Radiographers, <http://www.sor.org/career-progression/consultants>

The Value Added by Extending Practice

In October 2012 Derby NHS Hospitals conducted a pilot scheme called *Extended Role of Biomedical Scientists in Specimen Dissection and Reporting*. The scheme involved 12 biomedical scientists who undertook either a Diploma of Expert Practice in Histological Dissection or an Advanced Specialist Diploma in Specimen Dissection. The pilot scheme concluded that Biomedical Scientists were an untapped resource in Histopathology and that extending the scope of their roles led to increased staff satisfaction, staff retention, improved teamwork and, crucially, the delivery of a high quality cost-effective service.

In a similar study on Advanced Practice in Coventry and Warwickshire's Pathology evaluated enhanced roles in an extended role for Biomedical Scientists' in cutting up in colonic cancer. The report highlighted increased time for consultant pathologists for other duties, increased job satisfaction for scientists, enhanced teamwork and more flexible and efficient use of cut-up facilities. The study concluded that Medical Scientists performing cut-up saved 17.5 minutes per case that equated to 29.2 hours per year per caseload of 100 cases per annum. With more formal training and experience, the study stated that efficiencies would be higher¹⁵.



¹⁵Enhanced Biomedical Scientist Cut-Up Role in Colonic Cancer Reporting, (2012), Pp.12-13

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How Do We Get There?

As discussed earlier the Advanced Practitioner on the pathway to Consultant Scientist should:

- Lead in the development and innovation of Medical Scientific Practice
- Practice autonomously in his / her speciality within the clinical team
- Offer leadership as appropriate within a multi-disciplinary team
- Lead research in his / her speciality
- Manage, develop, and mentor junior medical/clinical scientists
- Offer leadership in managerial roles.

Many of the scientists described earlier in section “Advanced Practice and Extended Scope in Operation in Clinical and Laboratory Medicine” have the above requirements for Consultant Scientist or are on the pathway to those requirements. Professor John J. O’Leary in, *Pathology 2026: The Future of Laboratory Medicine and Academic Pathology*, sees a decline in medical pathology both within the UK and Ireland. O’Leary identifies the need to ‘make the pathologist / laboratory scientist more accessible and visible to clinical colleagues..... the laboratory needs to be redefined..... as a centre of diagnostics that is important and pivotal to the needs of the patient¹⁶. He stated moreover that ‘the introduction of advanced practitioner scientists, clinical diagnostic scientists... within the laboratory environment will revolutionise how we, as practitioners of laboratory medicine, will deliver our service to the healthcare sector’¹⁷.

Looking to 2026 O’Leary anticipates that ‘there will be formalised professional and academic MSc, PhD, and DSc, programmes for Medical Scientists. There needs to be a diploma / membership of the Royal College of Pathologists for scientists who wish to pursue advanced practitioner status in their relevant pathology disciplines’¹⁸.

¹⁶O’Leary JJ *Pathology 2026: The future of laboratory medicine and academic pathology*. In O’Leary JJ. *Understanding disease*. New York: John Wiley & Sons (2006), p. 220

¹⁷ibid. p.222

¹⁸ibid. p.229

The NHS has recognised the value of Higher Specialist Scientific Training (HSST) programmes in Healthcare Science. It has identified more than 600 Consultant Clinical Scientists who provide advice and care along side medical consultants¹⁹. These Consultant Clinical Scientists have completed Higher Clinical Scientific Programmes that conform to HSST; they lead within their teams and workplaces, and develop research and innovation²⁰.

Medical Scientists' roles in the Irish Health Service have developed in many directions over the last forty years in tandem with the developments in the health sector and scientific discovery. New roles have emerged such as Surveillance Scientists, managers of warfarin clinics, pathology advisor and haemo-vigilance officers. Medical Scientists have taken more prominent roles on histo-dissection, Rhesus disease tracking, and point-of-care / community clinics, organ-transplantation typing and allergy testing.

The role of the Medical Scientist must be able to meet the ever-evolving needs of the health service and while the current roles available meet many of the needs of the Irish Health Service, there is a real need to extend the role of a specific group of Medical Scientists to Advanced Practitioner and Consultant Medical Scientist level.

Whilst many Medical Scientists are already performing extended practice in clinical areas the ACSLM and MLSA recommend that the pathway into clinical practice should be formalised. Pathways such as those already in existence in the UK or the current pathway for Biochemists need to be developed and formalised for Medical Scientists in Ireland.

Figure 1 shows the Current Scientific Career structure for Medical Scientists, Biochemists and Clinical Scientists. Surprisingly the title and career pathway of Clinical Scientist remains unformalised in the Irish Healthcare system. Figure 2 shows the "possible Future Scientific Career Structure" as proposed by the ACSLM and MLSA.

¹⁹Health Education England, *Scaling the Heights: An Overview of Higher Specialist Training (HSST) in Healthcare Science*, (2014), p.7

²⁰ibid. p.8

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Figure 1: Current Scientific Career Structure

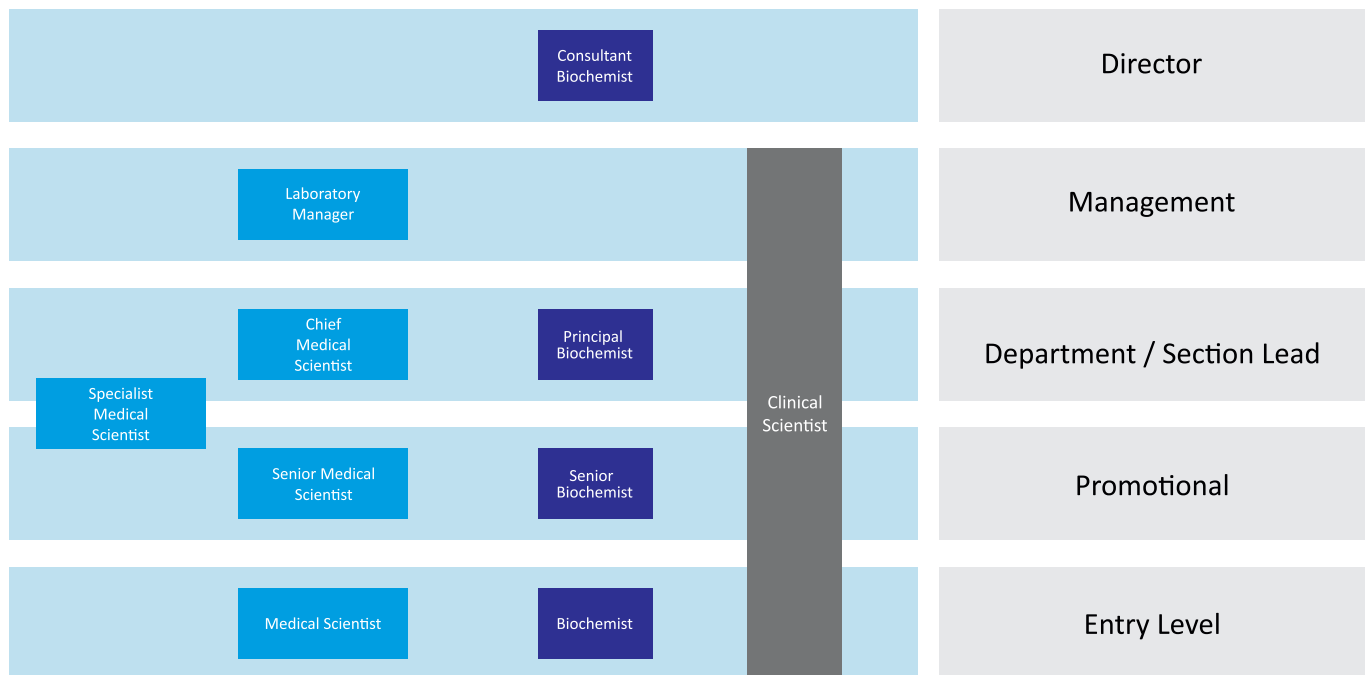
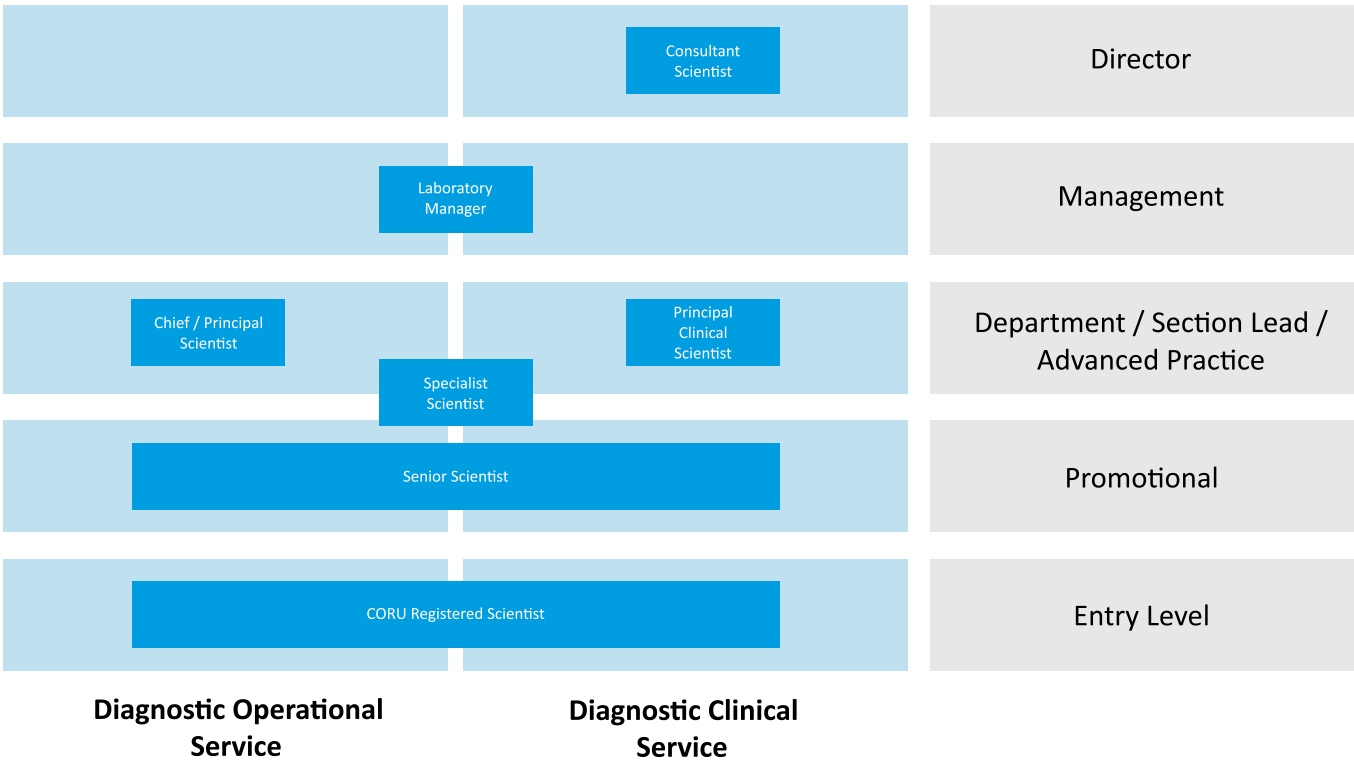


Figure 2: Future Scientific Career Structure







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Medical Laboratory Scientists Association
Cumann na nEolaithe Saotharlanna Míochaine

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