The Role of the Clinical Scientist in Physiological Measurement

1. Introduction

The provision of high quality physiological measurement services delivered in a safe and effective manner is of vital importance. The Clinical Scientist has a central role in the provision of these services. They maintain and improve the quality, efficacy and safety of measurement and investigation techniques - ensuring that technology is used appropriately and the services are provided in line with best practice. The Clinical Scientist also has a role in the introduction and advancement of new techniques for the benefit of the patient. Clinical Scientist is a protected title and professionals must be registered with the Health and Care Professions Council (HCPC) [1] to use it.

This policy statement aims to provide guidance on the role of the Clinical Scientist in physiological measurement. Whilst an overview of relevant training and entry routes into physiological measurement is provided, the reader is advised to seek further information on particular training routes through the Institute of Physics and Engineering in Medicine (IPEM) [2], the Association of Clinical Scientists (ACS) [3], the National School of Healthcare Science (NSHCS) [4] and the Academy for Healthcare Science (AHCS) [5].

2. What is physiological measurement?

Physiological measurement is the science of transforming physiological information into quantitative data, which can be used to assess or follow changes in specific physiological conditions. The procedures adopted must provide accurate, reproducible and timely information on the status of the patient and so contribute to their diagnosis or treatment. Some common examples include measurements of cardiac, peripheral vascular, microvascular, respiratory, neurological, audiological, ophthalmological, urinary tract and gastrointestinal function, etc.

3. Who performs physiological measurement?

Physiological measurement services should normally be led by a Clinical Scientist with technologists, engineers, nurses, doctors and trainees at all levels involved throughout its provision as appropriate. This guidance document is primarily focussed on physiological measurements performed within a medical physics department that encompasses staff with a clinical engineering

or physics background and has IPEM as the related professional body. In some NHS Trusts, certain physiological measurements and services, such as neurophysiology, audiology, gastrointestinal physiology, urodynamics or vision sciences, for example, may be organised separately to medical physics and have different professional bodies associated with them [6-10]. However, these departments will normally encompass the same roles and responsibilities and so to ensure best practice, it would be desirable for these services to have a contribution from a physical sciences Clinical Scientist with expert knowledge in physiological measurement.

4. Training of Clinical Scientists in physiological measurement

The training of Clinical Scientists in physiological measurements has undergone a number of changes in recent years. Medical physicists and clinical engineers working in this speciality first complete a period of broad based basic training, followed by a period of advanced specialised training before formal registration as a Clinical Scientist is possible.

At the time of writing (2019), the training scheme for medical physics and clinical engineering Clinical Scientists in the UK varies by country. In England, Wales and Northern Ireland interested applicants will need to progress through the Scientific Training Programme (STP) managed by the National School of Healthcare Sciences (NSHS) [4]. This is a three year work place based pre-registration programme and the candidates will be employed by an NHS trust during their training. In Scotland, trainees with a background in physical, computing or engineering sciences follow the clinical engineering branch of the Scottish medical physics Training Scheme in order to specialise in physiological/clinical measurement.

Clinical Scientists are subject to statutory regulation by the Health and Care Professions Council (HCPC) [1]. An essential requirement of this HCPC registration is a commitment to continuing professional development. To maintain registration, the Clinical Scientist must be able to demonstrate, on request, learning activities relevant to current or future practice that could contribute to the quality of their service delivery or be of benefit to the service user.

Senior HCPC registered Clinical Scientists demonstrating appropriate education, training and professional practice may seek entry to the Higher Specialist Scientist Register (HSSR). Those meeting the necessary requirement will be deemed to be working at the level required of a Consultant Clinical Scientist. Entry to the HSRR can be achieved by either:

- Award of the Certificate of Completion by the AHCS following completion of the Higher Specialist Scientist Training (HSST) programme. This is a five-year work-based programme supported by an underpinning part-time doctoral level programme.

- Award of the Certificate of Equivalence by the AHCS following an assessment process against the outcomes of the HSST.

5. Scientific Service Provision (diagnostics and treatment)

Clinical Scientists in physiological measurement have a central role in service provision and are often directly involved clinically when providing scientific, diagnostic and therapeutic services. The level of support depends on local circumstances but may include some or all of the following:

- Performing measurement procedures in the clinical environment,
- Diagnostic interpretation of results, ensuring that the reporting of results is appropriate given the limitations of and known errors associated with the technique,
- Treatment assessment and treatment planning,
- Supervising procedures performed by technical and nursing staff,
- Undertaking risk assessments and developing and maintaining the infection control protocols,
- Standardisation of test procedures through the development of standard operating procedures,
- Producing normative ranges for local clinical measurements,
- Managing a service and liaising with users to ensure it is appropriate to local needs.

6. Safety

It is the responsibility of any Clinical Scientist to maintain high standards of safety and quality control through training, regular audit and peer-review. Interaction with patients, clinicians, technical staff and nursing staff requires a high level of skill and communication. Much of the role of the Clinical Scientist focuses on ensuring physiological measurement services are carried out in an effective manner to ensure patient and staff safety in both diagnostic and therapeutic applications. This includes service design and development, acceptance testing and quality assurance, research and innovation, and education and training. Clinical Scientists have a duty of care towards their patients and colleagues to mitigate risks from equipment and devices, environmental hazards and infection prevention requirements through a system of risk management, methods of work, audit and user awareness. To aid the scientist, it is important to promote a work environment where staff and patients feel empowered to speak out about any matters relating to safety that they are concerned about.

7. Service Design and Development

Physiological Measurement services, like any other, are under constant pressure to meet the changing demands of users and service requesters. The Clinical Scientist is expected to keep up to date with advances in the field and advise on the adoption of new techniques and service modifications where appropriate. This will include the evaluation of clinical demand, assessment of clinical risk, resource management, critical evaluation of new techniques and the optimisation of

existing techniques and clinical applications. This will invariably require liaison and cooperation with other stakeholders and may include the drawing up of service level agreements.

The role of the Clinical Scientist may also include specification of new equipment, evaluation and trial of potential devices and system validation to ensure that a new system is working correctly whilst identifying normal limits and outputs for compliance. The Clinical Scientist has a key role to play in acceptance testing of new devices or equipment to ensure that they are safe and appropriate for clinical use. It will also include the establishment of a program of planned maintenance and electrical safety testing.

8. Quality Assurance and Improvement

The Clinical Scientist is involved in ensuring consistent, high quality, clinical results and safe and effective practice of physiological measurement through the process of quality assurance. The Clinical Scientist will often manage routine quality assurance procedures to monitor the performance of equipment using test devices traceable to national standards as appropriate. Where performance fails to meet acceptable tolerances, the Clinical Scientist will take measures to return the device to acceptable performance through actions such as in-house calibration or use of a suitable external service.

Services may also develop and improve through the medium of a quality management system and working towards service accreditation such as ISO 9001:2015 [11], IQIPS (Improving Quality in Physiological diagnostic Services) [12] or MPACE (Medical Physics and Clinical Engineering accreditation programme) [13]. The Clinical Scientist may also be involved with conducting internal and external audits to ensure that the services provide a safe, efficient and good quality patient centred care.

9. Leadership and Management

The NHS Long Term Plan [14] highlights the importance of visible senior clinical leadership in enabling and assuring the delivery of high quality care, both within organisations and in the wider NHS system architecture. An important role of the Clinical Scientist is therefore to engage with and motivate those around them in order to achieve shared objectives.

At a senior level, the Clinical Scientist will take responsibility for the management of people, resources and budgets. The senior scientist has management skills to ensure that the service provided is of high quality whilst remaining cost effective and responsive to the needs of patients and clinicians. This will require the scientist to demonstrate leadership and accountability in meeting Key Performance Indicators (KPI), work force planning, staff management and development, and service management and development.

10. Professional Activities

IPEM offers professional body representation for Clinical Scientists working within physiological measurement. In addition to the individual, involvement with a professional body brings wider benefits to the profession and representation of Clinical Scientists working within physiological measurement specialisms. Activities may include involvement with relevant special interest groups or committees, organisation of scientific meetings, mentoring and networking opportunities. An important role for the Clinical Scientist is to act as an expert in the field, not only to clinical colleagues but to industry, charities, policy makers or advisory boards. The senior scientist may also be called upon to act as an expert witness.

11. Education and Training

The Clinical Scientist is involved in education and training in a number of ways, which can include:

- Instructing medical, clinical, technical and scientific colleagues in the basic science and clinical application of physiological measurement techniques,
- Developing internal training standards and role requirements to ensure staff undertaking physiological measurement procedures are appropriately trained and up to date,
- Engaging with mentoring opportunities,
- Supporting continuous professional and personal development,
- Providing training and support for trainees in medical physics and clinical engineering, as well as those in cardiac, vascular, respiratory and sleep sciences and neurosensory sciences, where appropriate, to allow them to develop in the profession,
- Publishing and contributing to developments in the field or participate in appropriate national and international meetings,
- Supporting science, technology, engineering and mathematics (STEM) outreach activities to encourage the next generation of physicists and engineers into the profession,
- Giving formal lectures to university and college students studying subjects involving the physical sciences and physiological measurement in particular,
- Supervising students and academic projects to doctoral level.

12. Research and Innovation

The Clinical Scientist has a pivotal role in initiating, leading and collaborating in research and innovation within the field of physiological measurement. They will apply their expert scientific knowledge to improve or develop new clinical services, identify opportunities to innovate and create a culture where innovation flourishes. The Clinical Scientist will also be expected to be able to keep up to date and analyse and synthesise their understanding of key and emerging technologies that underlie recent innovations in healthcare science. When instigating change, they

will work with colleagues and patients as they plan, evaluate and deliver new physiological measurement services. The NHS Long Term Plan [14] places prominence on research and innovation and hence the Clinical Scientist is ideally placed to have a substantial role in driving future healthcare improvements.

Clinical Scientists are uniquely placed between academia and clinical practice with the potential to translate basic research into NHS practice. They can be involved in every research stage and level, including:

- Generating research proposals to secure grant funding,
- Developing new physiological measurement techniques and medical devices,
- Demonstrating good research practice through following regulations, principles and standards of good practice to ensure high quality research,
- Creating submissions for ethical and regulatory approval, for example submissions to the Medicines and Healthcare Products Regulatory Agency (MHRA) for clinical studies involving non-CE marked medical devices,
- Formulating and testing hypotheses through effective research study design,
- Providing leadership to Chief Investigator level for a project,
- Carrying out investigations for feasibility, pilot and to formal clinical trials,
- Performing data analysis and statistics,
- Financial management of grant funding,
- Appropriately managing, documenting and protecting intellectual property,
- Disseminating of the findings of the research at national and international levels through scientific symposia and also by the publication of scientific papers and books,
- Fostering academic and external links to international level,
- Providing peer review or editorial board input for journal publications.

13. Summary

A Clinical Scientist working within physiological measurement has a multitude of opportunities to positively apply professional, scientific, clinical, research and leadership aspects of their role for the benefit of healthcare and the patient. Each role will be unique and the successful Clinical Scientist will continually develop and adapt over a career in order to best meet local and national challenges. This will be achieved whilst collaborating and networking with others in order to develop and share specialist skills for the benefit of the physiological measurement specialism.

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