IPEM response to Department of Health and Social Care 'Healthcare regulation: deciding when statutory regulation is appropriate' consultation March 2022

1. Do you agree or disagree that a qualitative and quantitative analysis of the risk of harm to patients is the most important factor to consider when deciding whether to regulate a health or care profession?

Agree.

The apparatus to gather quantitative data, in order to make an informed analysis of risk of harm, must be robust or subsequent analysis will fail to represent the risk accurately.

The current risk assessment methodology for assessing and assuring occupational risk of harm has been published by the Professional Standards Authority (PSA).

This assessment process should be conducted in consultation with expert professional bodies and accredited registers who have detailed knowledge of professions, workforce intelligence, oversight of standards and current practice. This co-ordinated approach will ensure detailed evidence and workforce analysis is gathered, which will be essential for any decision making process.

2. Do you agree or disagree that proportionality, targeted regulation and consistency should also be considered in deciding whether to regulate a health or care profession?

Agree.

The regulatory landscape is currently inconsistent; due to existing targeted regulation, a side effect of which has already led to hampering a profession's (Clinical Technologists) ability to provide a public service. Such inconsistencies introduce risk to patients via variation in service provision. Care must be taken to correct existing inconsistencies and not to introduce further risks – see examples below.

- In Nuclear Medicine (NM) practice (including advanced clinical practice) operators are simultaneously subject to statutory regulation (Radiographers) and effectively deregulated (Clinical Technologists) - a wholly inconsistent framework.
    - **Radiographers and Clinical Technologists working in Nuclear Medicine (NM) have the same job descriptions and deliver the same role.** While statutory registration is required to act under the protected title 'Radiographer', employers advertise these posts to radiographers and clinical technologists. While PSA Accredited Registers exist for Clinical Technologists these are wholly voluntary therefore an employer may consider registration desirable but cannot currently require it. Health and Care Professions Council (HCPC) registration and maintenance is costly, yet there is no requirement to maintain registration, for example, a Radiographer in NM could work without the protected term as a Clinical Technologist. British Nuclear Medicine Society (BNMS) data demonstrates this is a mixed workforce with a deepening crisis in supply of trained operators [1] – making standardisation from statutory registration impetrative for service delivery and therefore patient safety – see examples below.
    - **Examples of hampering a profession to provide a public service:** Clinical Technologists routinely give intravenous (IV) Prescription Only Medicines

(POM), perform SPECT-CT scans and PET/CT. They operate under a Statutory Instrument, The Human Medicine Regulations 2012 to give POM, including radioactive POM. **Clinical Technologists are hampered due the legislative frameworks only open to Allied Health Professionals, for example, they cannot use Patient Group Directives, which would be useful for giving IV CT contrast.** [2] Also, to be a Practitioner under the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER), one must be a registered health care professional, for example, **if, while acting as an operator, it was obvious that a patient required an additional exposure, Radiographers may act as an IR(ME)R Practitioner and justify the exposure, while Clinical Technologists cannot - they may only function as Operators under IR(ME)R.** [3] **This inconsistency in the workforce introduces delay with its subsequent risks into the patient journey. In addition, Nuclear Medicine is a rapidly changing field due to the exponential clinical demand for hybrid imaging – radically changing Operators scope of practice.** [4-6]

3. Do you agree or disagree that the currently regulated professions continue to satisfy the criteria for regulation and should remain subject to statutory regulation?

Agree.

In response to question 2, we have demonstrated that the regulatory landscape is currently inconsistent; due to existing targeted regulation, a side effect of which has already led to hampering a profession's (Clinical Technologists) ability to provide a public service. This already exposes patients to inconsistencies in service provision and effective deregulation, as employers may not require employees to be on a PSA register. Removing statutory regulation would hamper the workforce, as access to enabling legislation is often linked to being on a statutory register. Hampering the workforce, leads to delays in service provision with its associated risk to the patient.

4. Do you agree or disagree that currently unregulated professions should remain unregulated and not subject to statutory regulation?

Disagree.

There is an opportunity for a review of current accredited registers as set out by the PSA in their document 'Right-Touch assurance: a methodology for assessing and assuring occupational risk of harm'. With the emergence of new professions that are being considered for statutory registration, then this should be extended to include professions that are evolving into new areas of work. The difference in registration requirements for Radiographers and Clinical Technologists working, for example, in the field of hybrid imaging, shows there is work required in this area to address any disparities. Statements concerning the joint Radiography and Clinical Technologist workforce have drawn attention to the increased risk to patients e.g. "CT examinations have potential to deliver relatively high radiation doses in very short time frames." [7]

Where it can be shown that a profession's scope of practice is changing, then the PSA should be commissioned to risk assess the profession to determine whether a current unregulated profession should remain unregulated or whether it should now be considered for statutory registration. For example, Clinical Technologists' training has recently been updated to specifically satisfy new National Occupational Standards (NOS) in hybrid imaging. [8]

Clinical Technologists already provide Advanced Clinical Practice, fulfilling roles previously performed by medical staff, with no requirement to be registered. Advanced practice profiles for Clinical Technologists and AfC Bandings are provided via the NHS Confederation pp 14-25. These roles are based upon national policy and framework documents which provide definitions of advanced and consultant level practice for multi-professional and Allied Health Professionals.

Advanced Clinical Practice in NM by Clinical Technologists is a mature and internationally recognised field of practice. [9 – 13]

Examples of Advanced Practice by Clinical Technologists in NM:

Cardiac Stress Testing

The skill level of non-medical staff undertaking a medical task is commensurate to that of a doctor. [14] The required skill set includes: Advanced physical assessment of the cardiovascular and respiratory systems via Observed Structured Observation and Clinical Examination (OSCE) with structured communication techniques. Knowledge of how comorbidities and associated polypharmacy affect stress testing. 12 Lead ECG and exercise interpretation. The selection / justification of suitable methods of stress. **The recognition of the deteriorating patient and selected therapies, for example, POM, to immediately correct potentially life threatening adverse physiology, for example, ischaemia.** Immediate to advanced level training in resuscitation. **Examples of risk of deleterious outcomes include: Death (1 in 10000) [15], Acute Coronary Syndrome (1 in 100) [16] or potentially life threatening dysrhythmia (3.6 in 100) [17].**

Radiotherapy

The therapy lead role is responsible for coordination of all procedures in a multidisciplinary spirit. **Requires multi-system advanced clinical skills, including physical assessment, cognitive and communication skills** to: consult with and assess patients, obtain consent, perform risk assessments, liaise with the Administration of Radioactive Substances Advisory Committee licence holder, Medical Physics Expert and the Multi-disciplinary Team (MDT). This may include organising appropriate imaging / biochemistry pre-therapy, delivery of therapy and adjuvant POM with associated (OSCE) and management of side effects, through to discharge of the patient with organisation of restrictions. Post therapy procedures, for example, Somatostatin analogue injections and post therapy imaging, with its associated interpretation. As necessary, in tandem with the MDT, refers to other modalities, including hospice. **Examples of risk of deleterious outcomes commonly (1 in 10) include: Osteonecrosis, leukopenia, neutropenia, and pancytopenia. Less commonly (1 in 100) include: osteonecrosis of jaw or lymphopenia.** [18]

Reporting

Reporting by non-medical professionals (technologists, radiographers, and Clinical Scientists) is an established and evolving field of advanced practice that has revolutionised the cost-effectiveness and time management of patients [19-24]. Practitioner work within an agreed Scope of Practice which may encompass the summation of information from: multiple related scans / procedures; finding such: as pre-test clinical assessment, exercise tolerance ECG and physiology data as well as the patients' history to form salient clinical conclusions / assessment of risk or recommendations. **Examples of risk**

associated with reporting are well known, for example, a false positive Myocardial Perfusion Scan may lead to a patient undergoing coronary angiography, which has a 1 in 100 chance of death of myocardial infarction. A false negative may lead to a diagnosis of non-cardiac chest pain which account for a third of those who die within 5 years of follow up (3 in 100). [25-26]

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