Mini Review

Australia and New Zealand, So Close Yet So Far: A Mini Review of Educational and Professional Standards in Medical Laboratory Science

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Medical scientists have a crucial role in diagnostic medicine but are undervalued as a profession. These practitioners must understand clinical laboratory tests and procedures and remain abreast of advancing technologies, emerging commercial analytical instruments and newly developed diagnostic testing kits. Globally all medical scientists require the same standard of training and professional performance.

Every country has professional and educational standards which are often aligned with the international standards and requirements for the quality and competence of medical laboratories (ISO15189 standards). Despite similarities in standards and increased global mobility of workforces, lack of formal recognition of medical scientists across the world has caused a shortage of competent and skilled laboratory professionals, who are restricted in their ability to move to other countries for work. This paper compares two very close countries which recognize and share many resources and professional standards. However, the oversight of medical laboratory science programs and staff varies significantly. One important factor is the lack of national registration for practicing medical scientists. Both countries have very high professional standards and high quality of patient care, but only New Zealand has both institutional and individual professional accountability while in Australia, medical scientists are not held responsible by the Australian Health Professional Regulation Agency (AHPRA).

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Introduction and Background

For over more than a century, the medical scientist (laboratory medicine) profession has evolved by constantly adapting to changing technology and educational demands coupled with growing medical knowledge. The role of medical scientists involves the interpretation of clinical data and consultations with medical staff in addition to the traditional tasks of patient sample analysis and testing. Medical scientists work in clinical laboratories located in hospitals, community-based settings including physician offices and large privately run organizations, reference laboratories, biotechnology laboratories, and non-clinical industrial laboratories. There is a need for both greater specialization and/or multidisciplinary work force to meet the needs of the population, requiring uniform adherence to national and international professional standards to maintain public safety.[1] Despite performing similar roles in health care internationally, do the differences in training, education, laboratory regulation and standards pose a barrier to the global mobility of this specialized workforce? What does this mean for the future development of the medical scientists and technicians' role and diagnostic patient care in a very mobile global patient population? Will tertiary education and its educators perform a vital role in reaching the goal of a cross-border and cross disciplinary globally mobile workforce with the confidence of providing services of equally high standards?

A medical scientist (also referred to as a clinical laboratory scientist, biomedical scientist or medical laboratory scientist) is a healthcare professional who performs chemical, hematological, immunologic, microscopic, and bacteriological diagnostic analyses on body fluids and specimens. Given the key role of the medical scientists in the diagnostic chain of patient care, standardised training, national accreditation of educational programs and registration/certification of practising scientists is essential. The role of the medical scientist is similar across the globe, yet educational requirements vary greatly in terms of accreditation of educational programs, routes into the profession, clinical placement requirements and certification or registration of graduate practitioners. Due to continually advancing techniques in pathology, the practitioner is required to remain informed of scientific advancements, making sure their expertise is always evolving with the implementation of new technologies instead of being replaced by them.

National or international recognition of qualifications permits medical scientists to work and gain experience in diagnostic laboratories across the world. However, the global diagnostic training programs have developed to a point where this can occur. Most developed countries have formal registration of medical scientists and technical officers to protect the public and set minimum standards for ongoing assessment of competency and continuing professional development (CPD). Compulsory registration or certification of practising scientists and technicians not only strengthens and encourages adherence to national professional standards but also benefits the profession, the employers and public in the form of patient care.

Countries including Australia and a few others, do not have formal national registration of medical scientists. The Australian Health Professional Regulation Agency (AHPRA) ensures that health practitioners in Australia are suitably trained, qualified and safe to practise, however it does not currently oversee the registration of medical scientists.[2] Australia does have stringent professional standards and guidelines for organisational accountability but not at individual practitioner level. In New Zealand and the United Kingdom, the qualifications of each medical scientist in the country is standardized under a nationwide regulating body, while other countries such as United States of America have variations in educational requirements between different states.[3-5] In the absence of national registration, the Australian Institute of Medical and Clinical Scientists (AIMS) has initiated a voluntary self-regulated certification scheme,

which requires on going continuous professional development (CPD) beyond a basic undergraduate and/or post graduate degree in Laboratory Medicine. [6]

Accreditation of clinical pathology laboratories

All public pathology laboratories must adhere to high standards in safety and quality.

Australia

Despite no formal recognition of medical scientist qualifications in Australia, most of the pathology laboratories in which they are employed (except some smaller specialized and private ones), must be registered with the National Association of Testing Authorities (NATA) which is the independent accreditation body for laboratories, inspection bodies, calibration services, producers of certified reference materials and proficiency testing scheme providers in Australia.[7] The National Pathology Accreditation Advisory Council (NPAAC) sets the standards and requirements that laboratories must meet in Australia for safe and quality laboratory practice.[8] Laboratories must adhere to these guidelines and obtain accreditation to be eligible for Medicare (publicly-funded universal health care insurance scheme in Australia, operated by the nation's social security department) rebate able services. NATA together with the Royal College of Pathologists Australia (RCPA) assesses laboratories against national standards set by NPAAC. A few testing protocols available through private pathologies may not be accredited, and as such they cannot offer services covered by the universal health care system and patients must pay out of pocket to cover diagnostic health care costs. The functions of NPAAC include providing advice to the Commonwealth, the States and the Territories on a range of accreditation issues. NPAAC also incorporates in its national standards the recommendations from Australian Commission on Safety and Quality in Health Care (the Commission) for improvements for safety and quality in health care across Australia.[1] In addition, medical laboratories are guided and governed by the National Blood Authority (NBA), established jointly by Australian, State and Territory Governments with an aim to improve and enhance the management and audit of the Australian blood and plasma products provided to hospital laboratories for patient care and research use. [9]

New Zealand

New Zealand requires most of their clinical pathology laboratories to be accredited by International Accreditation New Zealand (IANZ) which certifies medical laboratories in line with NZS/ISO 15189 "Medical Laboratories – Particular requirements for quality and competence."

A major difference to Australia besides laboratory accreditation, is that all practising scientists and technicians must also be registered and hold an annual practising certificate to work in pathology laboratories in New Zealand. This higher level of individual accountability is not seen in Australia.

Accreditation of educational programs and competency standards in Australia and New Zealand

Accreditation of university programs ensures a high standard of medical laboratory science undergraduate and post-graduate programs. The purpose is to continue to set university program educational standards as the industry minimum for diagnostic medical scientists. Competency has been defined as "the ability to perform the activities within an occupation or function to the standard expected in employment."[10] It embodies attributes such as knowledge, skills, abilities, attributes, and attitudes required in professional practice.

Australia

Competency standards for Australian medical scientists working in a diagnostic pathology setting have been developed to reflect the contribution normally expected from a person with a degree in a relevant area of science or applied science from an Australian (or equivalent) university, together with two years

relevant professional experience in an accredited laboratory. This is the entry level of a medical scientist to this profession and reflects a combination of qualifications, skills and the assumption of personal responsibilities and accountability. Educational programs have been designed to provide graduates with these skills and competences.

In Australia, the primary qualification for medical scientists is a three- or four-year degree in medical laboratory science / laboratory medicine, which is reviewed and accredited by AIMS.[11] The programs are then reviewed every five years to ensure standards are maintained. In the final year of these programs, most students specialize in one or more medical science disciplines. Upon successful completion of a biomedical laboratory science program, graduates are classified as medical scientists and eligible for graduate membership of AIMS. Alternatively, a graduate with an AIMS accredited two-year full-time Master's degree in laboratory medicine, is also eligible to work as scientist in the discipline of their specialization.

In the absence of compulsory registration of practitioners, AIMS provides the required guidelines aligned with professional standards set by the NPAAC to ensure the graduates are work ready and trained to the highest standards.[8] One of the means of accomplishing that is through clinical placement. Clinical placement is a core component of an AIMS accredited degree program which can be spread over the 4 years of the program. It must include $\geq$560 hrs. placement in a NATA /ISO accredited laboratory but should not be only observational. Students must always work under supervision and cannot release any patient results.[11] The Australian *Qualifications* Framework (the national policy for regulated qualifications in Australian education and training, AQF) level 7 (graduates at this level will have broad and coherent knowledge and skills for professional work and/or further learning) in Australia is equivalent to New Zealand Qualifications Framework (NZQF) level 7 in NZ. Currently 13 universities in Australia offer AIMS accredited laboratory medicine specific degree programs.

New Zealand

In New Zealand, accreditation of Medical Laboratory Science programs is granted by the Medical Sciences Council (the Council) of New Zealand.[3] The council provides guidelines for medical laboratory science education programs to institutions and organizations that issue qualifications that enable graduates to apply for registration with the Medical Sciences Council in the medical science profession. Accreditation is based on the "Policy and Guidelines: Accreditation of Prescribed New Zealand Qualifications." This policy document applies to providers of New Zealand qualification programs accredited by the Medical Sciences Council for the purpose of registration in the medical laboratory science profession.[3]

The Medical Sciences Council 2014 publication (revised in 2020) states the standards and procedures for the accreditation of education programs leading to registration in the medical laboratory scientist scope of practice. [12] As a responsible authority under the Health Practitioners Competence Assurance Act 2003 (the Act), the Council is charged with describing the work of the medical laboratory science practitioners it regulates by setting competence Standards for Medical Laboratory Science Practitioners in Aotearoa New Zealand (revised November 2018).[13,14] The accredited educational programs are aligned with the council's competency standards.

Previously there was a 5-year cycle of accreditation of degree programs, which has changed now to an ongoing cycle of monitoring. Following the initial review of the program and subsequent accreditation, a qualification program is subject to an ongoing monitoring schedule. It maximizes the likelyhood that students/trainees enrolled in the program can complete their studies and graduate with a qualification recognized by the Medical Sciences Council for registration.

To become a fully qualified medical scientist in New Zealand, a minimum of a 4-year

Bachelor of Medical Laboratory Science degree and work as a trainee medical laboratory scientist for at least 6 months is required.[3] The graduates are then required to register as a Medical Laboratory Scientist with 'The Medical Science Council of New Zealand.' Every employee of a clinical laboratory must hold a current annual practicing certificate. Currently 3 universities in New Zealand offer the recognized laboratory medicine specific degree programs.

Professional certification/registration and continuing professional development

The evolution of professions that must constantly adapt to both changing technologies and educational demands as the medical knowledge base grows, is maintained universally under the guidance and direction of professional bodies. The focus of registration or certification of practitioners in a profession is usually centred on the core areas of advocacy, members, events, professional development, continuing education, research and innovation. In addition to providing education, other activities include networking opportunities locally, nationally, and globally. As the medical science environment continues to change, certification and/or registration by professional organisations is a means of providing vital support to practitioners and an essential professional and educational partnership for their membership and the profession to ensure the sector is recognised and respected.

Australia

The AIMS offers voluntary certifications for medical scientists and technicians. Certification is valid for up to three years after a successful skills assessment. While this is not a requirement, certifications can help boost credibility in this field, and some employers require/recommend certification. Conditional certification runs for a maximum of two years, after which certified scientists/technicians are required to undergo competency assessment and provide CPD records to transition to full certification.

Status as a certified medical scientist is a formal recognition of scientific qualifications and is aligned with competency development and assessment processes and acknowledges their ongoing participation in CPD activities. Certification demonstrates increased professional credibility and prestige in the industry. It is anticipated and currently observed that employers are increasingly looking to certification as a desirable attribute during the recruitment process and online competency assessment tools used to register CPD. Certification demonstrates to employer the continued competence in a standardised way, reducing the burden of employers to update staff through providing professional development activities. This is one step closer to compulsory registration for all scientists and technicians working in the laboratory medicine industry. However currently, certification is voluntary and it does not guarantee uniform standards and accountability across the profession.

New Zealand

Medical scientists in Aotearoa New Zealand practise within a legislated regulatory framework under the Health Practitioners Competence Assurance Act 2003.[13] The Competence Standards revised in Nov 2018 (Aotearoa New Zealand) are directly linked to the three medical laboratory science scopes of practice defined by the Council under the Act.[14] Defined scopes of practice protect the health and safety of the public using professional titles. Only individuals who hold current registration with the Medical Sciences Council are permitted to use the professional titles of: Medical Laboratory Scientist, Medical Laboratory Technician and Medical Laboratory Pre-Analytical Technician.

New Zealand does have alternative pathways for the graduates of other non-accredited science degree programs. These graduates or medical laboratory science technicians may be able to do a shorter qualification in medical laboratory science courses to become a medical scientist, provided they are registered as a medical laboratory technician and have

worked in a New Zealand medical diagnostic laboratory for at least one year. Overseas trained scientists, including those from Australia, need to obtain provisional registration and apply for an annual practising certificate before working in a laboratory. Initially they work under supervision of their registered medical laboratory scientist for 3-24 months, before their provisional registration changes to full registration.

Discussion

Medical scientists comprise a very large health practitioner workforce that are required to generate accurate results following the analysis of biological samples and tissues and to communicate the outcomes to medical practitioners for the diagnosis and subsequent treatment of disease. While medical scientists are educated and trained to a very high standard in accredited clinical pathology laboratories across the world, there are significant barriers to the mobility of this workforce due to the inconsistent oversight of the qualifications and training of medical scientists between countries. This article highlights these differences between two countries in the Australasia region, Australia and New Zealand.

As in most countries, the practice of a profession in Australia requires evidence of an appropriate level of education and practical experience. However, there is no statutory registration or licensing of medical scientists or technicians in Australia, although there is a voluntary certification scheme approved by the Australian Council for the Certification of the Medical Laboratory Scientific Workforce. There are additional fragmented checks and controls that oversee the quality of clinical pathology laboratories that ensure a very high standard of diagnostic health care delivery in Australia and the justification by the Australian government for the lack of individual registration or annual practicing certificate requirements to work as medical scientist in the country. As there is no formal registration of medical scientists in Australia, the Commonwealth Government would be required to legislate mandatory registration of medical scientists and if they were to do so, the profession would be administered by AHPRA.

New Zealand which is very close geographically, politically, fiscally and has economic cooperation with Australia has different requirements for the registration of practicing medical scientists. There are also similarities in professional standards aligned to ISO15189 in both countries, with a significant variation in the recognition and accountability of medical scientists and technicians' work. Scientists from New Zealand can work in Australia unconditionally, however scientists trained in Australia must go through registration if they seek employment in New Zealand. One of the criteria to easily obtain registration in New Zealand is through providing evidence of current registration status in the candidate's home country. This is not available to Australian trained and experienced scientists. Lack of national registration of medical scientists with AHPRA in Australia has an impact on the mobility of graduates and practicing scientists despite very high and equitable standards of tertiary education and professional standards in laboratory practice.

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