# A comparative study of the medical scientist profession in Australia and around the world to provide evidence for a review of the current self-regulatory framework.

# A COMPARATIVE STUDY OF THE MEDICAL SCIENTIST PROFESSION IN AUSTRALIA AND AROUND THE WORLD TO PROVIDE EVIDENCE FOR A REVIEW OF THE CURRENT SELF-REGULATORY FRAMEWORK.

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*Submitted in fulfilment of the requirements of the degree of*

*Doctor of Philosophy on the 21st of June 2021*

## Statement of Originality

*This work has not previously been submitted for a degree or diploma in any university. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.*

Name: Allan James Hicks

Signed:

Date: 21st of June 2021

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| | |
|---|---|
| **AACB** | Australasian Association of Clinical Biochemists |
| **ABC** | Australian Broadcasting Corporation |
| **ABPath** | American Board of Pathology |
| **ACC** | American College of Cardiology |
| **ACIP** | Advisory Committee on Immunisation practices |
| **ACCMLSW** | Australian Council for the Certification of the Medical Laboratory Scientific Workforce |
| **ACSLM** | Academy of Clinical Science and Laboratory Medicine |
| **AHF** | Australian Heart Foundation |
| **AHPRA** | Australian Health Practitioners Regulation Agency |
| **AIMLT** | Australian Institute of Medical Laboratory Technology |
| **AIMS** | Australian Institute of Medical and Clinical Scientists |
| **ALG** | Accreditation Liaison Group |
| **ANZSCO** | Australian and New Zealand Standard Classification of Occupations |
| **APACE** | Australasian Professional Acknowledgement of Continuing Education |
| **AQF** | Australian Qualifications Framework |
| **ASC** | Australian Society of Cytology |
| **ASCP** | American Society of Clinical Pathology |
| **ASCP BOC** | American Society for Clinical Pathology Board of Certification |
| **ASM** | Australian Society of Microbiology |
| **ASMT** | American Society for Medical Technology |
| **BLS** | Basic Life Support |

| | |
|---|---|
| **BSc** | Bachelor of Science degree |
| **BSc (Hons)** | Bachelor of Science degree with Honours |
| **CAE** | Colleges of Advanced Education |
| **CDC** | Centres for Disease Control and Prevention |
| **CORU** | An Chomhairle um Ghairmithe Sláinte agus Cúraim Shóisialaigh |
| **CPD** | Continuing Professional Development |
| **CPSM** | Council for Professions Supplementary to Medicine |
| **CS** | Clinical Scientist |
| **CSANZ** | Cardiac Society of Australia and New Zealand |
| **CSMLS** | Canadian Society for Medical Laboratory Science |
| **CVD** | Cardiovascular disease |
| **DHS** | Department of Human Services |
| **ESC** | European Society of Cardiology |
| **EU** | European Union |
| **GMC** | General Medical Council |
| **HCPC** | Health and Care Professions Council |
| **HCA** | Human Capital Alliance |
| **HGSA** | Human Genetics Society of Australasia |
| **HRPA** | Human Resources Professionals Association |
| **IBMS** | Institute of Biomedical Science |
| **IMC** | Irish Medical Council |
| **IMLS** | Institute of Medical Laboratory Science |
| **IMLT** | Institute of Medical Laboratory Technology |

| | |
|---|---|
| **IANZ** | International Accreditation New Zealand |
| **IEC** | International Electrotechnical Commission |
| **IFCC** | International Federation of Clinical Chemistry and Laboratory Medicine |
| **ISA** | International Federation of the National Standardising Associations |
| **ISO** | International Organization for Standardisation |
| **MBA** | Master of Business Administration |
| **MPhil** | Master of Philosophy |
| **MSc** | Master of Science |
| **MCNZ** | Medical Council of New Zealand |
| **MoPH** | Ministry of Public Health (Qatar) |
| **MS** | Medical Scientist |
| **MSCNZ** | Medical Sciences Council of New Zealand |
| **NAACLS** | National Accreditation Agency for Clinical Laboratory Sciences |
| **NATA** | National Australian Testing Authority |
| **NPAAC** | National Pathology Accreditation Advisory Council |
| **NRAS** | National Registration and Accreditation Scheme |
| **NZIMLS** | New Zealand Institute of Medical Laboratory Scientists |
| **NZIMLT** | New Zealand Institute of Medical Laboratory Technology |
| **PBLAA** | Pathological and Bacteriological Laboratory Assistants Association |
| **PAC** | Pathology Associations Council |
| **PhD** | Doctor of Philosophy |
| **PLC** | Permanent Licensing Committee |
| **PSA** | Prostate Specific Antigen |

| | |
|---|---|
| **QCHP** | Qatar Council for Healthcare Practitioners |
| **QC** | Quality Control |
| **QML** | Queensland Medical Laboratory |
| **QUPP** | Quality use of Pathology program |
| **RCPath** | Royal College of Pathologists |
| **RCPSC** | Royal College of Physicians and Surgeons of Canada |
| **RMIT** | Royal Melbourne Institute of Technology |
| **SA Path** | South Australia Pathology |
| **SLS** | Safety Learning System |
| **SNP** | Sullivan Nicolaides Pathology |
| **RCPA** | The Royal College of Pathologists of Australasia |
| **TGA** | Therapeutic Goods Administration |
| **TO** | Technical Officer |
| **NHS** | UK National Health Service |
| **NICE** | UK National Institute for Health and Clinical Excellence |
| **UNSCC** | United Nations Standards Coordinating Committee |
| **WHO** | World Health Organisation |

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I hope that this inspires you to reach your own potential

and to my mother, Valerie, who helped me take the first steps on this journey

**Acknowledgement of Published and Unpublished Papers included in this Thesis**

Included in this thesis are papers in *Chapters 1, 4 5 and 9* for which I am the primary author. Appropriate acknowledgements of those who contributed to the research but did not qualify as authors are included in the acknowledgement section. The bibliographic details (published or submitted for publication) for these papers are:

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Additionally, included in the thesis are papers in Chapters 4 which are co-authored with other researchers. My contribution to each co-authored paper is outlined at the front of the relevant chapter. The bibliographic details (if published or accepted for publication)/status (if prepared or submitted for publication) for these papers including all authors, are:

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(Countersigned) _____ (Date) _____

Supervisor: Name of Supervisor

**Abstract**

In 2010 the Australian Government established the Australian Health Practitioner Regulation Agency (AHPRA) to oversee the registration requirements of fifteen healthcare professions. The official reason reported for the exclusion of Medical Scientists and technicians was that these laboratory personnel do not impact patient outcomes significantly and are sufficiently regulated by laboratory accreditation and the oversight of a Registered Pathologist. The Australian Institute of Medical and Clinical Scientists and the other pathology societies have communicated with the government on several occasions asking for a review of this decision.

In early 2020 a global pandemic provided a unique opportunity for the leaders of the Pathology industry in Australia to promote the work of Medical Scientists as pathology testing is the only definitive method to ascertain a patient's COVID status. However, in Australia there has been very little mention of Medical Scientists in a public forum. This document aims to address the main reasons that the Australian Government continues to be disinterested in the recognition and importance of Medical Scientists in the healthcare system of the country.

To better understand the advantages and disadvantages and provide possible recommendations for addressing these, the initial chapters describe the regulation of pathology laboratory workers in various countries. A close look at the common misconception that pathology testing influences approximately 70% of all clinical outcomes follows, finding in fact, this statement has no scientific basis. Therefore, following collaboration with colleagues a review of clinical guidelines for the most common cause of death around the world, Cardiovascular disease (CVD), was conducted.

The analysis found that the accepted guidance recommends pathology testing in closer to 80% of all cases of CVD and 94% of suspected cases in Australia. When coupled with nearly 100% of all cancer diagnoses and transfusions this shows definitively for the first time that laboratory testing has a considerable impact on patients' outcome. The other argument that is used by the Pathology industry leaders in Australia is that a registered Pathologist is sufficient to address any issue that might occur within a laboratory.

Internationally, developed nations have recognised that this is not the case and seek to regulate the scientist workforce to ensure that the public are properly protected by appropriately addressing incidents and implementing robust change. Unfortunately, analytical errors occurring in Australian laboratories that have been poorly investigated and therefore provide little apparent impetus for improvement. To support recommendations in the present study two surveys were conducted, initially of a group of international laboratory workers from a large group of countries working in a hospital in Qatar and a small number of Australian respondents.

Responses to the first survey were analysed and the themes of professional impact and personal implications of regulation were used to design a more focused survey for a larger group of Australian Medical Scientists. The results showed that the profession was under-recognised in Australia because of the lack of professional registration, however, further regulation to improve this did not have universal support. The most dramatic responses were to the question in the second survey about the impact of the COVID-19 pandemic on the workforce in Australia.

These highlighted a workforce under extreme pressure suffering burnout and exhaustion, with misguided recognition of their contribution to the nation's pandemic response being happily accepted by the other healthcare professions.

In Australia, AHPRA as the governmental regulatory body for those nationally recognised healthcare professions and works with the leaders of these professions to maintain an official register of practitioners. The duty of monitoring individual Continuing Professional Development (CPD) and disciplinary measures are given over to the respective governing body which are mandatory to hold a practicing licence.

At the highest level the National Pathology Accreditation Advisory Council (NPAAC) provide policy expertise to the Department of Health for the management of the Pathology service in Australia. As such this body provides occupational definitions, qualification requirements and employment controls which are largely currently not applied to Medical Scientists or are industrially irrelevant. This lack of recognition is likely to have a negative effect on the recognition of the importance of Medical Scientists in diagnostic laboratories and provision of pathology reports, at a time when their role and responsibilities are increasingly highlighted.

It is the purpose of this thesis to highlight current deficiencies in the regulation management of this group of workers in this dynamic industry and suggest appropriate recommendations that will hopefully raise awareness of the profession in Australia.

## 1. Background: Medical science - A forgotten profession in Australia

*Adapted from the article published by the Australian Journal of Medical Science, Vol. 40, No. 3, pg.76-82*

### 1.1 Introduction

Historically, the only professions recognized prior to the Industrial Revolution were: Divinity, Medicine and Law; these were called the "learned professions" [1]. During the 19th Century, the increasing global industrialisation led to an expansion of the skilled working population. This expansion provided an opportunity for like-minded individuals to begin meeting locally and to discuss the merits of their occupations. These meetings and their discussions led to the formation of the first professional societies, with a rudimentary form of self - regulation. By doing so they ensured that full legal incorporation and government recognition could be achieved.

The articles of professional membership afforded some protection for members and recognition of their contribution to the community at large. Some of the major milestones that mark an occupation as a profession include:

- a defined scope stating the profession's purpose and goals.
- qualifications for education, experience, and professional development.
- a code of professional conduct to guide what is to be done under given circumstances.
- recognized certification or practicing license that requires maintenance.
- Standards that are consistent with other peer groups. [2]

In Australia, this definition has been applied to many professions and is not restricted to healthcare occupations. Surveyors, teachers, builders, plumbers, and electricians all meet the above criteria. Members of these occupations are required to maintain a practicing license, which is recorded on an independently monitored register backed by legislation to protect the public and the worker. For example, the minimum requirement for renewing an electrician's licence is by approved CPD for skill maintenance and evidence of annual basic life support (BLS) training [3].

In June 2004, the Council of Australian Governments (COAG) commissioned a study of the health workforce in Australia. By the end of the following year a 400 page report was tabled by the Australian Government [4]. This extensive document only mentions "Medical Scientist" four times, in two tables and a paragraph about Medicare charges and recording the submission made by the Australian Institute of Medical and Clinical Scientists or as it was known at the time the Australian Institute of Medical Scientists (AIMS).

One of the recommendations of the report was for the formation of a national accrediting body for Healthcare Professions, at the time each state had its own registration process. This recommendation was based on the need for control of a profession that exposed an increased risk of harm to the public and to set national guidelines. As a consequence, National Registration and Accreditation Scheme (NRAS) established the Australian Health Practitioner Regulation Agency (AHPRA) in 2010 to implement the process [5].

In 2016 the Accreditation Liaison Group (ALG) of AHPRA, published a “Comparison of international accreditation systems for registered health systems”. [6] They identified the United Kingdom, Ireland, America, Canada and New Zealand as examples of developed western countries. Those nations were considered Australia’s closest philosophical neighbours “chosen as they have comparable health standards” [6] with “well established regulatory structures and comparable standards of education in their health professions” [6].

Despite the consistency in regulating the medical science profession among the comparable countries, this requirement for regulation does not extend to Australia. This point of difference is due to apparent legal constraints governing AHPRA, which is laid down in the 2008 document “Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions” [5] signed by the Premiers of each State and the Prime Minister.

In this document six criteria were defined to assess whether a profession required regulation and Chapter 7 of this thesis analyses them in depth. Initially querying if it is possible or practical to regulate the occupation, with further conditions around the nature of the work including potential harm to the public and existing controls. It would be beneficial, to take a closer look at those countries identified in the report and understand why the laboratory workers who perform medical laboratory tests on blood, other body fluids and tissues to assist clinicians in the diagnosis, treatment and prevention of disease [7] known as Medical Scientists in Australia are considered different and why this profession doesn’t meet the requirements set by AHPRA.

### 1.1.1 The United Kingdom

With the rise of technology and occupational specialization, many groups in the UK began to develop professional status. Occupations such as pharmacists, psychologists, nurses, and teachers could claim to have become professions by 1900. While laboratory workers at the time had varied duties and skills that assisted the medical profession, their professional status took longer to evolve.

In 1912, the Pathological and Bacteriological Laboratory Assistants Association (PBLAA) was founded in Liverpool as an initial step towards recognition. The members continued to be self-regulated up until the beginning of the Second World War, when the Emergency War Committee took over functions of the PBLAA. [8] Its reinvention as the Institute of Medical Laboratory Technology (IMLT) in 1942 led to the development of education frameworks for night school students and in 1945 they introduced a "Fellowship by Thesis". [8] The first PBLAA examinations were held in 1921, and the new IMLT revived these with their inaugural "Intermediate and Final" examinations in 1947. The "Fellowship by Dissertation" followed in 1953 [8].

By 1961, the first members were placed on the Council for Professions Supplementary to Medicine register (CPSM). The first Bachelor of Medical Laboratory Science was offered by Portsmouth Polytechnic in 1974. Four years later the IMLT was rebranded to become the Institute of Medical Laboratory Science (IMLS) and phased out the "final" examinations which had been in use for thirty years up to this point [9].

The Institute of Biomedical Science (IBMS) evolved from its predecessor ,the IMLS, in 1994, [9] and along with the Health and Care Professions Council (HCPC) [10] provides a model for regulation of Medical Scientists globally. This model comprises two critical parts, the first, the IBMS, provides education, training support and assessment of its member's competencies. The second, the HCPC, is an independent regulatory government body and was introduced to protect the public by defining standards of professional care and behaviour for the Health professions.

While foreign trained and educated Medical Scientists in the UK can be employed in laboratories without registration there is considerable financial advantage and professional recognition to being registered. Any UK national must hold a current registration with the HCPC to use the protected title of Biomedical Scientist as part of the registered profession.

### 1.1.2 Ireland

The story of Medical Laboratory Science in Ireland began in 1922 with the formation of the Irish Free State. Initially, the profession was governed as a branch of the IMLS. In 1961, the formation of the Medical Laboratory Technology section of the Workers' Union of Ireland provided the impetus for establishment of the occupation. However, the early years were not easy with the union calling several strikes to gain some respect for their members.

The pressure brought by the union paid off, and in 1974 the Academy of Clinical Science and Laboratory Medicine (ACSLM) was established to develop a framework of acceptable qualifications. By 1981, the Academy mandated that a degree course replace the diploma as the core requirement for employment in an Irish laboratory. The following year the

Fellowship qualification was revived, completing the domestic qualifications framework, and removing the last vestiges of the old system [11].

In 1984, the Union Executive "indicated the desirability of some form of membership of a single body", and the Academy was added to the new regulations. This removed the final barrier to recognition and in 1986, the Irish Government approved the Academy as the professional body to represent Medical Laboratory Scientists. [11] In order to be employed in a pathology laboratory in The Republic of Ireland today, an employee must be a member of the ACSLM [12].

An employee is responsible for maintaining their membership by completing the required CPD. A member can apply for Fellowship once they have completed a relevant post-graduate qualification and have been a member for two years. All Senior Scientists in Ireland must be a Fellow of the Academy. By the end of 2018, statutory registration of Medical Scientists was required of the Irish Regulation body, *An Chomhairle um Ghairmithe Sláinte agus Cúraim Shóisialaigh* (CORU) [13] which provides legal support to the Academy, this mirrors the framework in the United Kingdom.

### 1.1.3 The United States of America

The American Society of Clinical Pathologist's (ASCP) was established in 1922. It aims are "to achieve greater scientific proficiency in clinical pathology and to maintain the status of Clinical Pathologists on an equal plane with other medical specialties" [14]. Dr Philip Hillkowitz led the establishment of the Registry of Medical Technologists in 1928. This was

a significant step in allowing the formation of the American Society for Medical Technology (ASMT) to represent the interests of laboratory personnel [14].

By 1953 the ASCP made provisions to include the Board of Schools of Medical Technology, which approved education programs and for three Medical Technologists to sit on its Board. The ASCP updated its constitution in 1966 to include standards for the performance of various laboratory procedures, standards of training, maintenance of a voluntary program of certification and examination of medical technologists [14].

Today, more than 100,000 Medical Technologists are certified in the USA by the ASCP and holding current certification is a requirement for employment in twelve states. Most of the other states require a nationally recognised certification to practise. The ASCP is politically active at the highest levels of government and ensures, what are some of the highest laboratory standards and practices in the world. While the system of licensing is still complex due to the various state regulations, the ASCP is the most common certification available to laboratory workers and provides considerable professional recognition worldwide [15].

### 1.1.4 Canada

Canada began the path towards a robust provincial and federal registration framework in the early part of the last century. In a paper from 1966 the Canadian Medical Association stated in their journal that the "*The interests of the Canadian Medical Association in medical laboratory technology have been evident since the establishment in the early 1930s of the Committee on Approval of Training Programs for Medical Laboratory Technologists*" [16].

The Canadian Society for Medical Laboratory Science (CSMLS) is now the federal body which governs licensing countrywide with each state maintaining an internal register of Medical Laboratory Technologists.

The CSMLS offers the first level of certification through a national examination only after credentials have been verified and English fluency has been ascertained [17]. Only then may a scientist apply to the individual State or Provincial College to be added to the register. A Medical Laboratory Technologist in Canada must participate in a considerable level of CPD to retain their practicing license, and this is mandatory to continue employment.

### 1.1.5 Qatar

During my employment in the Arabic State of Qatar I was involved with the formation of its healthcare regulation framework. Licensing of healthcare practitioners began in Qatar in 1961 with a government ruling *1961:Rule#4* [21] which provided the first reference to the Permanent Licensing Committee (PLC) of the Ministry of Public Health (MoPH) and includes the first practicing requirements for Physician and Dentists.

Then in 1983 these requirements were amended under *1983: Law#2* [22] and added *1983: Law#3* [23] with the requirements for Pharmacists. In *1991: Law#8* [24] an expansion of the Healthcare professions saw the identification of requirements for several Allied Health professions including Nurses, Radiologists Physiotherapists and Laboratory Technicians.

The Qatar Council for Healthcare Practitioners (QCHP) was established by Emiri decree [28] in 2014 and the Government has completely redesigned this system. It now boasts a robust two-tier system of registration akin to the other nations described here. The PRC works under the authority of the MoPH to oversee the application of the laws governing healthcare practitioners, which is analogous to AHPRA. The administration of registration is managed by the Registration and Licensing department, until very recently known as the QCHP, in a similar way to the individual boards in Australia.

The first step was to review all the existing Scopes of Practice resulting in an increase from a single page document for Laboratory Technologists to the current nine-page document which was approved in 2015. The same year staff began to receive their practicing licenses and were required to start recording involvement in CPD on the QCHP website [29]. All healthcare workers must record a mixture of CPD over the course of each two-year cycle to renew their practicing license an example of which can be seen in Figure 1 below.


Figure 1 - A Qatar Council of Healthcare Practitioners practicing license

### 1.1.6 New Zealand

The history of the New Zealand Institute of Medical Laboratory Scientists (NZIMLS) started in 1923, but the formation of the New Zealand Association of Bacteriologists on the 9th of April 1946 marked the true beginning. The association was renamed the New Zealand Institute of Medical Laboratory Technology (NZIMLT) in 1960 and finally became the NZIMLS in 1990 [18]. Initially membership was voluntary with its members held to a code of ethics.

This all changed in 2000, following a highly publicized case involving a lone Pathologist working in Gisborne, which was documented in the Annual Report of the Medical Council of New Zealand (MCNZ) [19]. The subsequent enquiry made forty-six recommendations to government. In 2003 the Health Practitioners Competence Act [20] required all Medical Scientists to register with the newly formed Medical Sciences Council of New Zealand (MSCNZ).

The NZIMLS and MSCNZ now provide a two-tier registration platform in New Zealand that aligns with the UK model for Medical Scientists. The NZIMLS [21] is responsible for providing and monitoring Education, offering a CPD program and for the assessing the qualifications of Technicians, Pre-analytical Technicians and Scientists. The MSCNZ [22] issues annual practicing licenses for laboratory workers, monitors competency assessment and conducts disciplinary matters.

### 1.1.7 Australia

The story of the Australian Institute of Medical and Clinical Scientists (AIMS) began in 1913, with the formation of a branch of the Pathological and Bacteriological Laboratory Assistants Association UK, (PBLAA) in New South Wales. In 1932 it was renamed the "Society of Laboratory Technicians of Australasia" and it was incorporated on the 2nd of March 1937 at the University of Sydney. Their first order of business was to publish the "Laboratory Journal of Australasia" and to design examination criteria modelled on the British system.

A training platform was discussed and was in its infancy when the onset of hostilities in Europe halted proceedings until 1944. The history of AIMS mentions that "blackout restrictions at the University of Sydney proved an interference to the society's night classes" [23]. A landmark year in Australia was 1950 when the first federal meeting of the Executive Council was held in Melbourne under the revised Australian Institute of Medical Laboratory Technology (AIMLT). The result of this meeting led to each state establishing its own Examining Council, and issuing a Federal Diploma based on a countrywide minimum educational standard.

The diploma was adopted by every state, except New South Wales, which insisted on maintaining the original Certificate-level qualification [23]. The training of Medical Scientists continued through the newly formed Colleges of Advanced Education (CAE's) and from 1966 onwards students received "Professional Diplomas" and degrees were conferred by CAE's and Institutes of Technology in Australia, it was not until a 1988 review of higher education that these were recognised.

Today, AIMS accredits 11 undergraduate and three postgraduate degrees at 10 Australian Universities [24]. At this point the history of the profession in Australia has followed a similar path to those of the other comparable countries identified by the ALG in the "Comparison of international accreditation systems for registered health systems" [6].

In 2003, a survey was undertaken of the public and other health professions in Australia to ascertain their perception of Medical Scientists. The study showed that 46% of the Medical Scientists working in Australia had a low perception of their professional status and 28% experienced low occupational satisfaction [25]. The main reasons cited were a lack of respect or recognition of their skills and opportunities for CPD. However, of note are the survey results of the public and other health professionals including doctors, nurses, radiographers, and physiotherapists.

Among the public, only 3% were aware of the role of Medical Scientists, with 19% believing that only Pathologists performed laboratory tests. When it came to other health professions, 11% were aware of scientist's scope of practice and 48% thought that Pathologists were responsible for conducting testing within a clinical laboratory [25]. In a 2016 study "A Snapshot of the Australian workplace" [26], 72% of workers sought purpose and meaning through their work. Only a third believed they were supported toward professional development by their employers.

The leadership of AIMS decided that this was not an acceptable position considering Australia's standing as a developed nation like England, America, and New Zealand, all with

legally recognised Medical Scientists contributing to their healthcare systems. Therefore, they began a lengthy campaign to address this discrepancy.

In 2006 AIMS made a Submission to the Productivity Commission study position paper "Economic Impacts of Migration and Population Growth" in which the commission was informed that; "there is no registration of Medical Scientists in Australia" [27]. The submission also stated that, "there is no gap between migration assessment and employment assessment in the case of Medical Scientists" [27]. AIMS has the federal authority in Australia to assess competency for migrant laboratory workers in the country under the Department of Immigration.

In 2007 Dr Badrick described the difficulty in making strategic decisions regarding the profession and highlighted the lack of a register meaning "there is little accurate information on numbers and demographics of Medical Scientists" [28] or an up to date scope of practice for Medical Scientists and thus "there is no clear definition what Medical Scientists actually do in laboratories" [28].

The issue was raised again in 2008 where AIMS informed the National Health and Hospitals Reform Commission "there is no statutory registration for Medical Scientists on whose professional judgment so much of the health care system depends" [29]. The latter is supported by the Royal College of Pathologists of Australasia (RCPA) public information leaflets stating that "Pathology test results influence about 70% of healthcare decisions" [30]. The basis of the 70% claim is disputed, as there is a limited amount of evidence to support that contention, however data from the Mayo Clinic Electronic Result Enquiry system

published in 2000 indicates that pathology results could influence up to 94% of all clinical diagnoses [31].

AHPRA was established to provide services to a group of fifteen professions, these professions do not include Medical Scientists, which is inconsistent with comparable best practice in overseas jurisdictions. AHPRA did not consider Medical Scientist's work of high enough risk to monitor, citing that the National Australian Testing Authority (NATA) accreditation for laboratories and RCPA registration of the Supervising Pathologist to be sufficient to provide patient protection [32].

In March 2011, the Pathology Associations Council (PAC) highlighted the lack of licensing of Medical Scientists again and in response to a directive from the Australian Government that no other professions would be considered for registration under AHPRA (at that time) and that Medical scientists should investigate appropriate means of self -regulation. The decision was made to address this with "the creation of a Certification Board and ongoing certification of Medical Scientists" [33].

This initiative was promising and in 2012, Dr. Badrick mentioned the proposed changes in his letter published in Clinical Chemistry [34]. He talked of "poor retention of scientists in the workforce and lack of a career structure are inextricably linked to role definition" [34]. Dr Badrick stated that this was being addressed by the Pathology Associations Council through the following initiatives:

- identification of roles and functions linked to skills and competencies.

- recognition of qualifications/skills/competencies/experience across all states of Australia.
- removal of barriers to career progression leading to a better developed career path for Medical Scientists in Australia. [34]

The following year the South Australian Department of Health appeared to have recognized that Medical Scientists were unregistered and sought to develop measures to protect the public, by providing guidance for health practitioners who are not members of AHPRA. These measures required the application of a Code of Conduct for unregistered medical practitioners to apply to all laboratory workers in South Australia. It was stated that from March 13, 2013, the Code must be displayed, together with information on the complaint process and evidence of staff qualifications [35].

Paradoxically, a laboratory operating in any private or public hospital, licensed health service, Ambulance service or Aged Care facility is not required to display the above documents. These exclusions encompass most places in which a laboratory would be ideally established. The South Australia Department of Health's argument to support the exclusions was to assert that "The vast majority of unregistered health practitioners will already be practicing in a manner which is consistent with the requirements of the Code of Conduct because they are committed to the provision of safe and ethical health services" [35].

The Executive Officers of AIMS are still concerned about this situation and in a submission on their website in May 2015 they inform the members that "our case was rejected as medical laboratory scientists" as they do not "directly influence patient outcomes" [36]. In 2016,

Badrick and Wilson, wrote of these recurring themes saying "If further consideration is taken for certification in Australia, prior due diligence would include comparisons with other countries and professions" [37].

To address these issues AIMS and the Australasian Association of Clinical Biochemists (AACB) have used a grant from the Quality use of Pathology program (QUPP) to employ Human Capital Alliance (HCA) consultancy to research, conduct analysis and develop a plan for the "Establishment of a national model for professional certification of Medical Scientists and technicians working in Australian pathology laboratories" [38].

The Australian Council for the Certification of the Medical Laboratory Scientific Workforce (ACCMLSW) was established in January 2020 following many years of initial work. They now offer certification requiring evidence of qualification, competency, and CPD. However, because the certification is voluntary it cannot force industry recognition or offer the most important public protection as it is unable to sanction certificants because it is not recognised by AHPRA.

"*I took it up certification as I thought it would make a difference and put me in a better position for a better job. No one cared*." – **An Australian Laboratory Technician with 15-20 years' experience taken from the survey results in Chapter 6.**

## 1.2 Discussion

Over the last decade AIMS has unsuccessfully tried to establish and align the Medical Scientist profession in Australia with the international community. Its closest neighbours and historical partners all recognize the importance of laboratory workers. They have enshrined this in law with protected titles, standards of conduct, performance, proficiency, and ethics. This is demonstrated in Figure 2 below, the four types of professional organization published in a recent article of the Human Resources Professionals Association [39].

AIMS, AACB, ASM etc (Australia)


NZIMLS (NZ), ACSLM (Ireland), IBMS(UK) ACC, ACCMLSW (Australia)

CORU(Ireland), MSCNZ(NZ), ASCP(USA), HCPC(UK), QCHP (Qatar)

*Figure 2- The four types of Professional Organisations, the national bodies are placed to provide clarity* (*reproduced with permission see appendicies*)

AIMS has a role in accrediting domestic degrees and is restricted to providing credentialing of overseas degrees only, which means that it has some of the functions of a Professional regulatory body but not all. As there is no formal requirement for Medical Scientists to be members of AIMS and, critically, no mandatory registration requirement for employment within a laboratory, then the profession is voluntarily self-regulated.

Table 1- Role of Professional body in country

| | **Educational qualification accreditation** | **Professional licensing/certification** | **Continuing Professional Development** |
|---|---|---|---|
| **United Kingdom** | IBMS | HCPC | IBMS |
| **Ireland** | ACSLM | CORU | ACSLM |
| **USA** | NAACLS | ASCP BOC | ASCP BOC |
| **Canada** | CSMLS | CSMLS | CSMLS |
| **Qatar** | QCHP | QCHP | QCHP |
| **New Zealand** | NZIMLS | MSCNZ | NZIMLS |
| **Australia** | AIMS (non-mandatory) | ACCMLSW (non-mandatory) | AIMS APACE or any other society |

In practical terms, anybody can work in an Australian clinical laboratory as there is no legal requirement for any qualification. This, combined with voluntary membership of the only group that can provide any meaningful judgement of a person's skills and qualifications, leaves the Australian public open to unnecessary risk.

The RCPA report that "*Pathology test results influence about 70% of healthcare decisions…"* Given this statement, and the expanding role of Medical Scientists with recent advancements in laboratory technology allowing auto verification and relying on the professionalism and competence of Medical Scientists. A critical evaluation is required of the decision by AHPRA that Medical Scientists do not require regulation because they do not sufficiently influence patient outcomes.

The following chapters provide a hypothesis and analysis of the benefits of professional registration with evidence based on international best practice. By providing insight into the current Australian healthcare environment and inviting suggestions for improvements and increased recognition of the work of Medical Scientists in this country.

## 2. Hypothesis and Aims

### Hypothesis

In many countries, Medical Scientists are required to hold a practicing license to be employed in clinical laboratories. This license provides recognition of the profession and protection to the public, by providing legislative backing to the governmental regulatory bodies in these countries. They maintain a register of practitioners, monitor Continuing Professional Development, and provide disciplinary measures if required.

The Australian Health Practitioners Regulation Agency (AHPRA) has decided that Medical Scientists are sufficiently controlled by a Nationally Registered Pathologist and NATA laboratory accreditation. This is partly because of the difficulty there has been in proving the contribution of Medical Scientists to the healthcare of the public.

At the same time the increasing use of technology and the changing role of the Scientist, medical oversight is increasingly not required or provided. The hypothesis is that without comprehensive clinical leadership involved in day-to-day output of laboratories, there is risk of harm to the public unless Medical Scientists fill the gap.

Therefore, are modern diagnostic Pathology laboratories best served by having a Nationally Regulated Workforce?

**Null hypothesis**

Over the last decade the AIMS have frequently highlighted the lack of professional recognition of its members. The Australian Government believe that registration for Medical Scientists is unnecessary as the provision of pathology services are already sufficiently controlled by a Supervising Pathologist and laboratory accreditation, inferring that laboratory staff do not have enough direct patient contact and that Medical Scientists do not release clinically important laboratory tests except under direct supervision. They therefore suggest that they remain self-regulated.

Therefore, modern diagnostic Pathology laboratories are best served by maintaining the *status quo* of self-regulation.

**Aims**

- To describe the development of regulation of pathology laboratories around the world

- To critically define the direct influence of pathology in patient welfare by quantifying the contribution of pathology in the diagnosis and management of cardiovascular disease.

- To address the criteria used by AHPRA with evidence from other countries showing that licensing improves patient care and prove that medical science is a profession under their definitions.

- To provide recommendations for Medical Scientist licensing in Australia based on current practice and workforce data.

- To conduct a workforce survey of Medical Scientists employed in Australia and internationally.

## 3. Materials and Methods

The first study aimed to objectively asses the contribution of laboratory medicine to healthcare by examining five guidelines associated with the world's most common cause of mortality, CVD, namely the UK National Institute for Health and Clinical Excellence (NICE), the European Society of Cardiology (ESC), the American College of Cardiology (ACC), the Australian Heart Foundation (AHF) and the Cardiac Society of Australia and New Zealand (CSANZ).

An audit was conducted of each guideline available from the various healthcare advisory bodies. Any mention of laboratory testing required for initial diagnosis or follow-up monitoring was recorded and divided by the total number to derive a percentage. While this approach is not without its limitations, but it does supply reliable evidence-based information about the impact of pathology testing on the patient.

A second study of the opinion of Medical Scientists employed in Australian laboratories and a multi-national international laboratory in a Middle Eastern country (where the author was employed in) regarding their opinions and experiences of registration and licensing. This survey received research approval from Sidra Medicine (*Protocol #1804023942 see Figure 10*) and Griffith University ethics approval (*GU ref No: 2018/724 see Figure 11*).

A study design using descriptive qualitative content analysis based on an online survey was employed. The online survey was anonymous using the Survey Monkey platform and required informed consent from the participants before they were asked to answer 25 questions, taking

approximately 15 minutes to complete. The first 22 questions were demographic allowing descriptive analysis of the respondent's age, gender, and laboratory type (public v private).

The final three open-ended questions asked the respondent's perspective on the impact of registration on the practitioner's career and on a country's healthcare system. The survey was available from June to December of 2019. Additional invitations, including reminders were sent via email by the laboratory management and AIMS executive after three months.

The survey link was sent to the Director of the Pathology laboratory of Sidra Medicine in Qatar which has at least 15 nationalities and represented the international group. The Sidra Medicine laboratory management and AIMS were the only organisations which consented to promote the survey.

A third more focused study of Australian based laboratory workers was conducted to clarify the findings of the previous survey. This survey revised questions from the previous study adding pertinent issues such as professional impact and personal implications of AHPRA registration and asked for insight into the industrial impact of the COVID-19 pandemic. *(GU ref No: 2020/793 See Figure 16).*

The data from both studies two and three were analysed using a general inductive approach with content analysis to identify key themes from the responses. This method can produce reliable and

valid results by providing a simple qualitative approach and is used in research where there are limited previous studies dealing with the phenomenon or when it is fragmented. This allows the researcher to condense raw data into a summary, establish links between the evaluation and the summary findings and develop a framework of the underlying structure of experiences or processes that are evident in the raw data.

The third study also included a list of positive and negative statements based in the themes derived from the comments made by the respondents to the previous survey. Those themes of Recognition, Regulation, Competency, Quality, Education, Standardisation, and Patient Safety were assessed using a Likert scale of strongly agree through to strongly disagree and the results can be seen in Chapter Six.

## 4. Using clinical guidelines to assess the value of laboratory medicine

**STATEMENT OF CONTRIBUTION TO CO-AUTHORED PUBLISHED PAPER**

This chapter includes a co-authored paper. The bibliographic details of the co-authored paper, including all authors, are:

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**Contributorship**: MJH identified the issue. ESK conceived the idea. AJH developed the idea by adding to the original data collected by ZLC and wrote the paper. All authors reviewed and revised the paper

## 4.1 Introduction

The contribution of laboratory medicine to patient diagnosis, management and follow-up has proven difficult to quantify with systematic evidence of improved patient outcomes scarce. [40] The phrase that 'laboratory medicine influences 70% of clinical decisions' has been published many times but the evidence to substantiate this claim is anecdotal with those in the industry agreeing that this is an underestimation.

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) established a Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes in 2012. Its purpose was twofold: first, to evaluate the available evidence supporting the impact of laboratory medicine in healthcare; and secondly to develop a study design methodology for new retrospective and prospective studies capable of generating evidence to determine the contribution made by laboratory medicine to healthcare.

The IFCC Task Force published a summary of its findings in 2015 [40] which included as one of its suggestions that the contents of authoritative clinical guidelines could provide an objective means of assessing the role of laboratory medicine in the management of specific health conditions. Clinical guidelines are documents which aim to guide decisions regarding diagnosis, management, and treatment in specific areas of heath care by using the best evidence available.

CVD is the world's most prevalent cause of mortality [41] encompassing a large number of diseases including those of heart circulation, heart failure, rhythm and valvular abnormalities as well as cerebrovascular diseases, so this study has chosen to examine national and international

cardiovascular clinical guidelines to determine what proportion of their recommendations require the use of laboratory services.

### 4.1 Methods

A review was conducted of each of the individual guidelines available on the websites of the UK National Institute for Health and Care Excellence (NICE), [42] the European Society of Cardiology (ESC),[43] the American College of Cardiology (ACC), [44] and Cardiac Society of Australia and New Zealand (CSANZ) [45] and Australian Heart Foundation (AHF) [46] as of June 2021.

Additionally, the research recorded whether laboratory involvement was required for initial diagnosis or ongoing management of care. The proportion of guidelines containing laboratory medicine recommendations was then calculated by simply dividing the number of guidelines indicating pathology testing by the total number of guidelines.

## 4.2 Results

Table 2 below shows the guidelines related to CVD available from AHF/CSANZ, NICE, ESC and the ACC and the and summarises the number and percentage indicating pathology testing for either initial diagnosis, follow up pathology testing or a combination of both.

Table 2 Summary of International cardiovascular disease guidelines

| **Organization (Country)** | **Test required for initial diagnosis** | **%** | **Follow-up testing required** | **%** | **Total number of guidelines requiring testing** | **Total number of guidelines** | **%** |
|---|---|---|---|---|---|---|---|
| AHF/CSANZ (Australasia) | 15 | 94 | 9 | 56 | 15 | 16 | 94 |
| NICE (UK) | 10 | 50 | 13 | 65 | 15 | 20 | 75 |
| ESC (Europe) | 20 | 61 | 17 | 51 | 24 | 33 | 73 |
| ACC (USA) | 20 | 63 | 25 | 78 | 25 | 32 | 78 |
| Total | 65 | | 64 | | 79 | 101 | |

Tables 3, 4, 5 and 6 on the following pages show a breakdown of the individual AHF/CSANZ, NICE, ESC, and the ACC guidelines including the date published and the tests mentioned within the body of the document.

Table 3: Australian Heart Foundation (AHF) and the Cardiac Society of Australia and New Zealand (CSANZ) Guidelines

| | **Source** | **Year Published** | **Test(s) required for initial diagnosis** | **Test(s) required for follow-up** | **Indicated test(s)** |
|---|---|---|---|---|---|
| Australian Clinical Guidelines for the Diagnosis and Management of Atrial Fibrillation | AHF/ CSANZ | 2018 | Yes | Yes | Complete Blood Count (CBC), Renal Function Tests (RFT), Thyroid Function Tests (TFT), Haemoglobin A1c (HbA1c), International Normalized Ratio (INR), Electrolytes, Lipids |
| Guidelines for the Prevention, Detection, and Management of Heart Failure in Australia | AHF/ CSANZ | 2018 | Yes | Yes | Brain Natriuretic Peptide (BNP), Genetic Testing, RFT, Creatinine, Glucose, CBC |
| Coronary Artery Calcium Scoring | CSANZ | 2017 | Yes | No | Estimated Glomerular Filtration Rate (eGFR), Glucose, HbA1c, Lipids, |
| Clinical Guideline for the diagnosis and management of hypertension in adults | AHF | 2016 | Yes | Yes | Urinalysis, RFT, Glucose, eGFR, Creatinine, Lipids, CBC |
| Guidelines for the Diagnosis and Management of Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) | CSANZ | 2016 | No | Yes | Genetic Testing |
| Clinical guidelines for the management of Acute coronary syndrome | AHF/ CSANZ | 2016 | Yes | Yes | Cardiac Troponins (cTn), Lipids, Glucose, HbA1c, eGFR, APTT, CBC, |
| Diagnosis and Management of Familial Dilated Cardiomyopathy | CSANZ | 2016 | Yes | No | Creatine Kinase (CK), Genetic Testing, |
| Diagnosis and Management of Familial Hypercholesterolaemia | CSANZ | 2016 | Yes | Yes | Lipids, Genetic Testing, |

| | | | | | |
|---|---|---|---|---|---|
| Update on the Diagnosis and Management of Familial Long QT Syndrome | CSANZ | 2016 | Yes | No | Genetic Testing |
| Diagnosis and Management of Hypertrophic Cardiomyopathy | CSANZ | 2016 | Yes | No | Histological examination, Genetic Testing |
| Update on the diagnosis and management of inherited aortopathies, including Marfan syndrome | CSANZ | 2016 | Yes | No | Genetic Testing |
| The routine cardiac assessment of newborns with Down syndrome | CSANZ | 2016 | No | No | |
| Position Statement on the Diagnosis and Management of Brugada Syndrome | CSANZ | 2015 | Yes | No | Genetic Testing |
| Guidelines for the management of Absolute cardiovascular disease risk | AHF/ CSANZ | 2012 | Yes | Yes | Urinalysis, RFT, Glucose, eGFR, Creatinine, Lipids, CBC |
| Guideline for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease. | AHF/ CSANZ | 2012 | Yes | Yes | CBC, C-Reactive Protein (CRP), Blood Culture (BC), Infectious Serology (IS), Erythrocyte Sedimentation Rate (ESR) |
| Guidelines for the diagnosis and management of Arrhythmogenic Right Ventricular Cardiomyopathy | CSANZ | 2011 | Yes | No | Genetic Testing |

Table 4: National Institute for Health and Clinical Excellence (NICE) Guidelines

| | **Year Published** | **Test(s) required for initial diagnosis** | **Test(s) required for follow-up** | **Indicated test(s)** |
|---|---|---|---|---|
| Hypertension in Pregnancy: diagnosis and management | 2010 | Yes | Yes | RFT, Liver Function Tests (LFT), Full Blood Count (FBC), Creatinine |
| Chronic heart failure in adults: management | 2010 | Yes | Yes | BNP, RFT, Creatinine, eGFR |
| Stable angina: management | 2011 | Yes | Yes | cTn, Lipids |
| Hypertension in adults: diagnosis and management | 2011 | Yes | Yes | RFT, eGFR, Lipids |
| Hyperglycaemia in acute coronary syndromes: management | 2011 | No | Yes | Glucose, HbA1c, |
| Venous thromboembolic diseases: diagnosis, management, and thrombophilia testing | 2012 | Yes | Yes | D-dimer, eGFR, Activated Partial Thromboplastin Time (APTT), CBC, Calcium ($Ca^{2+}$), LFT, Urinalysis |
| Peripheral arterial disease: diagnosis and management | 2012 | No | No | |
| Stroke rehabilitation in adults | 2013 | No | No | |
| MI with ST-segment elevation: acute management | 2013 | No | No | |
| Varicose veins: diagnosis and management | 2013 | No | No | |
| Atrial fibrillation | 2014 | No | Yes | LFT, INR, Bilirubin |
| Cardiovascular Disease: risk assessment and reduction, including lipid modification | 2014 | Yes | Yes | eGFR, Lipids, Albumin, HbA1c, LFT, RFT, CK |
| Acute Heart Failure: diagnosis and management | 2014 | Yes | Yes | BNP, RFT |
| Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures | 2008 | No | No | |
| Stroke and transient ischaemic attack in over 16s: diagnosis and initial management | 2008 | No | Yes | INR, Glucose, HbA1c, |
| Familial hypercholesterolaemia: identification and management | 2008 | Yes | Yes | Lipids |
| Venous thromboembolism: reducing risk for patients in hospital | 2010 | Yes | No | eGFR, |
| Unstable angina and Non-ST-elevation myocardial infarction: early management | 2010 | No | Yes | RFT, Creatinine |

| | | | | |
|---|---|---|---|---|
| Chest Pain of recent onset: assessment and diagnosis | 2010 | Yes | No | cTn |
| Myocardial Infarction (MI): cardiac rehabilitation and prevention of further MI | 2013 | No | Yes | RFT |

Table 5: European Society of Cardiology (ESC) Guidelines

| | **Year Published** | **Test(s) required for initial diagnosis** | **Test(s) required for follow-up** | **Indicated test(s)** |
|---|---|---|---|---|
| Infective Endocarditis (Guidelines on Prevention, Diagnosis and Treatment of) | 2015 | Yes | Yes | CRP, ESR, IS, BC, Creatinine, Bilirubin, CBC |
| Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death | 2015 | No | Yes | Electrolytes, |
| Pericardial Diseases (Guidelines on the Diagnosis and Management of) | 2015 | Yes | Yes | CRP, CBC, ESR, CK, cTn, RFT, LFT |
| Acute Coronary Syndromes in patients presenting without persistent ST-segment elevation | 2015 | Yes | Yes | cTn, Lipids |
| Pulmonary Hypertension (Guidelines on Diagnosis and Treatment of) | 2015 | Yes | Yes | RFT, CBC, Iron studies, TFT. |
| Hypertrophic Cardiomyopathy | 2014 | Yes | No | BNP, cTn, CK, LFT, RFT, CBC, |
| Aortic Diseases | 2014 | Yes | No | BNP, cTn |
| ESC/EACTS Guidelines in Myocardial Revascularisation (Guidelines for) | 2018 | No | No | |
| Acute Pulmonary Embolism (Diagnosis and Management of) | 2014 | Yes | No | D-dimer |
| ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management | 2014 | Yes | No | cTn |
| Diabetes, Pre-Diabetes and Cardiovascular Diseases developed with the EASD | 2013 | Yes | Yes | Glucose, Lipids, HbA1c |
| Stable Coronary Artery Disease (Management of) | 2013 | Yes | Yes | Glucose, LFT, TFT, CBC, Lipids, HbA1c, CK, Creatinine |
| Cardiac Pacing and Cardiac Resynchronization Therapy | 2013 | No | No | |
| Arterial Hypertension (Management of) | 2018 | Yes | Yes | Glucose, LFT, RFT, eGFR, Lipids, Creatinine |
| Valvular Heart Disease (Management of) | 2017 | Yes | Yes | BNP |
| Atrial Fibrillation (Management of) 2010 and Focused Update (2012) | 2016 | No | No | |
| Acute Myocardial Infarction in patients presenting with ST-segment elevation (Management of) | 2017 | Yes | No | cTn |

| | | | | |
|---|---|---|---|---|
| Acute and Chronic Heart Failure | 2016 | Yes | Yes | BNP |
| CVD Prevention in clinical practice (European Guidelines on) | 2016 | No | No | |
| Dyslipidaemias (Management of) | 2011 | Yes | Yes | Lipids, CRP |
| Cardiovascular Diseases during Pregnancy (Management of) | 2018 | Yes | Yes | CBC, RFT, LFT, BNP, cTn, D-dimer, Urine protein |
| Peripheral Artery Diseases (Diagnosis and Treatment of) | 2017 | Yes | Yes | Glucose, Lipids, Creatinine, Urine Protein, CBC, RFT, HbA1c, |
| Grown-Up Congenital Heart Disease (Management of) | 2010 | No | Yes | Follow appropriate guideline for on-going complications |
| Device Therapy in Heart Failure (Focused Update) | 2010 | No | No | |
| Syncope (Guidelines on Diagnosis and Management of) | 2018 | No | No | |
| The Role of Endomyocardial Biopsy in the Management of Cardiovascular Disease | 2007 | Yes | No | Histological examination |
| B-Adrenergic Receptor Blockers (Expert Consensus Document on) | 2004 | No | No | |
| Angiotensin Converting Enzyme Inhibitors in Cardiovascular Disease (Expert Consensus Document on) | 2004 | No | Yes | RFT, Creatinine |
| Antiplatelet Agents (Expert Consensus Document on the Use of) | 2004 | No | No | |
| Supraventricular Arrhythmias (ACC/AHA/ESC Guidelines for the Management of Patients with) | 2003 | No | Yes | TFT |
| Estimation of ten-year risk of fatal cardiovascular disease in Europe: the SCORE project | 2003 | Yes | No | Lipids |
| Neonatal Electrocardiogram (Guidelines for the interpretation of the) | 2001 | No | No | |
| Chest Pain (Management of) | 2002 | Yes | Yes | cTn, CK |

Table 6:American College of Cardiology (ACC) Guidelines

| | **Year Published** | **Test(s) required for initial diagnosis** | **Test(s) required for follow-up** | **Indicated test(s)** |
|---|---|---|---|---|
| Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation | 2019 | No | Yes | CRP, CBC, TFT, RFT, LFT, Electrolytes, INR, Coagulation Monitoring |
| Guideline on the Management of Blood Cholesterol | 2018 | Yes | Yes | Lipids |
| Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay | 2018 | No | No | |
| Guideline for the Management of Adults with Congenital Heart Disease | 2018 | No | Yes | Follow appropriate guideline for on-going complications |
| Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death | 2017 | Yes | Yes | BNP, cTn, Electrolytes, Lipids, Calcium, |
| Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults | 2017 | Yes | Yes | Fasting Glucose, CBC, Lipids, Creatinine, eGFR, $Ca^{2+}$, Electrolytes, TFT, Urinalysis |
| Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure | 2017 | Yes | Yes | BNP, cTn, eGFR, Fe |
| Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease | 2017 | Yes | Yes | BNP, cTn, Electrolytes, RFT, Fe |
| Guideline for the Evaluation and Management of Patients with Syncope | 2017 | Yes | Yes | CBC, Electrolytes, BNP, cTn, Glucose |
| Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease | 2016 | No | Yes | Fasting Glucose, RFT, HbA1c |
| Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients with Coronary Artery Disease | 2016 | No | No | |
| Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction | 2015 | No | No | |
| Surgery for Aortic Dilatation in Patients with Bicuspid Aortic Valves | 2015 | No | No | |

| | | | | |
|---|---|---|---|---|
| Guideline for the Management of Adult Patients with Supraventricular Tachycardia | 2015 | No | No | |
| Guideline for the Management of Patients with Non–ST-Elevation Acute Coronary Syndromes | 2014 | Yes | Yes | cTn, BNP, Lipids, RFT Fasting Glucose, HbA1c, Creatinine, eGFR, |
| Strategies to Enhance Application of Clinical Practice Guidelines in Patients with Cardiovascular Disease and Comorbid Conditions | 2014 | No | Yes | Follow appropriate guideline for on-going complications |
| Guideline on Perioperative Cardiovascular Evaluation and Management of Patients Undergoing Noncardiac Surgery | 2014 | No | Yes | Follow appropriate guideline for on-going complications |
| Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease | 2014 | Yes | Yes | Follow appropriate guideline for on-going complications |
| Guideline for the Management of Patients with Atrial Fibrillation | 2014 | Yes | Yes | CRP, CBC, TFT, RFT, LFT, Electrolytes, INR, Coagulation Monitoring |
| Guideline for the Management of Patients with Valvular Heart Disease | 2014 | No | Yes | eGFR, BNP, INR, LFT, BC, IS, Histology, Rheumatoid Factor (RF) |
| Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) | 2013 | No | Yes | Fasting Glucose, RFT, HbA1c |
| Guideline on the Assessment of Cardiovascular Risk | 2013 | Yes | Yes | CRP, Creatinine, eGFR |
| Guideline for the Management of Heart Failure | 2013 | Yes | Yes | Fasting Glucose, CBC, Lipids, Creatinine, eGFR, $Ca^{2+}$, Electrolytes, TFT, Urinalysis |
| ST-Elevation Myocardial Infarction | 2012 | Yes | Yes | Lipids, Glucose, HbA1c, cTn, RFT, Coagulation Monitoring |
| Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy | 2011 | Yes | Yes | cTn, Genetic testing |
| Guideline for Coronary Artery Bypass Graft Surgery | 2011 | No | No | |
| Guideline for Percutaneous Coronary Intervention | 2011 | Yes | Yes | Glucose, HbA1c, RFT, cTn, BNP, Fe, Lipids |
| Secondary Prevention and Risk Reduction Therapy for Patients with Coronary and Other Atherosclerotic Vascular Disease | 2011 | Yes | Yes | Lipids, RFT, Electrolytes, |
| Cardiovascular Disease Prevention in Women | 2011 | Yes | Yes | Lipids, Glucose, HbA1c, Hormone levels |
| Extracranial Carotid and Vertebral Artery Disease | 2011 | Yes | Yes | CBC, $Ca^{2+}$, Lipids, Glucose, HbA1c, |

| | | | | |
|---|---|---|---|---|
| Thoracic Aortic Disease | 2010 | Yes | Yes | Genetic Testing, IS, BC, D-dimer, CRP, CBC, Coagulation Monitoring, Blood Type and Screen, Urinalysis |
| Device-Based Therapy of Cardiac Rhythm Abnormalities | 2008 | No | No | |

### 4.4 Discussion

Guidelines are designed to inform optimum decision-making by clinicians, and therefore provide a measure of the value of laboratory medicine. This study has shown that UK (NICE), European (ESC), United States (ACC) and Australasian (AHF/CSANZ) guidelines related to cardiovascular diseases (CVD) state that laboratory testing of some sort is recommended by 75% (15/20), 73% (24/33), 78% (25/32) and 94% (15/16) of their guidelines, respectively. The topics of these guidelines tend to be related to specific clinical conditions, so it means that an average 78% of clinical recommendation pathways involving each of these cardiovascular diseases require laboratory assistance in their management.

The most common metric stated for the value of laboratory testing in patient care is the claim that "laboratory medicine influences 70% or more of all clinical decisions". An editorial in the Annals of Clinical Biochemistry [31] stated that the 70% figure was first published in 1996 and was based on anecdotal evidence and unpublished studies. The editorial lists various examples of the use of this phrase, albeit with slight modifications ranging from 60-80% and a quote from *Clinical Laboratory News* in 2004 "*…the laboratory represents 5% of a health system's costs, yet it affects 95% of the remaining costs*" [31].

A related and also oft-quoted statistic is that 70% of the electronic patient record is composed of laboratory data, [47] but the main limitation of this observation is that the presence of laboratory results in a patient record does not necessarily equate to it being used in any clinical decision-making process. Over-requesting of testing is a common feature of many healthcare systems and panels of tests may include many analytes which are unrelated to the patient's clinical condition.

A 2016 study of laboratory use by oncologists and cardiologists found that 75% of all their patients underwent laboratory testing, and that this testing led to a substantial clinical decision in 66% of the patients [48].

Over time the 70% claim has apparently gained legitimacy simply due to the number times that it had been repeated. In 2012, the IFCC established a Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes. When it published its findings in 2015 one suggestion was that clinical guidelines could be used as a more accurate indicator of the laboratory's involvement in clinical decisions, the rationale being that the number of guidelines that required any laboratory involvement would show a direct connection between the laboratory and evidence-based practice [40].

The British Heart Foundation report that CVD account for almost 170,000 deaths in the UK [49] costing the National Health Service £6.8 billion in 2012/2013. [50] In Europe, CVD is responsible for 3.9 million (45%) of all deaths [51] annually. The American Heart Association has reported that Coronary Heart Disease is the leading cause of death among Americans, accounting for nearly accounting for 840,678 (30%) deaths in 2016 [52].

According to the Australian Institute of Health and Welfare Alliance, CVD directly contributed to 45,400 deaths in 2015 which accounts for 29% of all deaths that year in Australia [53]. The World Health Organisation (WHO) consider this to be the number one cause of death globally reporting that an estimated 17.9 million people worldwide die from CVDs annually which equates to 31% of all deaths and, of these, 85% were due to myocardial infarction or stroke [41]. The authors

decided to look at guidelines associated with CVD as this would necessarily influence the largest group of patients

There are both limitations and strengths to the approach taken with one potential limitation being that clinical guidelines are not necessarily followed by all physicians or other healthcare staff. A clinician's own pathway for patients may therefore involve more or less testing than is being recommended. However, the main advantage of our method is that the guidelines define or provide an evidence-based recommendation for best practice in each specific clinical scenario.

The guidelines also tend to be specific in the test or tests that are recommended, which is advantageous in two ways. First, it helps ensure that the contribution of laboratory medicine to healthcare is not exaggerated by over-requesting - as could be the case if health records were solely being examined and secondly, that a clinical decision relevant to the health condition is intended to be taken on the basis of the result.

It should be noted that the guidelines examined in this study were produced in relatively affluent countries with developed healthcare systems and so the use of laboratory medicine testing advocated in other, less wealthy, countries may well differ. Nonetheless, this does not preclude the same methodology that is here being applied to any alternative guidelines.

## 4.5 Conclusions

In summary, this study has found a requirement for the use of laboratory testing in 79 of the 101 cardiovascular guidelines produced by four different organisations. This does not provide a direct link to improved patient outcomes but does provide an index of the value of laboratory medicine which can complement other metrics. Using this objective methodology, it ought to be possible to determine the contribution of laboratory medicine to other, less prevalent, disease groups. Together, these datasets should provide a more accurate measure of the significance of laboratory medicine in providing optimal patient care.

Currently the increased use of technology means that many results are released without clinical oversight from a Pathologist and rely on the professionalism and competence of the scientific staff. This influence on patient outcomes means that Medical Scientists have a significant impact on clinical profiles. Therefore, if errors do occur despite the best efforts of pathology workers and the quality monitors in the laboratory, they can affect a significant proportion of tests conducted in a pathology laboratory and by extension a large section of the population of a country. This chapter attempts to provide evidence to refute the claim that Medical Scientists do not influence patient care. The next chapter reviews several laboratory incidents in Australia and around the world to assess their impact on the public.

## 5. Analytical errors in pathology

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### 5.1 Introduction

In April 2016 a South Australian newspaper reported that there had been a medical misadventure at the state's largest private pathology laboratory, South Australia (SA) Pathology [54]. This laboratory was established in the 1930's near the Royal Adelaide Hospital, partnered with the existing hospital laboratories and has evolved over the last 75 years to include training and research arms that support the healthcare system in South Australia.

SA Pathology performs a large range of clinical diagnostic tests, among them testing for levels of Prostate Specific Antigen (PSA). PSA testing was initially described in America in the late 1980's and led to the development of a national Australian guideline for the monitoring of patients who had undergone radical prostate surgery [55]. In 2015, SA Pathology used the Siemens ADVIA


Figure 3- Westgard rules

Centaur platform for this testing and, critically, this platform carries two alarms that inform staff that an assay is malfunctioning: The $4_{1s}$ rule shows four consecutive measurements exceed one standard deviation on the same side of the mean whereas the $10_x$ rule means that ten consecutive measurements are on the same side of the mean and are describe by Westgard as showing a level of inaccuracy, illustrated in Figure 3 [56].

A report issued by the Australian Commission on Safety and Quality in Healthcare in October 2016 stated that these alarms were not being correctly used by SA Pathology staff. *"The $10_x$ rule was no longer functioning*" and "*while the $4_{1s}$ rule was functioning, its reports were accepted despite the repeated warnings*" [57]. As a consequence, the SA Pathology PSA test reports should have been considered unsafe as critical control measures may have violated two quality metrics and the review team identified that*; "…a lack of clinical expertise available when interpreting test results and examining the impact of quality assurance issues"* [57] may have contributed to erroneous results for 52 patients with six of these receiving further treatment.

This is not unusual in a large laboratory which could be running hundreds of different chemistry tests on each of its analysers. The recent Barnes report for the British (UK) National Health Service (NHS) concluded that the current quality assurance systems used in UK laboratories have gaps [58]. This is not limited to the UK, a review of twenty-one large Academic Medical Centers in the USA showed that there is large variation in understanding and usage of quality control rules [59].

However, it wasn't until SA Pathology had received multiple (customer) complaints from clinicians and patients that the laboratory recognised the issue and began to act. At the beginning

of February 2016 SA Pathology conducted an internal review. The problem was identified and confirmatory testing of the PSA assay with an external reference lab began at the end of the same month. SA Pathology released the following statement on its website as a Quality Improvement Program

*"Whilst our PSA results have been highly accurate and reliable in the core range, we have moved to improve values below 0.15μg/L, where some patients have required repeat testing"* [60].

Enquiries by reporters of the Adelaide Advertiser newspaper identified the truth of the confirmatory testing [54]. An urgent review was commissioned by the Health Authority, which was convened in late April and its findings published on the 16th of July 2016 [57]. The 22 page report, providing a comprehensive timeline of the issue was conducted by a group comprising a Senior Clinical Pathologist, a Senior Consultant Urologist, a former Commissioner of the New South Wales Health Care Complaints Authority and two members of the Australian Commission on Safety and Quality in Healthcare.

The report identified major deficiencies in analytical processes, governance, and quality assurance which led to the following five recommendations:

| | |
|---|---|
| ***Recommendation 1:*** | *Formal apology and implementation of lessons learnt* |
| ***Recommendation 2:*** | *New management structure for SA Pathology* |
| ***Recommendation 3:*** | *Immediately ensure appropriate pre-analytical, analytical, and post-analytical quality control procedures are operational within SA* |

*Pathology which meet national standards and are reinforced and regularly audited*

***Recommendation 4:*** *National Accreditation to confirm that SA Pathology meets national laboratory standards.*

***Recommendation 5:*** *SA Pathology ensures that the Safety Learning System is fully implemented and that all incidents are logged in the Safety Learning System. Clinical staff are trained in open disclosure.*[57]

Similar incidents in other laboratory services such as A review of cellular pathology governance at Sherwood Forest Hospitals NHS trust by the Royal College of Pathologists in 2013 led to 57 recommendations [61]. New Zealand Ministerial inquiries into the under-reporting of cervical smears led to 46 recommendations,[62] and the Health and Disability Commissioners report into PSA Testing Procedures at Gisborne Hospital provided sixteen [63]. These investigations resulted in fundamental changes to the Pathology services in those countries.

*"The success of the National Australian Testing Agency (NATA)/ Royal College of Pathologist, Australasia (RCPA) laboratory accreditation scheme has given Australia one of the best pathology sectors in the world and the government's view is there is no evidence that scientist registration is required."* [64]

One of the common findings in these investigations was to highlight the lack of staff education regarding the issue at hand. In Australian laboratories, there is no legal requirement for laboratory staff to hold a practicing license or seek any CPD to maintain employment.

In the recent NPAAC document for Supervision in the Clinical Governance of Medical Pathology Laboratories

**S1.1** *Every laboratory must be under the direction and control of a Designated Person who is a medical practitioner and who is responsible for and accountable for the* ***clinical governance*** *of the Medical Pathology Services provided by the laboratory* [65].

The Pathologist has sole responsibility for the clinical supervision of the laboratory in Australia, NATA have the responsibility for the assessing the technical competence of a laboratory and providing nationally recognised accreditation.

These mechanisms seem to have been inadequate in this case, as observed by this comment by the review team "*It appears that there was little understanding within SA Pathology of the clinical use to which the low level tests could be put and little appreciation of potential harm to patients*." [57].

## 5.2 Discussion

The central document that was analysed in this article was the Australian Commission on Safety and Quality in Health Care "*Review of serious failure in reported test results for PSA testing of patients by SA Pathology"*. It is a twenty-two page document released in July 2016 following three months of investigation into SA Pathology [57]. An experienced team of Clinicians and Safety experts was assembled and charged with gaining information through meetings and interviews with key stakeholders, general observation of laboratory practices and a review of all materials relating to the PSA testing incident.

They had access to all stakeholders including patients, clinicians, laboratory staff, SA Pathology Executive team members and key members of the South Australian Healthcare departments.

"*The terms of reference for this review require it to "advise on improvements required relating to clinical governance systems and processes, incident management, professional standards and accountability within SA Pathology"* [57].

The published recommendations were as follows.

***Recommendation 1:*** *Formal apology and implementation of lessons learnt. That SA Pathology issue a public apology for distress and anxiety experienced by the patients because of the inaccurate PSA testing, and provide regular updates to the community on the implementation of lessons learnt from the incident and the new measures introduced to assure the quality control of clinical testing in SA Pathology laboratories* [57].

This first recommendation was made in response to the lack of general disclosure given by SA Pathology following its discovery of inaccurate results. That discovery only resulted in communicating the unsafe test reports to referring clinicians. The report recognised that this level of communication complied with the principle of open disclosure but critically added the need for a public apology stating.

*"Although somewhat belated, the review recommends that an apology should now be offered."*[57].

In both the UK and New Zealand there is a robust system for open disclosure of incidents through those countries regulatory authorities: the HCPC in the UK and MSCNZ. The latter was established in 2003 in response to two incidents in Gisborne the first involving 117 patient's PSA results and the other requiring the re-screening of more than 10,000 cervical smear slides.

In Australia the regulatory authority is provided by NPAAC with accreditation duties provided by NATA and its findings should be available to the public. However following an exhaustive search of both the SA Pathology [66] or the NATA website [67] the author could find no reference to the incident or any subsequent indications to the public that the review findings had been implemented.

***Recommendation 2:*** *New management structure for SA Pathology. The Program Director of South Australia Statewide Clinical Support Services engage an appropriately qualified and experienced person to implement an organisation restructure for SA Pathology that: aligns appropriately skilled staff placement with the operational needs of the service; provides adequate*

*clinical expertise to monitor and inform the production of results; clearly defines the responsibilities and accountabilities of staff; and ensures the requirements of referring clinicians are reflected in the work rules of the service* [57].

The report noted in relation to the management of SA Pathology; "*During the review it became apparent that the structure of the organisation did not provide sufficient clinical input and management accountability at appropriate levels*"[57]. In a concurrent review of the Governance and Management of SA Pathology areas of concern were identified within the management structure of SA Pathology [68]:

- A top down management process, which is identified on paper but carries no accountability or responsibility.
- A horizontal management structure termed "Directorates" that identify senior Pathologists and Scientists as line managers, who cover all twelve laboratory sites, but are confined to one site. Hence management is off-site and distant.
- A central large Automated Department is identified in each of the three metropolitan laboratories which is managed by a Scientist, but the Pathologists do not have active management influence within this area.

Interestingly, this deficiency identified in SA Pathology mirrors the deficiency identified in the PSA testing issue at Gisborne Hospital in 2003 which reported that; "*Communication between all levels of management and technical staff must be improved. Problems will recur if there is a continuation of the dysfunctional relationship evident in the past.*"[63].

It is worth noting that SA Pathology had a Quality Manager in position since 2009 and NATA would have conducted multiple periodic inspections to ensure compliance with International Organisation for Standardisation (ISO) 15189 standards. As part of the Flett review of SA Pathology [68] a new, more conventional structure was adopted in 2018 that included a Training Manager as an important addition.

***Recommendation 3:*** *Immediately ensure appropriate pre-analytical, analytical, and post-analytical quality control procedures are operational within SA Pathology which meet national standards and are reinforced and regularly audited. It is the role and responsibility of the senior management of a pathology service to see that policies, procedures and practices are in place that ensure staff understand the quality control system in use, and that staff understand their role in relation to quality control including reporting requirements. This review recommends that an immediate review is undertaken to ensure appropriate quality control procedures are operational within SA Pathology and staff are regularly assessed to ensure their understanding and compliance with quality control procedures* [57].

Training and competency documents are available to any review team as required under NATA and ISO stand 15189

***5.1.6 Competence assessment***

*Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria. Reassessment shall take place at regular intervals. Retraining shall occur when necessary* [69].

Competency assessment documents are required for every test system (any process within the laboratory that produces a result) and are required to be reviewed following any change to the standard operating procedure [69]. Therefore, all staff using the Siemens ADVIA Centaur must have had an annual competency document that recorded compliance with the six parts of full competency described in the standard:

a) direct observation of routine work processes and procedures,

b) performance of equipment maintenance and function checks.

c) recording and reporting of examination results.

d) review of Quality Control records.

e) assessment of problem-solving skills.

f) examination of specially provided samples e.g. Proficiency testing samples

These records are explicitly stated in the NATA guidance for its assessors [70]. Critically, the inadequacy of competency documentation appears to be a universal issue, as noted by Chittiprol *et al "The most common areas of deficiencies among all the agencies include: testing personnel qualifications and competency evaluation."* [71].

Throughout the report references are made about the apparent lack of knowledge of SA Pathology surrounding the PSA test among the staff at SA Pathology with a urologist interviewed by the review team stating that *"when he called SA Pathology he spoke to a scientist who appeared to have no understanding of the clinical implications of the inaccurate low level tests."* [57].

These observations, and the fact that NATA accreditation had been awarded to SA Pathology, appear conflicted. The third recommendation highlights a serious flaw concerning training and competency and may identify an underlying issue of CPD in Australian laboratory staff is being ignored. This is not uncommon and was identified in New Zealand following the incidents in Gisborne: *"Staff therefore had to ask for training opportunities and these were frequently declined."* [63].

The Therapeutic Goods Administration (TGA) of Australia released a Safety Advisory note in August of 2016 regarding a number of PSA testing kits that were showing errors [72]. This would constitute an excellent opportunity for education within a laboratory and in many other countries there is a requirement for CPD for Medical Scientists. A nationwide CPD scheme does exist for medical scientists but is voluntary. Therefore, there is no mechanism to assess whether this important information reached the bench level staff.

Despite being an AS/ISO 15189 and NATA requirement for an inspection team to review all training documentation to ensure that CPD is being maintained by the employers and workers. This is not mentioned as being done by the review team, while this doesn't prove that they didn't see the documents in this instance where the education of the staff was called into question it would have provided evidence of compliance.

### *5.1.8 Continuing education and professional development*

*A continuing education programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of*

*the continuing education programme shall be periodically reviewed. Personnel shall take part in regular professional development or other professional liaison* [69].

International accreditation standards require staff education and records of training whenever a laboratory introduces a new test or changes the procedure around an existing one. This can be as simple as calling a huddle or as elaborate as giving an off-site presentation. In any case competency documents must be modified appropriately to reflect changes and the events recorded as CPD by the staff. Due to the fact that it is not a requirement for staff in Australia there was no mention made of this in the SA Pathology report [57] nor is it required of a NATA inspection, despite it being explicit in the ISO 15189 standards which NATA uses as its basis for accrediting Australian laboratories.

***Recommendation 4:*** *National Accreditation to confirm that SA Pathology meets national laboratory standards, the service, as soon as practical, seeks independent assurance of technical competence through accreditation by the National Association of Testing Authorities (NATA)* [57].

NATA was established in 1947 and is a member of many international accreditation organisations. For any Pathology Laboratory to be approved by the Australian Government Department of Human Services (DHS) and to claim Medicare benefits, the laboratory must be accredited by NATA.

*"NATA is the authority that provides independent assurance of technical competence through a proven network of best practice industry experts for customers who require confidence in the delivery of their products and services."[67].*

In New Zealand prior to 2004, International Accreditation New Zealand (IANZ) held a similar position within the healthcare system as NATA does in the Australian Healthcare system today. *"Gisborne Hospital viewed IANZ as the "primary watchdog for community safety" through its accreditation and assessment processes."[63].*

SA Pathology was established prior to NATA and has a close relationship with the South Australian Health system and has maintained NATA accreditation since 1992 [67]. Recommendation 4 appears to cast NATA assessments of SA Pathology in a critical light. NATA advises its assessors to audit, amongst other things, training and competence records [70].

The review team for the PSA testing errors in Gisborne the authors make mention of reviewing the previous accreditation document and came to the following conclusion about laboratory accreditation.

"*It is clear from subsequent events and investigations by International Accreditation New Zealand (IANZ), and from my investigation, that many of the concerns raised by previous assessments had not been adequately addressed*." [63].

The SA Pathology inspection team makes no reference to any previous NATA document in their review or the implications this has on previous NATA assessments. If the previous NATA report

had identified the same deficiencies, according to the NATA website, the Chemical Pathology department was reaccredited at the end of 2018 [67] there would be little value in repeating the same process which occurring every three years would have been last completed in 2015.

This is mentioned in the annual report from the Central Adelaide Local Health Network in 2015-2016 which stated *"SA Pathology's Genetics and Molecular Pathology laboratory is the first in Australia to receive National Association of Testing Authorities (NATA) accreditation for whole exome sequencing*."[73].

The NATA Annual reports for 2016 or 2017 does not refer to the PSA test reporting discrepancies and customer complaint procedures. The assessors may have reviewed the SA Pathology Chemical Pathologist directive to report PSA levels as low as 0.3ng/mL with the report mentioning that the manufacturers lowest checked value was much higher than this [57] as it was a modification to a test. However, the report does not mention that there was any additional education provided to laboratory staff about the clinical implications of the new testing criteria.

This is required by ISO 15189 standards **5.1.5** Training**, 5.1.6** Competence assessment and **5.1.7** Reviews of staff performance [74] which state that; "*The effectiveness of the training programme shall be periodically reviewed"* and *"Retraining shall occur when necessary".* In NPAAC is an Australian governmental ministerial advisory body responsible for oversight and regulation for the pathology service. It explicitly mentions CPD standards in "*Requirements for Medical Pathology Services"*.

**C6.1(ii)** "*All qualified staff involved in the provision of Medical Pathology Services must provide documented evidence of participation in continuing professional development commensurate with their role and responsibilities."*[75].

In the NATA document provided to inspectors, they are required to address the following questions pertaining to each ISO standard; [76] as documented in Table 7. Remedial training is required when staff work in unfamiliar areas of the laboratory, work out of hours or at weekends. It is also required for all staff, especially if competency is lacking or when a new test is introduced, and this training must be documented.

Table 7: NATA ISO 15189 Assessment Worksheet

| **Clause No.** | **Activities** | **Evidence (outcome of discussion with staff; observations; procedures & documentation reviewed** | **Complies Yes/No** | |
|---|---|---|---|---|
| **5.1.5** | **Training**<br>Staff undergoing training must be supervised and does training include:<br>• QMS and work procedures.<br>• LIS.<br>• Health and Safety.<br>• Ethics and Confidentiality.<br>Are the effectiveness of the training programme periodically reviewed? | | | |
| **5.1.6** | **Competence assessment**<br>• How is the competence of staff assessed after training?<br>• Have defined criteria been established to assess competence?<br>• How often does competence take place? | | | |

| | | | | |
|---|---|---|---|---|
| | • Refresher training where staff are expected to work in areas other than those in which they normally work (e.g. weekends or on-call)<br>• On-going training for dedicated out-of-hours and/or weekend staff | | | |
| **5.1.7** | **Reviews of staff performance**<br>• Does staff performance reviews consider the needs of the laboratory and the individual to maintain or improve the quality of the service? | | | |
| **5.1.8** | **Continuing education and professional development**<br>• Does all staff involved with managerial and technical processes partake in continuing education activities (In-house and/or external)?<br>• And are records of these activities kept?<br>• Are staff encouraged to attend professional society meetings?<br>• Is there support for conference attendance? | | | |

However, in the latest "*Guidance to NATA assessors*" document this is conflicting as there appears to be no requirement for an inspection team to review training or competency documentation as the only instructions provided are as follows.

**Staff training and competence** [70]

As a routine aspect of every assessment visit, an appropriate range of tests or inspections should be witnessed to ensure that:

- staff are familiar with test/inspection methods and can carry them out;
- appropriate training and education have been provided;
- staff are appropriately supervised and technical direction is provided; and
- staff understand test/inspection principles and limitations according to their responsibility.

Standard laboratory practice is to run periodic Quality Control (QC) materials for every test that is conducted which is detailed in ISO 15189 standard **5.6.2** Quality control [74]. This is done to confirm that the analyser is providing a result that reflects the known value of the QC sample. Typically, there are statistical biases built into the system, as no test is completely accurate, but varies regarding its sensitivity and specificity. However, the review team observed that.

"*In SA Pathology it does not appear that bench level staff were able to assess the significance of potential warnings being generated by analytical systems*" [57].

The analyser software provides the user with information aligned to these rules and if the test violates these conditions then it will alarm to bring it to the operator's attention. The "Westgard

rules", which are explained in Figure 3 are used on most laboratory analysers that run multiple QCs and usually require manual input to disable. The report implies that the technical staff ignored a warning from an analyser for some time, before it came to the attention of a senior member of staff or clinician who was aware of these implications.

The laboratory is required to record QC results, which may be done electronically, and are usually reviewed monthly by senior staff. The understanding of QC particular to any test system is one of the requirements of a competency assessment and these documents must be provided to accreditation inspectors if required. Once again this was highlighted by the review team *"The clinical significance of the inaccurate low level PSA readings was not appreciated and action to investigate the cause was not pursued with any sense of urgency" [57].*

There are several ISO15189 standards that mention this practice such as:

***4.9 Identification and control of nonconformities***

*The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination, or post-examination processes.*

***5.6.2.3 Quality control data***

*The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.*

### *5.7.1 Review of results*

*The laboratory shall have procedures to ensure that authorised personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results, and follow up with actions to address issues in a systematic and managed way, with closer monitoring in the implementation of any change in processes [69].*

The review team's recommendation of seeking national accreditation with NATA appears redundant as SA Pathology was accredited by NATA at the time of the incident. The fundamental laboratory errors associated with PSA testing may have been missed by the previous NATA inspections, but these reports are not publicly accessible. The NATA Annual reports for 2016 or 2017 do not refer to the SA Pathology PSA test reporting discrepancies and customer complaint procedures.

***Recommendation 5:*** *SA Pathology ensures that the Safety Learning System is fully implemented and that all incidents are logged in the Safety Learning System. Clinical staff are trained in open disclosure. SA Pathology should cease using Q-Pulse as its exclusive incident reporting system and fully implement the statewide Safety Learning System (SLS) together with a program that ensures that staff understand how the system operates and the mandatory reporting requirements when clinical incidents are identified. SA Pathology should also review its open disclosure policy and how it will operate in the event of incidents involving patient results. SA Pathology should ensure that its systems allow for all relevant information to be provided to treating clinicians who will conduct the appropriate discussion with the patient [57].*

A standardised approach to safety is always desirable in a large organisation as it reduces errors that might be easily be missed by divergent practices. The SLS was introduced into the South Australian Health system in 2010 and despite its use being a requirement of all organisations providing services on behalf of SA Health, it had not been adopted by SA Pathology at the time of the incident. They were still using Qpulse, [77] which is a software solution for quality management, document control, and training and competency in use in many laboratories.

The review team's recommendation for SA Pathology is to surrender its use of Qpulse for incident reporting and adopting the universal SLS. The approach would allow for more robust management of incidents by a team that are appropriately trained and unbiased, and it would also require little to no resource commitment from SA Pathology. This highlights another failure of SA Pathology management team to provide its staff with the required training that may have recognized this incident much earlier.

## 5.3 Conclusion

The report into the 2015 PSA testing incident by SA Pathology describes the incident as being poorly managed by the executive of the organisation. There are many lessons that should be learnt from how it was handled that could have been implemented into the wider Australian pathology service. As it was in New Zealand fifteen years before, however, it seems that the warning signs were not heeded.

The SA Pathology report found that neither of the regulatory controls in place were deficient, which contrasts with the findings of the review of the Gisborne Health Board which suggested that reliance on a single form of regulation would come with an element of risk.

"*Accreditation by IANZ is no guarantee that all is well in the registered laboratory*" and." *It has become clear in the course of my investigation that, in light of IANZ's limited statutory role, this confidence may be misplaced*." [63].

An experienced and qualified team of specialists spent three months succinctly tying up all the issues in only five recommendations. They decided that the IT system was inadequate, the organizational chart needed review and, despite a recent accreditation inspection, that it needed to be reaccredited [57].

There were certain questions that went unanswered by the review team, namely.

- Was there any investigation of the other laboratories using the same reagent?
- Did they review the previous accreditation report?

- Were the required training and competency record made available?
- Were the employee's qualifications appropriate for pathology analysis?

AHPRA supports many healthcare professions, all of which require some evidence of CPD. If the Medical Scientists involved had been supported with education and training on the clinical implication of the testing changes, then possibly, many of the errors that contributed to this incident may have been prevented. The contention that supervision by an RCPA-accredited Pathologist and NATA accreditation are the necessary and efficient controls required by laboratories was clearly shown to be inadequate by the fundamental failings of both precautions.

In New Zealand following the two incidents in Gisborne, a registration framework for Medical Scientists was in place two years later, but the New Zealand Government were committed to this process as early as 1997 when a cabinet paper from Ministry of Health included the following statements

"*In the Ministry's view, the risks of wrong diagnosis (which could in some cases be life threatening) are managed through a variety of measures of which licensing is but one … measures include quality assurance processes and management structures which ensure that the more highly experienced staff act as "peer reviewers' of the analysis carried out by less experienced technicians. …..these occasions are sufficiently frequent, and the possible outcomes of incompetent practice so severe, that a continuation of some form of occupational registration is justified*." [78].

The certification project is a positive step but needs more support from industry or legislation to be truly effective. Any framework must ensure that clinical decision-making be made more frequently with the full support of those performing the testing, and licensing of Medical Scientists and require participation in a CPD scheme should be supported.

The purpose of this chapter is not to criticise SA Pathology but to highlight an incident that could have provided the impetus to develop an effective framework to prevent it occurring again. SA Pathology has put into place the recommendations to ensure this, however it is possible that this incident could have been prevented through better education of the pathology staff, training which could have been managed through a regulatory programme.

The author understands the difficulty of introducing a universally recognised system in Australia with its various states and territories. However, if the assumption that Medical Scientists have little influence on the delivery of healthcare in Australia is flawed and for the protection of the public this needs to be addressed.

Quality incidents such as this will continue to occur and a reactive approach such as this will do little to prevent them. An opportunity has been missed by the leaders of the Pathology industry in Australia and continues today with the public ignorance and professional disregard during the COVID global pandemic.

**Summary of major points**

- The review by the Australian Commission on Safety and Quality in Healthcare made five recommendations compared to similar incidents in the UK (57) and NZ (46).

- None of which were effective beyond SA Path despite 14 other laboratories in Australia using the same chemistry no other investigations have been conducted.

- International standards suggest that staff re-education is important following changes to testing protocols. Despite multiple references to a lack of knowledge among the staff of SA Path, none of the recommendations addressed this.

- NPAAC responded by removing a Scientist ability to supervise laboratories in Australia.

- Staff competency records and inspection reports are important supporting documents for this type of investigation and should be referenced as part of the report.

- The Australian Commission on Safety and Quality in Healthcare is now responsible for the accreditation of all pathology laboratories in Australia.

# 6. Medical Scientists' perception of their profession – A survey of two groups of practitioners in Australia and Qatar

## 6.1 Introduction

In 2010 AHPRA was established by the Australian Government to oversee the actions of the various medical boards entrusted with regulation of the fourteen recognised healthcare professions in Australia. This body decided previously that Medical Scientists did not meet its criteria and that national accreditation and clinical oversight by a member of the RCPA provided sufficient control and that pathology workers should remain self-regulated [5].

AIMS has highlighted many times the lack of professional recognition of its members. [36, 64, 79] In a study published in its journal in 2003 regarding the professional status of Medical Scientists in Australia [25], it showed that the public believed that Pathologists and not the scientists conduct pathology testing. In many other countries around the world [9, 10, 15, 17, 21], Medical Scientists are required to hold a practicing license in order to be employed in clinical laboratories, this license provides professional recognition, public protection through regulatory oversight.

The aim of the first study was to survey laboratory workers regarding their perceptions of registration of Medical Scientists and its impact on a country's healthcare system and identify possible benefits to the practitioners. An online survey invitation was sent to the AIMS (AIMS), Queensland Health, Sullivan Nicolaides Pathology (SNP), Queensland Medical Laboratory (QML) and the Director of the Pathology Laboratory of Sidra medicine in Qatar.

Replies were received from AIMS and Sidra medicine and they forwarded the online survey link to their members. (*see Figure 13 and 14*)

A second survey was designed to focus on the themes prevalent in the responses from the primary group. This survey asked questions of Australian laboratory workers to understand if they agreed with the first group of local and international respondents. This survey asked for some basic demographics, their opinion on some quotes derived from the first survey and the following questions. (*see Figure 15*)

1. What would the personal implications be if AHPRA registration for Medical Scientists was required in Australia?

2. What would the professional impact on Medical Scientists if AHPRA registration was required for employment in Australian Pathology laboratories?

3. Do you think that Medical Scientists are recognised by other healthcare professionals in Australia?

4. Do you think that Medical Scientists are recognised by the Australian public?

5. What has been the impact on the industry due to the level of testing during the COVID-19 pandemic?

### 6.2 Data Analysis

The first survey provided 82 responses received through Survey Monkey. IBM SPSS version 26 was used to analyse the first 22 questions. Six respondents did not answer any questions and they were removed leaving 76 valid responses, 56 International and 20 Australian respondents, these were analysed using IBM SPSS version 26.

Twenty-six participants who had not responded to the final three structured questions were removed from the cohort as they would bias the analysis. This left 42 international and 16 Australian respondent's data which was analysed using a general inductive approach with content analysis to identify key themes arises from the responses.

This approach was used to determine the presence of certain words, themes or concepts within the qualitative data [80]. Initially the responses were grouped based on geographical location, International versus Australian laboratories. Then further distinctions were made regarding level of tertiary education e.g. Bachelor, years of occupational experience and level of seniority i.e. Technician v Scientist.

Once grouped, the investigator A.H addressed and coded each comment individually based on the two categories of perceived personal benefit and possible professional impact. These responses were also grouped based on the positive or a negative nature of response to the question. The analysis was then reviewed in collaboration with the investigation team (E.H, I.S and A.K). Any difference in interpretation and coding was discussed until a census was reached and the result presented in Table 8.

The second survey had 74 respondents from various laboratories around Australia with 1 duplicate, 6 respondents who did not consent and 30 which had high levels of missing data leaving 37 respondents with usable data. The survey took quotes from respondents in the first

survey to assess whether the opinion followed the group from the original survey. The same distinctions were made with respect to experience, qualification, and position.

A second group of questions were informed by the overarching themes from the first survey of professional and public recognition of Medical Scientists. The second survey allowed an opportunity to focus on the professional impact and personal implications of registration in Australia which was highlighted in the first survey. A final question was added to ask respondents about their experiences during the ongoing COViD-19 pandemic which will be discussed separately in a later chapter.

## 6.3 Results

### 6.3.1 Descriptive analysis – Demographics

*(numbers of responses shown in brackets)*

In the first survey there were 20 respondents from Australia, with the majority from Public laboratories (12), female (12) and between 20-29 years of age (12). They were spread evenly across all levels of responsibility with 50% of them being in the job for more than 15 years. 40% of the respondents reported holding a Bachelor of Medical Laboratory Science degree and for 70% of them that was their highest qualification. Despite membership of a professional society being voluntary in Australia 19 of the 20 respondents held memberships. This result is probably biased because of AIMS being the only organisation to support the distribution of this survey. Only one of those who responded was a Fellow of any society. *(see Table 8 below*)

In comparison 56 responses were received from an international pool comprised of more than 15 nationalities, an equal number of males and females' respondents, with 73% (41) working in private institutions the largest group between 30-39 years of age 37.5% (21). Most of the international respondents were scientists (29) with 54% (30) of them having between 5-15 years of experience. 37.5% (21) of the international cohort held Bachelor of Medical Science degrees with 48.5% of them holding a post graduate degree. In this group 90% held membership of a professional society with 9 of the 56 (18%) of them holding fellowships with their respective national society. As this is mandatory for employment in Qatar and many international jurisdictions, therefore, this result reflects the industry globally.

Table 8: International v Australian demographics

| | | Do you currently work in Australia? | | | |
|---|---|---|---|---|---|
| | | No | | Yes | |
| | | *n* | % | *n* | % |
| **Gender** | **Male** | 28 | **50.0%** | 8 | **40.0%** |
| | **Female** | 28 | **50.0%** | 12 | **60.0%** |
| **How long have you worked in the field?** | **1-5 years** | 3 | **5.4%** | 6 | **30.0%** |
| | **5-10 years** | 14 | **25.0%** | 1 | **5.0%** |
| | **10-15 years** | 16 | **28.6%** | 3 | **15.0%** |
| | **15-20 years** | 7 | **12.5%** | 5 | **25.0%** |
| | **>20 years** | 16 | **28.6%** | 5 | **25.0%** |
| **Level of responsibility** | **Technician** | 6 | **10.7%** | 3 | **15.0%** |
| | **Scientist** | 29 | **51.8%** | 6 | **30.0%** |
| | **Senior Scientist** | 7 | **12.5%** | 5 | **25.0%** |
| | **Supervisor/Manager** | 9 | **16.1%** | 6 | **30.0%** |
| | **Clinical Scientist** | 3 | **5.4%** | 0 | **0.0%** |
| | **Pathologist** | 2 | **3.6%** | 0 | **0.0%** |
| **What type of Lab do you work in?** | **Public** | 11 | **19.6%** | 12 | **60.0%** |
| | **Private** | 41 | **73.2%** | 6 | **30.0%** |
| | **Mixed** | 4 | **7.1%** | 2 | **10.0%** |
| | **Bachelor of Science** | 24 | **42.9%** | 5 | **25.0%** |

| | | | | | |
|---|---|---|---|---|---|
| **Which undergraduate degree do you hold?** | **Bachelor of Medical Laboratory Science** | 21 | **37.5%** | 8 | **40.0%** |
| | **Bachelor of Biomedical Science** | 5 | **8.9%** | 3 | **15.0%** |
| | **Bachelor of Medical Science** | 0 | **0.0%** | 3 | **15.0%** |
| | **Diploma** | 6 | **10.7%** | 1 | **5.0%** |
| **What is your highest degree?** | **Bachelors** | 26 | **46.4%** | 14 | **70.0%** |
| | **Masters** | 24 | **42.9%** | 3 | **15.0%** |
| | **Doctorate** | 3 | **5.4%** | 2 | **10.0%** |
| | **Diploma** | 3 | **5.4%** | 1 | **5.0%** |
| **Are you a member of a Professional Society?** | **No** | 5 | **8.9%** | 1 | **5.0%** |
| | **Yes** | 51 | **91.1%** | 19 | **95.0%** |
| **Which Level of membership do you hold?** | **Graduate** | 0 | **0.0%** | 3 | **15.8%** |
| | **Member** | 42 | **82.4%** | 15 | **78.9%** |
| | **Fellow** | 9 | **17.6%** | 1 | **5.3%** |

In the second survey the demographic questions were simplified and of the Australian laboratory workers of the 37 respondents who provided complete data, the majority worked in public laboratories, were female (26) and with more than 20 years' experience (14). AIMS was the most popular professional society (18), almost half working as Medical Scientists (18) and holding a bachelor's degree (23).

### 6.3.2 Descriptive analysis – First survey qualitative data

*(numbers of responses shown in brackets)*

The first survey then asked to answer 12 more question regarding their opinion of various aspects of the occupation with the results being shown in Table 9 below. Beginning with whether they believed that medical science was a profession. Both groups agreed strongly with this statement, 94% of Australian and 98% of International respondents. As described previously medical science is not a recognised healthcare profession in Australia.

The next questions asked about whether they thought that their work was recognised by the public or other healthcare professionals. Both groups from the initial survey did not believe that the public recognised their work. This was confirmed in the second survey with 78% (25/32) of the responses believed they were not recognised by the public.

The international group from the first survey believed that the other healthcare professions did recognise their work but 68% of Australian workers did not feel that they were recognised by the other healthcare professionals. This was confirmed by the Australian respondents in the second survey with 83% (26/31) commenting that they didn't feel recognised by their healthcare colleagues.

When asked about whether they considered that the occupation was respected by the public and other healthcare professionals, respondents did feel that their work was respected by the healthcare professions, however, the Australian respondents did not believe they were respected by either group.

Table 9: International v Australian opinions

| | | Do you currently work in Australia? | | | |
|---|---|---|---|---|---|
| | | No | | Yes | |
| | | *n* | % | n | % |
| **Do you think of Medical Science as a profession?** | **No** | 1 | **2.0%** | 1 | **6.3%** |
| | **Yes** | 49 | **98.0%** | 15 | **93.8%** |
| | **Don't Know** | 0 | **0.0%** | 0 | **0.0%** |
| **Do you think your work is recognised by the public?** | **No** | 26 | **52.0%** | 11 | **68.8%** |
| | **Yes** | 23 | **46.0%** | 4 | **25.0%** |
| | **Don't Know** | 1 | **2.0%** | 1 | **6.3%** |
| **Do you think your work is recognised by the other healthcare professions?** | **No** | 14 | **28.0%** | 7 | **43.8%** |
| | **Yes** | 34 | **68.0%** | 9 | **56.3%** |
| | **Don't Know** | 2 | **4.0%** | 0 | **0.0%** |
| **Do you feel your work is respected by the public?** | **No** | 23 | **46.0%** | 8 | **50.0%** |
| | **Yes** | 21 | **42.0%** | 5 | **31.3%** |
| | **Don't Know** | 6 | **12.0%** | 3 | **18.8%** |
| **Do you feel your work is respected by the other healthcare professions?** | **No** | 19 | **38.0%** | 8 | **53.3%** |
| | **Yes** | 28 | **56.0%** | 5 | **33.3%** |
| | **Don't Know** | 3 | **6.0%** | 2 | **13.3%** |
| **Do you think Continuing Professional Development (CPD) is important?** | **No** | 4 | **8.0%** | 0 | **0.0%** |
| | **Yes** | 45 | **90.0%** | 16 | **100.0%** |
| | **Don't Know** | 1 | **2.0%** | 0 | **0.0%** |
| | **No** | 2 | **4.1%** | 5 | **31.3%** |
| | **Yes** | 46 | **93.9%** | 11 | **68.8%** |

| | | | | | |
|---|---|---|---|---|---|
| **Does your workplace provide Continuing Professional Development?** | **Don't Know** | 1 | **2.0%** | 0 | **0.0%** |
| **Does your workplace provide protected time to do Continuing Professional Development?** | **No** | 16 | **32.0%** | 12 | **80.0%** |
| | **Yes** | 30 | **60.0%** | 2 | **13.3%** |
| | **Don't Know** | 4 | **8.0%** | 1 | **6.7%** |
| **Does your laboratory conduct annual competency assessments?** | **No** | 4 | **8.2%** | 3 | **18.8%** |
| | **Yes** | 43 | **87.8%** | 13 | **81.3%** |
| | **Don't Know** | 2 | **4.1%** | 0 | **0.0%** |
| **Do you think there are promotional opportunities within the profession?** | **No** | 22 | **44.9%** | 10 | **62.5%** |
| | **Yes** | 23 | **46.9%** | 6 | **37.5%** |
| | **Don't Know** | 4 | **8.2%** | 0 | **0.0%** |
| **Do you think governmental regulation or registration will improve the profession?** | **No** | 12 | **24.0%** | 4 | **25.0%** |
| | **Yes** | 36 | **72.0%** | 9 | **56.3%** |
| | **Don't Know** | 2 | **4.0%** | 3 | **18.8%** |
| **Do you think that pathology testing has a direct impact on patient care?** | **No** | 0 | **0.0%** | 0 | **0.0%** |
| | **Yes** | 48 | **100.0%** | 15 | **93.8%** |
| | **Don't Know** | 0 | **0.0%** | 1 | **6.3%** |

The next questions were regarding CPD. Both groups strongly agreed that it was important, but while 94% of the international respondents indicated that their workplace provided CPD only 69% of the Australians did. The respondents in the second survey made several comments about their CPD practice.

ISO standards require employees undertake CPD and most employers will allow time for completion.

### 5.1.8 Continuing education and professional development

- A continuing education programme shall be available to personnel who participate in managerial and technical processes.
- Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed.
- Personnel shall take part in regular professional development or other professional liaison activities. [69].

However, 80% of Australian respondents indicated that this was not done in their laboratory. Conversely, as the standards also require annual competencies to be conducted, more than 80% in both groups agreed that this was done in their workplace. Almost 100% of respondents believing that pathology testing has a direct impact on patient care with 62% of Australian respondents believing that few promotion opportunities existed within the profession.

Table 10 on the next page shows the eight subthemes of *Recognition, Regulation, Competency, Quality, Patient care/safety, Standardisation, Education and Waste* (time and or money). These were derived from analysis of the comments made in the first survey alongside these are pertinent comments that represent the findings and were used in the second, focused survey of Australian Medical Scientists to prove their validity.

Table 10 - Subthemes and comments from first survey

| Subtheme | Definition | Respondent quotes (*The numbers in brackets refer to the respondent which made the comment*) |
|---|---|---|
| **Recognition** | appreciation or acclaim for an achievement, service, or ability | The profession in my opinion lacks recognition in the public eye. The technologist/biomedical Scientist is not seen as playing a critical role in providing care to the patient (*53*) |
| **Regulation** | a rule or directive made and maintained by an authority | Poor quality scientists cannot simply go from lab to lab using very selective referees, it would also provide a basis for campaigning for scientists to have a recognised role in laboratory supervision (*34*) |
| **Competency** | the ability to do something successfully or efficiently | A countries health system would benefit as training, qualifications and CPD would hopefully increase competency and standards. Leading to an increased profile of profession, personal standards and conduct of those practicing in profession, (*67*) |
| **Quality** | the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production | More reliable results. Lower quality of applicants (*41*) |
| **Education** | a body of knowledge acquired while being educated | If ongoing professional education was required to maintain registration, then employers should be obliged to provide paid time to do such activities. With increasing pressure on all staff this is unlikely to happen. (*2*) |
| **Standardisation** | the process of making something conform to a standard | Improve the consistency and standard of care, as well as ensuring practitioners are adhering to the appropriate guidance and evidence base. (*13*) |
| **Patient safety** | the prevention of errors and adverse effects to patients associated with health care | Provide assurance this is good for the profession, the quality of scientist and helps to protect patients/ public (*35*) |
| **Waste** | an act or instance of using or expending something carelessly, extravagantly, or to no purpose | The plan to draw Medical Scientists into AHPRA (or other similar body) is a construct by people who have little to contribute in science and medicine and instead are focused on making time wasting petty rules and duties for everyone else. (*28*) |

Figure 4, below, shows how many responses were received in each category and their perceived positive or negative connotation. What is immediately apparent is that that both groups understand that the greatest professional impact would come in higher standards of patient care or safety. The largest number of responses identified that recognition held the greatest benefit both professionally and personally to pathology workers followed by and awareness of the importance of regulation.

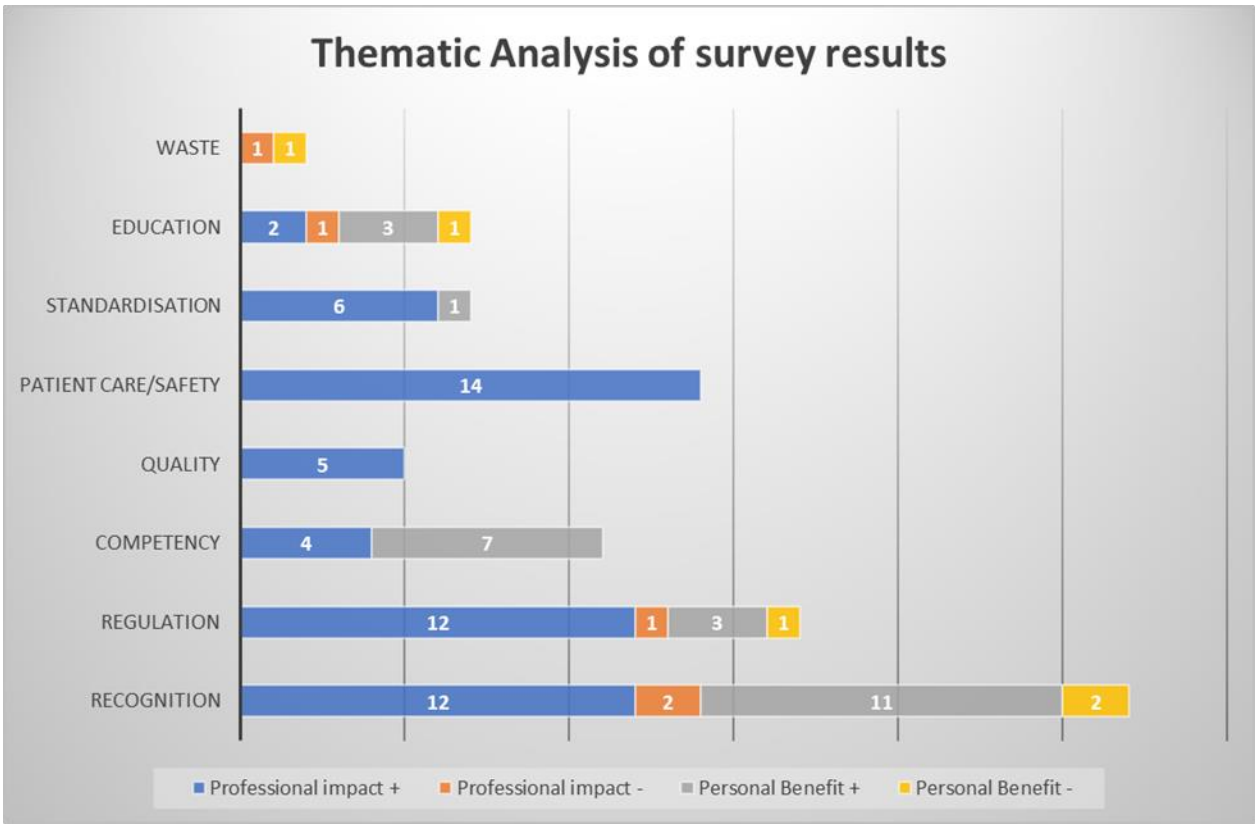


Figure 4- Thematic analysis of First survey data showing the relative numbers of positive and negative responses of Professional impact and Personal benefit for each of the themes

Overall, the comments were strongly in favour of registration being beneficial for the profession with 84% of the comments being positive. A further breakdown showed 88% of the international respondents were positive, with only 72% of the Australian based responses being positive.

### 6.3.3 Descriptive analysis – Second survey qualitative data

A second survey was conducted between November 2020 and February 2021 of Australian based Medical Scientists. It took the findings of the first survey and focused solely on the themes developed from analysis of the first survey data. This was to provide better understanding of the workforce's opinion of the professional impact and personal implications of registration and so that the number of responses were deemed to be sufficient to provide assurance around any findings.

Based on years of experience, the Australian based scientists who were new to the occupation were the most positive about registration. However, the most negative comments came from those with over 20 years of experience who highlighted the need to ensure that registration is not a waste of time or resources.

When levels of education are considered, the overwhelming number (86%) of positive comments for both themes of Personal Benefit and Professional Impact are from respondents with Bachelor's or Master's degrees. This reflects the workforce with the minimum requirements for employment in Pathology laboratories being a bachelor's degree in most countries.

The following analysis of each individual question provided some interesting insight into the opinions of the Australian pathology workforce.

1. "**What would the personal implications be if AHPRA registration for Medical Scientists was required in Australia?***"*

The answers to the first question were split with 17 of the 29 being negative, highlighting that the cost and time would be a waste. This would indicate that more education would be needed to increase awareness of the administrative processes. The models used by the other professions to mitigate the cost and time requirements to maintain their registrations

"*Registration seems like just extra fees and red tape with no real benefit*". **Medical Scientist with between 5-10 years' experience.**

"*A bit more pride, feeling like we are recognised a bit more as a profession rather than an afterthought"* **Supervisor with less than 5 years' experience**

The respondents for both survey groups highlighted recognition of their work as being the primary failure of the industry currently. It is beneficial for all parties that workers are proud of the work they do and being recognised for it.

"*It would mean that all staff working in the medical pathology services would be recognised as professionals and not be referred to by such terms as little lab girl, pathology boy*." **Medical Scientist with more than 20 years' experience.**

2. "**What would the professional impact be on Medical Scientists if AHPRA registration was required for employment in Australian Pathology laboratories?**"

Responses to the second question were much more biased with 23 of 31 highlighting positive professional impacts due to registration, predominantly identifying the increased regulation and competency leading to better recognition of pathology workers and higher levels of patient safety.

*"We are recognised however, have the stigma that since we are not patient facing, we do not 'care' about the patient as much as other healthcare professionals."* **Medical Scientist with less than 5 years' experience.**

**"***The professional standards of all Medical Scientists would improve as CPD would be compulsory. Employer groups would have to provide some additional sponsored or in-house CDP programs*." **Medical Scientist with more than 20 years' experience.**

"*There will be better accountability and probably more equitable salary scale based on qualification and experience*." **Manager with more than 20 years' experience.**

*It would maintain a high level of professional integrity of the medical laboratory science profession particularly scope of practice. This is important as there are examples of people employed with a generic biomed degree that are rotated through different areas and then lack suitable expertise."* **Manager with more than 20 years' experience.**

There were several comments which may have highlighted some less than ideal business practices which due to the lack of regulation and control seem to be prevalent. The lack of stringent scopes of practice and occupational definitions are discussed in detail in the final chapter of the thesis. It is possible that the industry is utilising this loose framework for the benefit of the employers by allowing them to ignore qualifications and experience and employ them at lower levels i.e. technicians.

*"There is one full-time Scientist position in our unit (of 30) and everyone else is employed as a Tech Officer or Tech Assistant. It is cheaper for our employer to do that."* **Technician with 10-15 years' experience**

*"Employers employ PhD as Tech Assistants as we need a job, and they can get away with it. I took it up certification as I thought it would make a difference and put me in a better position for a better job. No one cared."* **Technician with 15 - 20 years' experience**

There are several thousand highly qualified individuals employed in the pathology industry in Australia and it is clear from the responses that a significant proportion believe that AHPRA registration or a stringent, well-constructed self-regulation framework of the profession would be beneficial. Not only allowing for tighter regulation of the employee's competency but also their career opportunities by providing transparent framework for employers.

### 6.3.2 Descriptive analysis - Likert scale questions

*(number of responses appear in brackets)*

The final group of questions took 15 quotes provided by respondents of the first survey that provided both positive and negative aspects of the subthemes defined during the initial analysis. Using a Likert scale 35 respondents provided their opinion ranging from Strongly disagree through to Strongly agree to the following statements.

Table 11 - "The Medical Scientist is not seen as playing a critical role in providing care to the patient"

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 7 | 18.9 | 20.0 | 20.0 |
| | Disagree | 7 | 18.9 | 20.0 | 40.0 |
| | Neutral | 2 | 5.4 | 5.7 | 45.7 |
| | Agree | 12 | 32.4 | 34.3 | 80.0 |
| | Strongly agree | 7 | 18.9 | 20.0 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

More than half (54.3% or 19/35) of the respondents agreed or strongly agreed with this statement there were a significant number (40% or 14/35) which disagreed suggesting that this is inconclusive and could be attributed to an individual's personal experience or that the statement is not specific enough i.e., professional, or public recognition.

Table 12- "Medical Scientist should hold an approved degree"

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Disagree | 2 | 5.4 | 5.7 | 5.7 |
| | Neutral | 2 | 5.4 | 5.7 | 11.4 |
| | Agree | 6 | 16.2 | 17.1 | 28.6 |
| | Strongly agree | 25 | 67.6 | 71.4 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

The question of whether a Medical Scientist should hold an approved degree was almost universally supported with 71.4% (25/35) strongly agreeing with the statement. This would suggest that the Australian occupational standards which allow for the laboratory management to deem an employee's qualification relevant for a scientific position insufficient control of the education and training required. Approval should be provided by a recognised educational provider or accrediting body to standardise this process.

"*a degree at Australian Qualifications Framework level 7 with subjects relevant to the field of pathology, as determined by the person responsible for the scientific management of the laboratory and/or person responsible for the clinical governance of the laboratory, awarded from a university in Australia*" [65].

Table 13 - “Registration is a form of recognition and of professional standing”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 1 | 2.7 | 2.9 | 2.9 |
| | Disagree | 5 | 13.5 | 14.3 | 17.1 |
| | Neutral | 2 | 5.4 | 5.7 | 22.9 |
| | Agree | 12 | 32.4 | 34.3 | 57.1 |
| | Strongly agree | 15 | 40.5 | 42.9 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

With 77.1% (17/37) of respondents agreeing or strongly agreeing with the statement that registration is a form of professional recognition. It would imply that the lack of such recognition has some effect on Australian laboratory workers when they compare themselves with their colleagues in other healthcare occupations or overseas.

Table 14- “The current oversight by laboratory executive is enough”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 8 | 21.6 | 22.9 | 22.9 |
| | Disagree | 10 | 27.0 | 28.6 | 51.4 |
| | Neutral | 8 | 21.6 | 22.9 | 74.3 |
| | Agree | 6 | 16.2 | 17.1 | 91.4 |
| | Strongly agree | 3 | 8.1 | 8.6 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

In 2018 the NPAAC revised their documentation and responsibility for supervision of a laboratory in Australia now rests solely with a designated person who is a medical practitioner (RCPA registered Pathologist) with accreditation provided by NATA. Most workers believe this insufficient, considering that only 25.7% (9/35) agree that the current oversight by laboratory executive is enough.

Table 15 - "Employers should provide paid time for CPD, with increasing pressure on all staff this does not happen"

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Disagree | 5 | 13.5 | 14.3 | 14.3 |
| | Neutral | 6 | 16.2 | 17.1 | 31.4 |
| | Agree | 8 | 21.6 | 22.9 | 54.3 |
| | Strongly agree | 16 | 43.2 | 45.7 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

To ensure staff compliance and with 68.6% (24/37) agreeing or strongly agreeing with this statement it could be an area of improvement for employers in Australia.

Table 16- “Registration would just be another fee to pay”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 4 | 10.8 | 11.4 | 11.4 |
| | Disagree | 9 | 24.3 | 25.7 | 37.1 |
| | Neutral | 10 | 27.0 | 28.6 | 65.7 |
| | Agree | 8 | 21.6 | 22.9 | 88.6 |
| | Strongly agree | 4 | 10.8 | 11.4 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

Being the most common negative comment regarding registration made by respondents in both surveys, cites time and cost as the two chief forms of waste. However, the responses to this question show an even distribution with 37.1% (13/37) disagreeing and 34.3% (12/37) agreeing with the statement. It would suggest that more education around the administration of any prospective registration scheme to provide information of the benefits versus any extra financial cost to registrants is needed.

Table 17- "The Medical profession takes credit for the results or distribute blame to the Laboratory whichever is most convenient"

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Disagree | 5 | 13.5 | 14.3 | 14.3 |
| | Neutral | 4 | 10.8 | 11.4 | 25.7 |
| | Agree | 17 | 45.9 | 48.6 | 74.3 |
| | Strongly agree | 9 | 24.3 | 25.7 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

Another very common observation made by respondents to both surveys with 74.3% (26/37) believing that their contribution to the clinical results being unrecognised by the medical community at large. This would suggest that those responsible for increasing the recognition of the work done by Medical Scientists are not reaching the right audience and those strategies may need to be reviewed.

Table 18- “It would better protect the line between scientist and lab tech/assistant positions”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Disagree | 7 | 18.9 | 20.0 | 20.0 |
| | Neutral | 5 | 13.5 | 14.3 | 34.3 |
| | Agree | 18 | 48.6 | 51.4 | 85.7 |
| | Strongly agree | 5 | 13.5 | 14.3 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

To apply for a scientist position in Australia the applicant must hold an Australian Qualifications Framework (AQF) level 7 qualification or above (bachelors) and technicians need an AQF level 5 or 6 (Diploma/Advanced diploma). The AQF is the national policy for regulating qualifications in the Australian education system from 1 (certificate 1) to 10 (Doctoral degrees) [81]. Several comments from the second survey respondents highlighted a practice of employing applicants with bachelor’s degrees in technical positions. As 65.7% (23/37) agreed that registration would better define the roles of scientist and technician this would seem to confirm that the NPAAC occupational definitions, together with a defined scope of practice for each group need clarification. A national registration framework would inform this procedure and allow for greater control.

Table 19- "Registration provides a single governing body that provides guidance and direction to pathology practices"

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 3 | 8.1 | 8.6 | 8.6 |
| | Disagree | 2 | 5.4 | 5.7 | 14.3 |
| | Neutral | 6 | 16.2 | 17.1 | 31.4 |
| | Agree | 15 | 40.5 | 42.9 | 74.3 |
| | Strongly agree | 9 | 24.3 | 25.7 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

In other countries, the model for governing the medical science profession is that a single body has authority over all aspects with special interest groups providing discipline specific education e.g., IBMS, ASCP. In Australia although AIMS represent all disciplines its authority is diluted because the only governmental mandate it has is to oversee the immigration process for overseas applicants. While the smaller groups represent the interests of the single pathology disciplines 68.6% (24/37) agree or strongly agree with the need for a single body to govern a profession, it may be time to address the confused professional body framework in Australia.

Table 20- “Regulation prevents poor quality scientist moving from lab to lab with no control”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 3 | 8.1 | 8.6 | 8.6 |
| | Disagree | 5 | 13.5 | 14.3 | 22.9 |
| | Neutral | 5 | 13.5 | 14.3 | 37.1 |
| | Agree | 9 | 24.3 | 25.7 | 62.9 |
| | Strongly agree | 13 | 35.1 | 37.1 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

One of the most important aspects of Governmental regulation of a profession is the ability to revoke a license and prevent a member being employed in the field if they have seriously breached any of the requirements to continue to practice. This is the case in many international jurisdictions and is an important protection for the public, but there is no mechanism to achieve this in Australia including the new certification scheme. The respondents agree with 62.9% (22/37) understanding that this is an important control and reflects well on the profession.

Table 21- “Registration will improve the service to patients”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 3 | 8.1 | 8.6 | 8.6 |
| | Disagree | 4 | 10.8 | 11.4 | 20.0 |
| | Neutral | 6 | 16.2 | 17.1 | 37.1 |
| | Agree | 11 | 29.7 | 31.4 | 68.6 |
| | Strongly agree | 11 | 29.7 | 31.4 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

62.9% (22/37) of the respondents believe that a registration framework will improve the service to patients. In Australia membership to a professional society is voluntary and although CPD programs such as Australasian Professional Acknowledgement of Continuing Education (APACE) [82] which is available through AIMS, however involvement is also voluntary. Many of the comments received identified that mandatory CPD would increase the overall competency of workers.

Table 22- "It is waste of money and time for CPD points if the education is irrelevant to their specific profession"

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Disagree | 7 | 18.9 | 20.0 | 20.0 |
| | Neutral | 5 | 13.5 | 14.3 | 34.3 |
| | Agree | 18 | 48.6 | 51.4 | 85.7 |
| | Strongly agree | 5 | 13.5 | 14.3 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

65.7% or 23/37 agreed with this statement, considering the large number of societies that exist in Australia there is an opportunity for a discussion of the quality of education produced and whether ensuring consistency by appointing a single body to standardise the CPD being delivered across the country would be beneficial.

Table 23- “Registration would make minimal impact on the Australian healthcare system”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 5 | 13.5 | 14.3 | 14.3 |
| | Disagree | 10 | 27.0 | 28.6 | 42.9 |
| | Neutral | 10 | 27.0 | 28.6 | 71.4 |
| | Agree | 8 | 21.6 | 22.9 | 94.3 |
| | Strongly agree | 2 | 5.4 | 5.7 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

Although 43% (15/37) respondents disagreed with this statement the same number had a neutral response showing that most pathology workers are undecided as to the impact that professional registration of Medical Scientists in Australia would make on the Australian healthcare system.

Table 24- "Registration could lead to a better structure and help protect, promote and maintain the health and safety of the public"

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 2 | 5.4 | 5.7 | 5.7 |
| | Disagree | 5 | 13.5 | 14.3 | 20.0 |
| | Agree | 18 | 48.6 | 51.4 | 71.4 |
| | Strongly agree | 10 | 27.0 | 28.6 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

This statement provided one of the strongest responses with 80% (28/37) agreeing or strongly agreeing with it. It shows that Medical Scientists view patient safety as paramount in their role and are aware of the clinical implications attached to their work. A robust regulation framework can provide a platform for increased safety measures to be implemented further protesting patients and increasing recognition of a workforce.

However, when the results for the previous table are considered Medical Scientists in Australia are unsure whether a registration or licensing framework will have a tangible impact on the public. Therefore, more education should be provided to show that increased education through mandatory CPD and recognition can realistically impact patient outcomes and the current pandemic conditions have certainly educated the world's population about the importance of pathology testing.

Table 25- "Standardised training, qualifications and CPD would lead to increased competency and standards"

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | Strongly disagree | 1 | 2.7 | 2.9 | 2.9 |
| | Disagree | 2 | 5.4 | 5.7 | 8.6 |
| | Neutral | 3 | 8.1 | 8.6 | 17.1 |
| | Agree | 14 | 37.8 | 40.0 | 57.1 |
| | Strongly agree | 15 | 40.5 | 42.9 | 100.0 |
| | Total | 35 | 94.6 | 100.0 | |
| Missing | | 2 | 5.4 | | |
| Total | | 37 | 100.0 | | |

The majority of respondents (82.9% or 29/37) agree with statement that standardised training, qualifications and CPD would lead to increased competency and standards. All of this could be provided under a well-designed modern regulatory framework as the education of the workforce can be effectively governed through a single entity. Increased competency of practitioners can lead to better outcomes for patients by reduction of errors and a more educated workforce.

### 6.4 Discussion

Patient safety is always at the core of any healthcare profession and is one of the World Health Organisation (WHO) primary concerns. It has developed many strategies including the "5 moments for Medication safety" and World Patient safety day this year on the 17th of September [83]. It was therefore only fitting that the majority respondents recognise and agree with this sentiment.

By placing this at the centre with the major themes of Recognition, Regulation and Competency forming the framework, we can begin to understand the connections between the themes that were brought out of the analysis. The interconnectivity between the concepts of quality, education and standardisation as demonstrated in the diagram below.

Recognition is underpinned by quality of service and the education of the practitioners supporting greater patient care. Education is important in any field and while its impact within the laboratory setting is not well researched, many other fields recognised this higher education [84]. However, in a dynamic field like pathology continuing professional education is an important tool to maintain staff morale and knowledge.

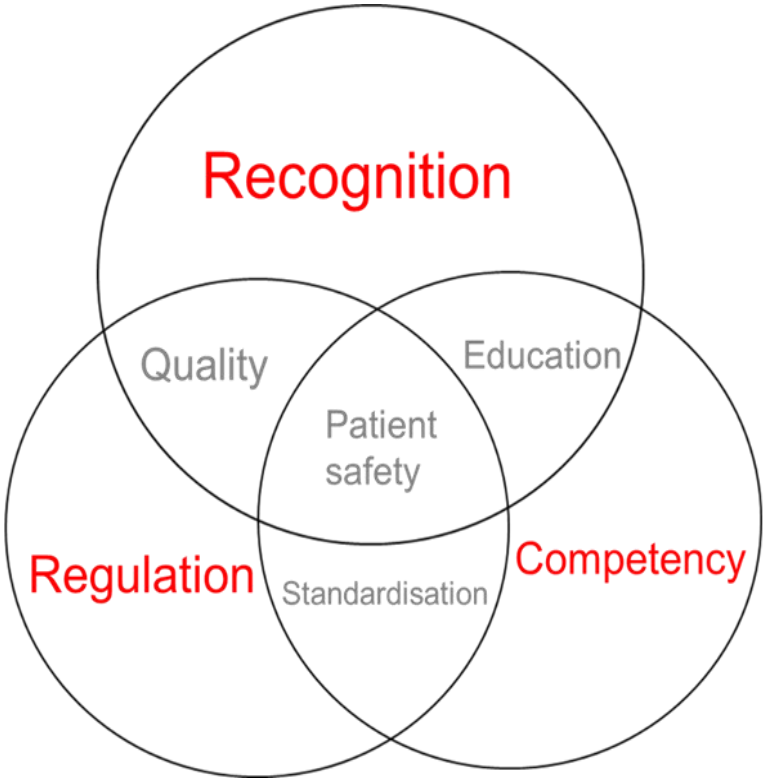


Figure 5- Thematic analysis diagram

Likewise, regulation which promotes better quality and standardisation within any arena leads to reduced errors and greater protection for the public [83]. Following the Second World War the rebuilding effort prompted the first true standardisation through safe building practices [83]. Standardisation of methods and material not only makes economic sense as it allows the business model to be more efficient, it also removes confusion over, not only products but clinical facets such as units of measure [85]. This practice standardisation reflects in quality measures with regulatory oversight becoming more transparent.

Finally, higher individual competency driven by better education and standardisation of procedures means that patient outcomes are maximised. Laboratory Technologists/scientists provided with the appropriate information will be able to make better, more informed decisions about the most efficient and safe way to provide the best clinical information.

The requirement for CPD is explicit in the ISO 15189 document which underpins laboratory accreditation in Australia [67]. However, NATA does not provide any guidelines for minimal requirement for CPD for technicians/scientists nor does it provide minimum time between CPD points collected. This means many practitioners in the lab may not be updated with changing diagnostic systems/techniques.

By applying these concepts to the current framework in the Australian pathology practice a degree of robustness could be achieved. Currently, the contribution of the scientists to the welfare of a patient is considered minimal. Recognition is something which is, perhaps, missing in the current scheme, but has been shown to be of paramount importance.

## 7. Do Medical Scientists meet the Australian Health Practitioner Regulation Agency definition of a healthcare profession?

### 7.1 Introduction

During the establishment of AHPRA Medical Scientists were excluded from the group of health professions that would be required to register with this federal body. The reason given was that laboratory workers were not seen to directly influence patient outcomes, as much as other professionals such as Doctors, Dentists, Nurses or Occupational therapists [5]. That means that there is effectively no regulation of Medical Scientists, clinical governance is provided by the registration of the Pathologist supervising the laboratory and by NATA accreditation.

Six criteria are applied to any occupation that applies for inclusion into the AHPRA registration framework.

1. *It is appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?*
2. *Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?*
3. *Do existing regulatory or other mechanisms fail to address health and safety issues?*
4. *Is regulation possible to implement for the occupation in question?*
5. *Is regulation practical to implement for the occupation in question?*
6. *Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?* [5].

Internationally, many Medical Scientists are regarded as a profession equal to other associated healthcare occupations. Australia stands out as an anomaly in this regard; consequentially there is no national registry for laboratory scientists/technicians, or records of CPD, nor commensurate recognition of the work of the profession in Australia as a whole. This chapter serves to review each of the six stipulations cited above and to provide evidence as to whether Medical Scientists meet each stipulation and should therefore be recognised by AHPRA.

## 7.2 Discussion

In 2008 the Council of Australian Governments ratified the formation of a national registration program for healthcare occupations. Correspondence the following year from the Pathology Associations Council and published on the AIMS website stated, due to the *"…success of the NATA/RCPA laboratory accreditation scheme …the government's view is there is no evidence that scientist registration is required"* [64]. The AHPRA was established on the 1st of July 2010 and now oversees fifteen healthcare professions in Australia.

One of the most common reasons for Medical Scientist's exclusion was that they are perceived as not having enough direct patient contact despite having influence on patient welfare. Published in 2011, a comprehensive study of 57 nurses in two wards of a large Sydney teaching hospital found that the staff spent on average 37% of their time in direct patient contact [86]. The amount of contact time a nurse has with a patient will obviously differ depending on the department in which they are working.

Conversely a phlebotomist [87] spends almost their entire workday collecting specimens through direct contact with a patient. Initially during the negotiations to decide which professions would or would not become regulated under AHPRA, six criteria were used to define an occupation to be included, which are detailed in the following pages.

### 7.2.1 It is appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?

The incumbent Minister of Health has always been responsible for the regulation of Pathology services in Australia. NPAAC was formed in 1979 after the Commonwealth and indirectly the Australian parliament signed new legislation allowing its formation and representatives are appointed by the Minister. Their role is to develop guidelines that govern pathology within Australia such as the Requirements For Medical Pathology Services (2nd Edition 2018) [75] and the Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (4th Edition 2018) [65].

All Pathologists practicing within Australia and New Zealand are required to hold registration with the Medical Board of Australia which is supported by AHPRA and reports to the Australian Health Ministers Advisory Council. The MSCNZ monitors the registration of Medical Laboratory Scientists and Pre-Analytical Laboratory Technicians on behalf of the Ministry of Health in New Zealand [22].

In the United Kingdom, Pathologists are registered under the General Medical Council (GMC) while Biomedical Scientists can register with the HCPC [10] as one of the nine statutory healthcare regulatory bodies recognised by the Professional Standards Authority for Health and Social Care in the UK. Irish Pathologists are governed by the Irish Medical Council (IMC) with the CORU [13] was set up in 2005 as an independent regulator of fourteen recognised professions, including Medical Scientists, governed by the Department of Health in Ireland.

American Pathologists and Technologists in more than 40 states must hold ASCP [15] certification to be employed. In Canada it is the purview of the Royal College of Physicians and Surgeons of Canada (RCPSC) [88] and the CSMLS [17], along with analogous provincial registration for both professions. In Qatar all Pathologists and Technologists working in the country must hold a practicing license provided by the Qatar Ministry of Public Health – Department of Licensing and Registration through the QCHP [89].

These professional associations are listed in Table 26 below and shows that every organisation providing registration is either directly or indirectly governed by its countries Health Authorities.

Table 26- International Registration bodies

| | **UK** | **Ireland** | **USA** | **Canada** | **Qatar** | **New Zealand** | **Australia** |
|---|---|---|---|---|---|---|---|
| **Pathologist** | GMC | IMC | ABPath | RCPSC | QCHP | RCPA | RCPA |
| **Medical Scientist** | HCPC | CORU | ASCP | CSMLS | QCHP | MSCNZ | NONE |

It would seem a reasonable assumption that regulation of Australian Medical Scientists should therefore also fall under the responsibility of the Ministry of Health in Australia.

"*The system at present causes problems internationally, as most countries require licenses for professional staff to work and Medical Scientists do not have this.*" **Manager with more than 20 years' experience.**

### 7.2.2 Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?

It is widely accepted that laboratory medicine influences approximately 70% of all clinical decisions, which is covered in more detail in Chapter 4 [31]. According to the WHO more people die annually of CVD than any other cause [41]. This may suggest that almost 16 million Australians, 64% of the population, are potentially affected by CVD with almost all of them requiring some laboratory investigation [53]. Thus, there is no other discipline that is able to provide the information that the Physician requires to make an informed diagnosis; and so, any misdiagnosis would likely constitute a risk to the public.

All cancer diagnoses require a Pathologist's expertise, but before any Pathologist sees a slide for review the Medical Scientists in the laboratory must prepare the specimen. If their work is not of the highest quality, it will certainly impair the ability to make critical decisions. The International Agency for Research on Cancer reported through the WHO that 18.1 million new cases of cancer were diagnosed worldwide in 2018 [90] making the magnitude of this work substantial. Pathologist assistants, Advanced Dissectionists and Medical scientist with more than 3 years experience in Australia are able to perform cut up on complex specimens [75] implying that they are part of the diagniostic process.

Every blood transfusion comes with a certain amount of risk to the patient and while there has not been a transfusion–related death in Australia since 2004, between 2010 and 2014 there were 2,243 adverse events related to transfusions reported to the National Australian Haemovigilance program

[91]. If we consider the societal, health and financial implications of the work produced by Medical Scientists, it will seem reasonable to argue that their services may pose a significant risk of harm to the public in the event of inaccurate laboratory findings.

### 7.2.3 Do existing regulatory or other mechanisms fail to address health and safety issues?

The existing regulatory mechanism in Australian laboratories is two-fold: First it involves a registered Pathologist who governs all aspects of the Laboratory testing; and secondly, periodic NATA inspections are conducted to ensure compliance with ISO 15189 standards. The Australian Government considers these controls to be sufficiently successful. In correspondence to AIMS the Federal Minister for Health stated that pathology testing relies on the collaborative relationship between Pathologists and laboratory staff [92], however due to the lack of regulation the laboratory staff cannot be held accountable for any laboratory errors beyond any human resources process, whereas the Pathologists risk losing their registration.

Registration is not purely concerned with disciplining registrants, but sets standards for education, training and CPD. Regulatory mechanisms in place in the UK have conducted 181 hearings, leading to 34 Scientists being removed from the register [93] and 4 disciplinary actions in New Zealand [94] of laboratory workers in the past four years. Both countries have investigated a number of significant incidents that have resulted in potential harm to patients due to laboratory errors [61, 63].

While the ultimate responsibility for the test result lies with the Pathologist, this system was exposed in 2016 through the South Australia (SA) Pathology Prostate Specific Antigen (PSA) testing incident and described in detail in Chapter 5. SA Pathology is a NATA accredited laboratory in Adelaide with Pathologists on staff. However, due to a number of analytical errors, a lack of clinical oversight and poor management, a number of false positive PSA test results were released by the laboratory [57]. The subsequent review resulted in five recommendations, requiring SA Pathology to undergo another NATA inspection, recommended a managerial change and also various IT improvements.

### 7.2.4 Is regulation possible to implement for the occupation in question?

In Australia, despite there being a federal regulatory body, the AHPRA decision stands out because it prevented the adoption of a framework for an occupation that exists in many other western developed nations. Internationally, the regulation of Medical Scientist started over a century ago in the UK and has been subject to governmental monitoring in other countries for greater than 25 years.

Globally, various nations recognise medical laboratory science as being a formal profession. As recently as December 2018, Irish Medical Technologists were required to register with CORU.[13] and in March 2021 the Indian Government passed legislation to enable registration of pathology workers [95]. This requirement was achieved in a relatively short time frame, in the case of New Zealand, a registration mechanism was implemented two years following a decision by the government [22].

In a 2016 AHPRA document entitled "*Comparison of international accreditation systems for registered health professions"* [6] the researchers confirm the aforementioned, by comparing the regulated professions in Canada, Ireland, New Zealand, the UK and USA. Each of these nations have comparable health, regulatory and education standards in their health professions. In each country Medical Scientists are listed as a registered health profession, but this is not so in Australia.

### 7.2.5 Is regulation practical to implement for the occupation in question?

The well-established framework already exists in Australia, with AIMS providing a suitable membership structure, professional assessment, education accreditation, CPD program and quality assurance services aligned with the guidance from NPAAC. The only missing aspect is the political acknowledgement and legislative support which is enjoyed by its counterparts in the international community.

In 2020 the Australian Council for the Certification of the Medical Laboratory Scientific Workforce (ACCMLSW) was implemented and currently certifies 260 pathology laboratory workers in Australia [36]. Occupational certification is an important and practical step in professional recognition however the Author would question the need to establish a new entity in an already crowded and confused landscape of pathology professional societies. Although it is preferable to be supported by AHPRA a robust system of regulation could have been achieved independently if the designers had considered a change from the traditional registration framework which is clearly not engaging the workforce sufficiently with < 1% of eligible pathology laboratory staff applying for certification.

A blockchain credentialing model has been recently used internationally to monitor the movements of medical personnel in America and by the University of Melbourne and the Royal Melbourne Institute of Technology (RMIT) [96]. This platform could have been used by all the pathology employers in Australia. This open-source solution was developed initially for security of bitcoin transactions. By engaging the laboratory human resources function from across the country every employee of a pathology lab could be set up with a blockchain account with information such a qualifications and competency data securely attached to them.

Manipulation of this data by the stakeholders would provide accurate workforce data for the users, such as skill set distribution among separate sites, current CPD or competency levels. This data will inform the employer, inspection teams and professional societies depending on their specific needs. This provides a form of register with the added security of being able to identify poor practitioners and lock them out of the system for a non-compliance, a critical function not currently available in Australia and the most important public protection.

Unfortunately, the designers of the ACCMLSW neglected to address this considering the credibility of the certification framework to be more important. In the following statement "*…compulsory participation is not a feasible option for the proposed certification scheme… the primary purpose of sanctions will be to protect the credibility of the scheme"* [97].

Any robust licensing framework needs to be compulsory to all workers and the members of the Australian pathology industry need to find a way to use the tools already available in a cohesive

fashion, as it is futile to continue with the fragmented system that currently exists. It is this authors opinion that a compulsory certification using the AIMS APACE framework supported by a Blockchain credentialing system would benefit employers and professional bodies alike.

### 7.2.6 Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

The reporting of laboratory errors is of great benefit to the public and AHPRA registration offers a legal forum for open and transparent reporting of laboratory investigations. There is no mechanism in Australia for action against laboratory workers as there is in many other countries. The federal government believes that a Code of Conduct is all that is necessary to protect the public. A Code of Conduct carries no legal leverage and despite the existence of a robust regulation framework Medical Scientists are still excluded.

In the report of the SA Pathology incident several comments were made regarding the knowledge of the staff involved. *"The urologist told the review that when he called SA Pathology he spoke to a scientist who appeared to have no understanding of the clinical implications of the inaccurate low level tests."* [57]. A voluntary framework of self-regulation or certification means that there is no mandatory requirement for scientists to seek professional development and keep up with current standards of practice. AIMS have a CPD program in place but cannot currently mandate its use across the workforce [82].

Mandatory CPD is a requirement of ISO15189 and appears in the NPAAC document Requirements for Medical Pathology services.

**C6.1(ii)** *All qualified staff involved in the provision of Medical Pathology Services must provide documented evidence of participation in continuing professional development commensurate with their role and responsibilities.*

If we consider that the current model of self-regulation may not be sustainable given the increasing reliance on laboratory findings by physicians, the increased use of technology and reduced clinical oversight and responsibility for the quality of test results provided by scientific staff the benefits to the public of regulation clearly outweigh the potential negative impact of a quality incident such as was seen in SA Pathology.

### 7.3 Conclusions

AHPRA applies six criteria to any occupation to ascertain whether accreditation is beneficial and therefore is in the best interest of the public and the medical community in Australia. This study has shown that Medical Scientists seems to meet all these requirements. The Australian Government appears content with the current measures in place which only requires a laboratory to have a Registered Pathologist, and NATA accreditation. The most common argument is that pathology workers "*don't have enough patient contact*" or "*influence patient outcomes sufficiently"*, however, as we have seen, this seems unreasonable. Also, considering that this is not the case among the international community, the current Australian position is an anomaly.

A professional regulatory body is responsible for setting appropriate standards for education, training, and practice. Arguably, the most important public protection provided by an accredited profession is accountability through the threat of professional; disciplinary processes against a member, when or if it is deemed appropriate; without regulation this is not possible. The increased use of technology and automated verification of results to overcome the huge amount of testing requested means that oversight by a Pathologist becomes increasingly reduced, with the responsibility thrust more upon the unregistered Medical Scientist particularly in remote or regional facilities where a Pathologist may not be immediately available.

The regulation of the Medical Scientist profession is managed in many countries and should be easily implemented in Australia if the available tools are used in a cohesive fashion. Despite the good intentions of the certification scheme, it needed to be better designed and implemented. A

blockchain based credentialing system akin to that used by the University of Melbourne and Royal Melbourne Institute of Technology (RMIT) would provide a more robust solution.

A framework utilising this type of platform would have addressed the major failings of the ACCMLSW which has opted for a traditional method and has seen <0.5% workforce engagement, while admitting that in their opinion that the most important function of a registration was unachievable. A blockchain site could be used to provide valuable resources to both employers and professional societies with the ability to inform either of non-compliance or restrict a practitioner's scope remotely providing control that is absent currently.

The use of a blockchain credentialing system could be used as a form of registration with the employer adding the employee's annual competency documents coupled with the employee adding their completed CPD. Once they have met all requirements the licensing body can add a block for the calendar year. In order to gain employers, buy in by providing workforce data on their employees nationwide allowing their HR to redeploy staff based on skill set, they can assess a new employees competency. The licensing body would have up to date workforce data for the country which currently relies on census data.

It remains concerning that the Australian Government appears comfortable with funding a less rigorous and largely opaque system of a code of conduct for Australian Medical Scientists. A comprehensive review of the current career framework would benefit the occupations as we can see in Chapter 8.

# 8. A review of the current medical science career framework in Australia and recommendations for the future

## 8.1 Introduction

The International Organisation for Standardisation (ISO) was founded in 1947 to promote conformity in worldwide standards [98]. It is a union of two earlier organizations: The International Federation of the National Standardising Associations (ISA) and the United Nations Standards Coordinating Committee (UNSCC).

The ISA was established in New York in 1926 but was based in Switzerland and its standards were adopted by many European countries that used the metric system; however, the ISA ceased operation at the beginning of hostilities in Europe. In contrast, the UNSCC was adopted by those countries that used the imperial system such as America, Canada, and the United Kingdom. The UNSCC was established as a branch of the International Electrotechnical Commission (IEC) from 1944 to aid the reconstruction efforts following the Second World War [98].

In 1987 ISO published its first quality management systems standard, ISO 9001, which described the fundamental principles of quality management. This standard has become one of the most popular management tools used today. In 1999, the ISO published the *General requirements for the competence of testing and calibration laboratories* as document ISO/IEC 17025:1999, which is used to assess the competence of most laboratories.

Then in 2003, the first edition of ISO 15189 *Medical Laboratories – Requirements for quality and competence* was released which provides specific advice for pathology testing [99]. These documents have provided the basis for standardisation of clinical laboratories worldwide and have been adopted by all 162 of the ISO member nations including Australia, where the NATA was formed in 1947.

Initially established to ensure the standard of munitions produced in Australia, NATA eventually grew to provide services for a third of all chemical and mechanical laboratories in Australia by the end of the 1970's and began accrediting medical facilities in 1983. In 1988, NATA signed a Memorandum of Understanding with the Commonwealth Government of Australia to provide accreditation services across Australia, which would allow accredited facilities to claim Medicare benefits. Today, any Pathology laboratory in Australia must be inspected biennially to ensure that they hold to the standard required in order to practice [67].

NPAAC are the government appointed body which are charged with ensuring that laboratory staff are "*appropriately qualified, competent and have a relevant scope of practice and accountable for the testing performed*" [92]. This is done through the *"Requirements for Medical Pathology Services"* [75] and" *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories"* [65].

The scope of these documents is described as providing standards for good medical pathology practice, describes the categories of pathology laboratories, roles of key staff, including, Pathologists, Clinical Scientists (CS), Medical Scientists (MS) and Technical Officers (TO) and to ensure that all tests are supervised by competent persons who are working within their Scope of Practice, a scope of practice which is out of date [65, 75].

AIMS is considered the largest professional body representing Medical Scientists in Australia. They provide many services that adhere to the NATA and NPAAC requirements for Australian laboratories. AIMS along with the AACB commissioned the ACCMLSW using funding from the Australian Government's Quality Use of Pathology program (QUPP).

All these important bodies have significant roles in defining the pathology service in Australia. With the imminent implementation of this scheme, it would seem prudent to review these documents and assess the impact on the occupation. Where possible it would be valuable to recommend improvements to ensure that the new framework is relevant and meaningful to the Pathology service in the future.

### 8.2 Australian Pathology Occupational Definitions

Internationally, the medical science profession is controlled by a governmental registration body and a professional society. The former has legal authority to apply sanctions to practitioners while the latter acts as a credentialing body and ensures the highest level of professional practice through CPD. In Australia, medical science is not a recognised as a profession and the laboratory is controlled by a registered Pathologist and industry accreditation.

NPAAC has provided the standards of practice for the pathology services within Australia since the "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories"* was first published in 1999 and was revised and reprinted in 2018 [65]. This document includes definitions of the roles and functions of a pathology laboratory, and guidelines to ensure legislative compliance. All laboratories must comply to receive funding through Medicare.

To this end NPAAC has defined four grades of pathology laboratory workers in Australia. These grades are based on education and experience and encompass Technical Officer (TO) through to Clinical Scientist.

A Technical Officer is someone who has completed a 2-year certificate or diploma level qualification in the field of pathology. These qualifications match those required of a Medical Laboratory Technician which is a classification provided under the Australian and New Zealand Standard Classification of Occupations (ANZSCO) 311213 [100].

The question arises as to why this level of practitioner carries two different titles one assigned by the NPAAC and the other by ANZCO.

A Medical Scientist requires.

*(a) a degree at Australian Qualifications Framework level 7 (Bachelor) with subjects relevant to the field of pathology, as determined by the person responsible for the scientific management of the laboratory and/or person responsible for the clinical governance of the laboratory, awarded from a university in Australia; or*

*(b) a degree at Australian Qualifications Framework level 7 (Bachelor) with subjects relevant to the field of pathology awarded by an overseas tertiary institution if the qualification is assessed as equivalent to a degree accredited by the AIMS, according to their authority approved by Australian Education International via the National Office of Overseas Skills Recognition (AEI−NOOSR); or*

*(c) An associate qualification conferred by the Australian Institute of Medical Technologists before 1 December 1973.*

In practice, however, there are only two pathways to employment as a Medical Scientist in clinical laboratories in Australia, as the third is historic. The first pathway suffers from the problems of relevance and responsibility. In the context of relevance, what subjects are considered relevant to pathology?

Any life science graduate could be considered to have the requisite background to fulfil this criterion. But they will not necessarily have any understanding of test validations, quality control metrics or proficiency testing requirements. The net is therefore cast very wide and lacks any appreciation of vocational training. The issue of responsibility lies with the person determining the relevance of degrees, which appears to lie with either the scientific or clinical lead of an individual laboratory. Critically, the second pathway includes an objective body (i.e., AIMS) assessing the relevance of degrees, with universal responsibility for that assessment; however, this independent assessment only has authority over foreign qualifications.

The requirements to work as a Medical Scientist in Australia have evolved since the 2007 edition of the NPAAC "Requirements for the Supervision of Pathology Laboratories" [101]. In which a Medical Scientist needed to have a three year science degree from an Australian university "*that provides for direct entry or following examination to a professional class of membership of the AACB, AIMS, Australian Society of Microbiology (ASM), Australian Society of Cytology (ASC),or the Human Genetics Society of Australasia (HGSA)"* [101].

Therefore, in 2007 NPAAC acknowledges Australian professional societies as appropriate credentialing bodies with the understanding that the scientist's qualification/education would allow membership. It is concerning that since 2007 NPAAC has allowed an erosion of the significance of medical science professional societies in Australia. By allowing domestic applicants to bypass the only credible assessment of their education NPAAC has effectively negated the need for vocational degrees in Australia and any universal oversight of the relevance of Australian degrees.

Internationally, professional societies such as AIMS are used to assess the relevance of higher education degrees for working in pathology laboratories. For example in the UK a Biomedical Scientist must hold "*a BSc (Hons) degree in biomedical science accredited by the Institute of Biomedical Science (IBMS)*" [9]. In New Zealand a graduate must hold a Bachelor of Medical Laboratory Science or a Graduate diploma in Medical Laboratory Science to be registered and to work in a pathology laboratory [22]. In Canada no one is considered for registration without graduating from a degree program approved by the CSMLS programs and then passing a certification exam [17]. In the United States, in order to be certified and credentialed as a medical laboratory scientist by the ASCP , you must meet two criteria: 1) have a bachelor's degree and 2) successfully complete a NAACLS accredited MLS program [15].

The same NPAAC document goes on to define a **"credentialing body"** as a; "*formally constituted committee of practitioners and managers who collectively analyse and verify the information submitted by an applicant,."* [65]. This definition allows the management of each individual laboratory in Australia to decide whether the applicant's qualifications are adequate for employment. Suggesting that, in the case of Medical Scientists, anyone who is working in the field can provide primary source verification of every domestic qualification available within Australia and its *"subjects relevant to the field of pathology".*

One of the main directives of NPAAC which offers an extremely important layer of security for the public, is to ensure a consistent and transparent application of occupational definitions within the pathology environment. This can only be achieved if a single body is responsible for it and as

AIMS is already providing the service for international applications. It is the author's view that professional society's involvement should be required as a gateway for all graduates.

The next recognised level of appointment available to a Medical Scientist is described as the "Onsite Manager of a Category B or branch laboratory". This role is defined as a scientist with at least two years relevant experience in a larger laboratory. A subset of this role is the Quality Manager which is described *"as a member of staff appointed with delegated authority to ensure that processes needed for the Quality System (QS) are established, implemented and maintained"*.

Therefore, in a branch laboratory, only the onsite manager may be responsible for this role which adds a large level of complexity to an already demanding role. To effectively manage a compliant laboratory of any size it would be prudent to have some managerial training, financial education, and functional appreciation of human resources concepts.

In the UK a Laboratory Manager (Training, Quality or Operational) has a very specific set of well-defined responsibilities to ensure these important, and largely non-clinical obligations support the laboratory and with none of these roles defined in the Australian pathology workforce it would seem beneficial to establish definitions for the future of the service and its workers. There is an opportunity for the Australian professional societies to demonstrate valuable leadership, using the fellowship program as a vehicle for the role of Laboratory Manager.

Fellowship is a well-respected professional qualification around the world and is worthy addition to any resume. It should be used to provide professional recognition of the role of manager in a pathology laboratory not only for Clinical Scientists. The requirements for Laboratory Managers should include a master's level qualification coupled with a professional fellowship.

Currently, fellowship is only available in a clinical discipline and in some instances, it is too specific for many of the regions in Australia, for example, the Anatomical Pathology Fellowship requires examination in Electron Microscopy. A valuable alternative for many experienced scientists would be the development of a general management fellowship with management, financial and human resources components. This structure is shown in Figure 6 below


Figure 6 – A proposed pathology managerial pathway

The final level of promotion available to Medical Scientists is that of a Clinical Scientist which is defined as a scientist who has five years laboratory experience. They must also be in possession of a Doctor of Philosophy or a Fellowship from AIMS, AACB, ASM, HGSA, ASC or RCPA.

Clinical Scientists in Australia hold important positions in a pathology laboratory. Their advanced education is valuable in the clinical setting and provide clinical assistance to Pathologists. Their career pathway is prescribed by the Royal College of Pathologists (UK) and provides a valuable alternative for interested and experienced Medical Scientists. Medical Scientists in Australia can also train under a Pathologist or Clinical Scientist to gain a Fellowship of the Faculty of Science of the RCPA.

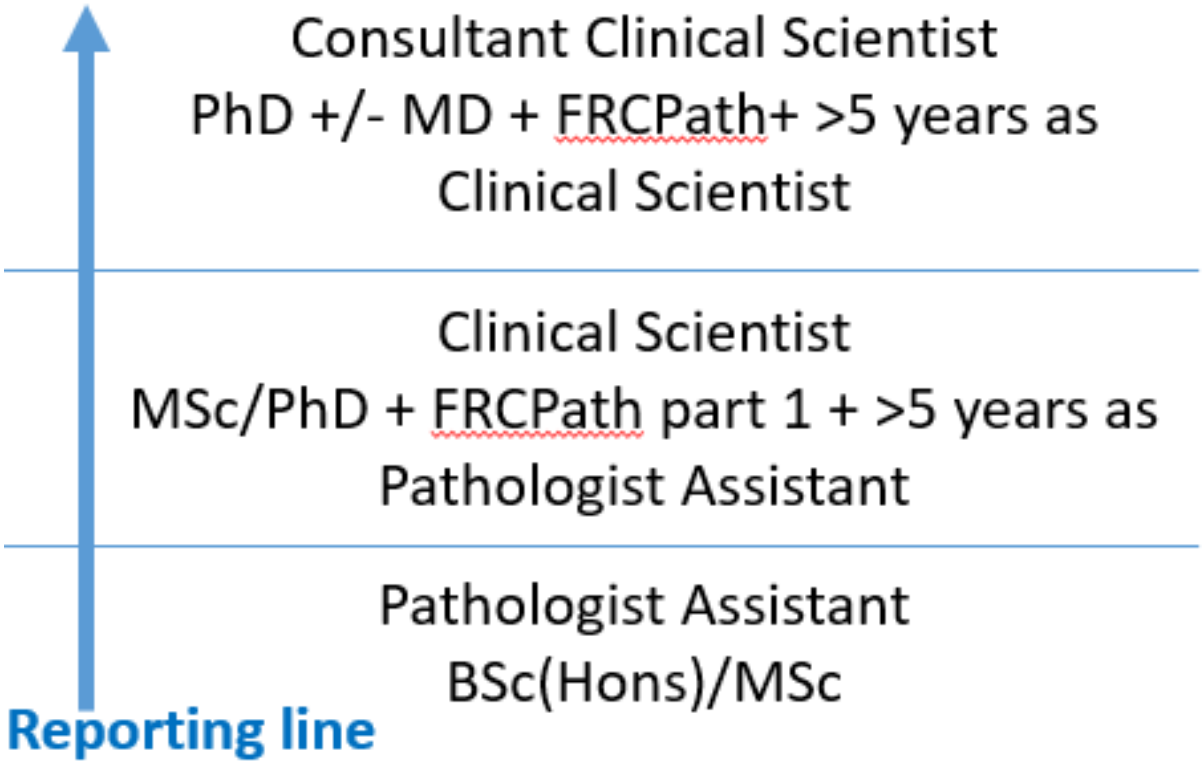


Figure 7- Clinical Scientist pathway used in the UK

However, the current NPAAC definition "*in a subject relevant to the scope of diagnostic testing of the laboratory they are supervising*" [65] does not consider PhD graduates of non-clinical subjects such as education or management. It would seem unrealistic to label these members as clinical scientists in view of their specialist subject. The career structure in Figure 7 describes an appropriate alternative pathway for an experienced Medical Scientist who might hold or be completing a PhD in a relevant subject to gain Medical Council registration which is modelled internationally is unavailable currently within Australia.

### 8.3 Scope of Practice

Any occupation's "Scope of Practice" is a foundation document that is commonly used to "*describe the procedures, actions and processes that a healthcare practitioner permitted to undertake in keeping with the terms of their professional license"* [102]. NPAAC has provided a definition of the scope of practice for any pathology worker in the "Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories" which states.

"*the discipline and/or areas of testing in which a person has been trained and successfully examined or assessed as competent by the relevant College, professional society, or credentialing body and in which they have met current Continuing Professional Development and recency of practice requirements."[65].*

Ironically this definition is more applicable to those countries that require registration of their laboratory workers but seems at odds with the current environment in Australia. The second part of the phrase that mentions competency assessment and CPD requirements, stipulating that this can only be done by "*the relevant College, professional society, or credentialing body"* is difficult for Medical Scientists to comply with. Given that there is no relevant college overseeing Medical Scientists in Australia, and while several professional societies do exist, membership is not mandatory, and it has been transferred to NATA to determine competency as part of the laboratory accreditation process in Australia.

However, NATA does not provide practicing licenses to individuals and is only required to ensure that the staff are competent during inspection. The individual laboratories are left to ensure CPD, training and competency requirements are met. As the laboratory management can be defined as a credentialing body, it can impose any scope of practice that they deem appropriate on their staff.

This leads to an inconsistency across the entire pathology service, which can only be addressed through standardisation.

The current guidance provided by the Pathology Associations Council in the "*Competency-based Standards for Medical Scientists*" [103] released in 2009 in consultation with each of the professional societies and approved by the AIMS board seems to be the recognised scope of practice. However, the AACB released a "Scope of Practice of the Scientific Workforce of the Pathology Laboratory" [104] in 2011. While these documents seem to complement each other there is some confusion over which is the official version and who it would apply to within the workforce.

Since there is no relevant college or recognised single over-arching professional society these documents need to be reviewed with respect to the recently released NPAAC document as the definitions are now out of date. However, as we have seen, it is of no consequence as the new definition means that it need not be applied unless the laboratory chooses to adopt it. This situation will not be resolved until the NPAAC revises its own definitions.

*"As a vocational educator required to maintain 'currency' in my fields of teaching, I believe registration is a good idea. However, the AIMS process for accreditation appeared circular. I could not see a clear way of having my teaching acknowledged as valid practice."* **Supervisor with more than 20 years' experience.**

### 8.4 The role of the certification scheme

AIMS and the AACB have proposed a certification scheme for Medical Laboratory Scientists which was implemented in 2020. This project was backed by funding from the QUPP, which is a national program for promoting and funding initiatives within the pathology services. In principle, this project has many redeeming qualities and addresses many of the deficiencies currently facing the profession in Australia. However, there are flaws in its execution, notably over its voluntary nature, the inability to regulate practitioners, including their removal from the register for misadventure determining qualifications, clarification of scope of practice for the profession or providing a transparent career framework.

Between 2017 and 2019 several stakeholder meetings were held and the certification scheme's Implementation Plan was published in April 2019 [105]. Beginning with the recruitment of a Registrar and Administrative Assistants in December 2019 and initial certifications being issued in July 2020. The Australian professional societies have placed their support behind the scheme, but the implementation plan identified a lack of support by employers, which could be promoted using a blockchain platform which could be used to provide valuable workforce data.

The voluntary nature of the scheme leading to the scheme's inability to sanction members are, in the author's opinion, devaluing elements that are a fundamental protection of a regulatory framework. This important protection mechanism cannot be applied indiscriminately to different members of the laboratory community based on a non-mandatory requirement. This would be manifestly unfair and the only realistic method to achieve this important public security is for certification to become mandatory for employment in Australia.

The obvious solution of pressuring the Australian Government to allow Medical Scientists inclusion into AHPRA has been unsuccessful. Therefore, it is the opinion of this Author that a new strategy needs to be applied, along the lines of those used in the international community, most notably in the United States of America.

The ASCP provide a rigorous certification program which is now used in most States. This program is given weight by being recognised by the CAP which has governmental support for accreditation of laboratories in America as NATA does in Australia. If the certification program could be built to ISO standard, then it could be promoted by NPAAC and NATA as its sole recognised Medical Scientist competency framework.

Emerging blockchain technology is being used to provide security to credentialing programs for medical staff and other industries such as Mining and Oil. This approach has wide ranging benefits in Human resource management across a profession, including up to date workforce data. The certification scheme was ideally placed to take advantage of this, but it was decided to adopt a more traditional framework albeit missing some fundamental characteristics.

"*I took certification as I thought it would make a difference and put me in a better position for a better job. No one cared*." **Technician with 15-20 years' experience**

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### 8.5 A New Fellowship

The current fellowship model used by the Australian professional societies for Medical Scientists is very different for each group.

- The AACB require two written and an oral exam
- The ASM has a 3-part process with an exam, 3 written essays and 5-10 high impact journal publications.
- The ASC require a written, and oral exam, and a 5000-word literature review
- AIMS require 4 written exams, a viva, and a scientific dissertation or research degree thesis.
- The HGSA send their applicants to the RCPA Faculty of Science program.

The proposed certification scheme is striving to provide a standardised structure for the profession, then a standardised fellowship would also be beneficial. It would seem an unnecessary expense for each society to offer a unique pathway when the entry requirements could be standardized across the profession. The common feature of all the current models is an oral exam and this should continue to be conducted by experienced members of each distinct society.

The IBMS in the UK offer many educational opportunities for scientists, but I would like to highlight the certificates in extended practice that they offer [9]. A recent graduate in any laboratory who has completed an AIMS accredited degree will have enough clinical training to work and will necessarily develop their skills on the job. If they are considered by NPAAC to be eligible for supervisory positions after two years of employment the professional society should provide easily accessible, basic managerial education specific to their role.

An online offering would be the easiest to develop and maintain and should become a mandatory requirement for prospective Supervisors together with topics in employee relations and financial responsibility. A second offering for Scientists with an interest or duties involving health and safety, document management or quality and risk and a third for those involved in training and education. The completion of one of these courses would be the initial step toward a professional fellowship.

A Doctor of Philosophy (PhD) is the highest level of qualification offered by a university for a very good reason, it's extremely difficult to achieve. When you consider the time that it takes and the fees that may be required it is nearly impossible for anyone working full-time and supporting a mortgage and a family in Australia today. An M-level or master's degree is a much more achievable goal and completely ignored in the NPAAC documents, the management structure of a laboratory needs to recognise this, with the PhD being the province of the clinical scientist.

There are many taught master's courses, such as a Master of Science (MSc) or Master of Business Administration (MBA), which are currently available from several respected Australian universities, all of which would be appropriate for a laboratory manager to have. These could be either science or management based as either would develop skills and education required to be proficient and successful in the role. There is a third avenue, through the Research Training Program available from the Department of Education and Training [106].

This is a program which essentially removes any fee burden and is provided for research only degrees. This includes a Master of Philosophy (MPhil) program, which requires a shorter dissertation than a PhD, or by publication, which means four journal articles, which could promote the society's journal. This degree can be done remotely and is therefore is an accessible route for any regional employee who doesn't live close to a major university and can be on any topic which is relevant to the individual's practice.

The current offerings do not offer the required flexibility to be valuable to all of the workforce, online management programs could be accessed wherever the Scientist might be. The courses would require centralised oversight and maintenance to ensure relevancy and reduced costs but the main benefit to the societies is that all the expenses are borne by professional training organisations. The societies only need to provide subject matter experts to conduct the viva exam schedule for prospective fellows who have completed the pre-requisites.

A transparent career pathway doesn't exist for Medical Scientists currently, which is an indication of how little the leaders of the Pathology industry respect the skilled workforce. In Figure 8 the Author proposes a simple scheme that will allow workers to aspire to and gain promotion whereas currently there is no formal recognition of post graduate qualifications and the industry standard seems to be based on length of service alone.

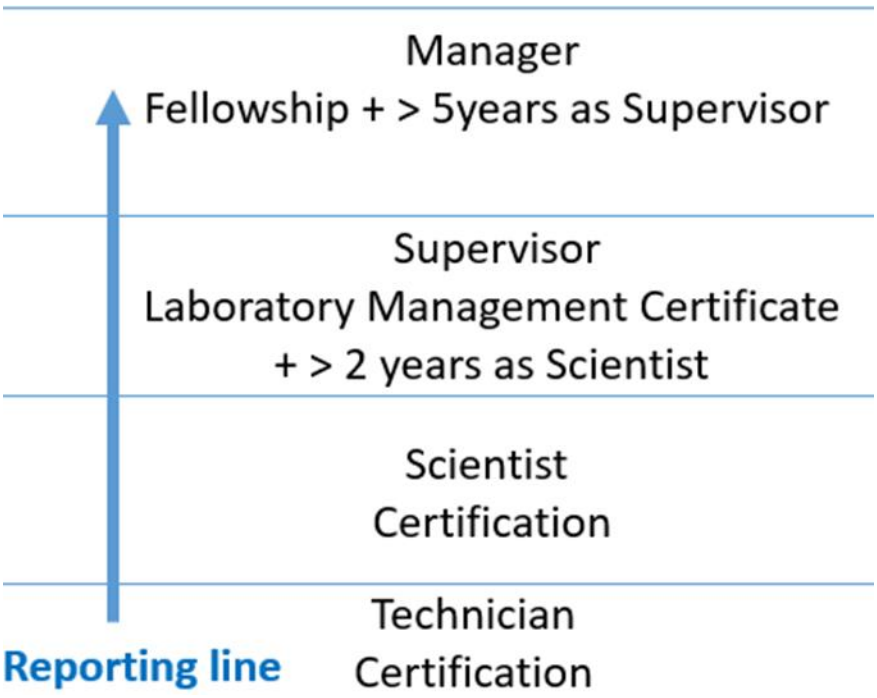



Figure 8- Laboratory managerial qualifications

## 8.6 Conclusions

To appreciate the current career pathway for Medical Scientists in Australia it is necessary to review the foundational documents governing the occupation. Two documents have been published by the NPAAC; whose members are appointed by the Minister of Health to advise on best practice accreditation of the Pathology service in Australia.

The two critical documents "*Requirements for Medical Pathology Services*" [75] and "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories*" [65] and have been reviewed recently to improve clarity regarding the governing principles of the occupation.

During this critical evaluation several discrepancies were identified that appears to erode the role of the professional societies in governing the profession in Australia. The definitions of occupational titles have changed from the previous editions. Initially, societies such as AIMS provided credentialing services as the NPAAC definition of a Scientist mandated that the qualifications held must "provide for direct entry or following examination to a professional class of membership" [101].

The latest edition allows the appropriateness of a domestic qualification and the scope of practice for any Australian Medical Scientist to be decided by the individual laboratory management, "as determined by the person responsible for the scientific management of the laboratory and/or person responsible for the clinical governance of the laboratory" [65]. This fundamental function needs to be reviewed by NPAAC to allow this requirement to be governed by a single authority.

This single authority should be responsible for governing the certification of Medical Scientists and should undertake the primary source verification of all degrees, both domestic and international alike, allowing for a standardised application of the appropriate scope of practice. A single overarching society (whether AIMS or otherwise) would reduce costs, increase quality, and provide clarity. The number of laboratory workers in Australia is not large enough to support the multifaceted framework that exists in a cohesive manner. This is important for the successful implementation of the certification framework, which is a process that is critical to legitimise a profession that needs recognition.

In the author's opinion the best way to ensure recognition of the certification program is for the program to gain ISO accreditation and to couple certification with NATA accreditation of laboratories. The ISO accreditation of a certification program would give the scheme the traction it requires to be adopted nationally by laboratories, thereby providing legitimacy.

The certification scheme executive provided a traditional framework for a credentialing program that requires a certain level of engagement from pathology workers, for it to be self-sustaining. Currently the industry engagement is less than 0.5% of an estimation from the last Australian census. The emerging blockchain technology would have reduced the overhead costs for a secure, transparent framework with the ability to provide timely and industry relevant human resources data.

Learning tools need to be developed specifically for those staff who wish to pursue a career path that leads them away from the purely clinical orbit into a supervisory role. This would ideally be provided online to allow access by Medical Scientists across Australia. The online format would allow easy maintenance and ensure that the information is relevant to the role.

The above would require the development of three distinct supervisor certifications: operations, training, and quality, a service provided by many professional societies internationally. Following on from this a scientist holding a supervisory certification could pursue a MSc, MBA, or MPhil programme as appropriate for recognition as a management candidate. This approach would not only substantially simplify the current process, but also reduce costs to the profession by pushing the bulk of the work back to Universities, utilising existing qualifications fully.

## 9. What has been the impact on the pathology workers due to the level of testing during the COVID-19 pandemic?

*Adapted from the article published in the July 2021 issue of The Biomedical Scientist (UK)*

A novel corona virus, identified as SARS-CoV-2, was first documented in China as early as November 2019 and declared a pandemic by the WHO on the 30th January 2020 [107]. Five days earlier on the 25th of January, the first case was detected in Australia in a man who had entered Australia from China on the 19th of January 2020 [108].

Along with a series of regional lockdowns used to contain the spread of the virus, the most obvious public measure was to set up mobile "COVID Clinics" and begin the largest testing program ever seen in the country. This campaign began on the 22nd of January 2020 and has completed almost 15 million tests when the first vaccines were administered in March 2021 [109]. These community-based specimen collection centres have enabled an agile public health response and has been the model used all over the world.

A survey was sent to several pathology laboratories around Australia including SNP, QML, Queensland Health, NSW Health, Tasmanian Pathology Laboratories and all the Australian Pathology Professional societies, AIMS, AACB, etc. One of the questions within the survey asked the respondents to describe their assessment of the impact of the pandemic on the Pathology industry in Australia with the only organisations that replied being the AIMS and the AACB.

Of the 74 respondents, 30 had high levels of missing data and 6 did not consent, leaving 31 comments provided to that question with the overwhelming number 28/31 (90%) being negative describing fatigue, burnout, and mismanagement of the increased workload. These quotes are included throughout this document.

*"The industry has been stretched to the limit with many groups unable to function due to lack of trained, qualified personnel."* **Laboratory Medical Scientist with more than 20 years' experience**

Due to the fact that the virus is completely new the only definitive way to ascertain a patients COVID status is by using a molecular diagnostic platform, a process that can take several hours [110]. Therefore, a direct specimen, a naso-pharyngeal swab, must be taken and sent to a central laboratory for testing. When a specimen arrives at the laboratory the highly trained scientists employed to manage the molecular testing platform will be required to follow the very stringent requirements to ensure a valid test result and a specialist Pathologist releases the result.

Experienced molecular pathology staff are very difficult to find and hence those parts of the laboratory suffer chronic staffing shortages due to the highly skilled nature of the discipline. Intensive research has been conducted into Point of Care testing modalities, simpler testing platforms that can be done directly from the patient, with 23 platforms currently approved for use by the Doherty Institute on behalf of the Therapeutic Goods Administration in Australia [111].

However, if this is not all done correctly the possible consequences were highlighted during the “Blackwater incident”. Blackwater is a coal-mining town in the Central Highlands region of Queensland, with a population of less than 5000 and geographically isolated. The locals had enjoyed a COVID free experience until May 27, 2020 [112] when it was reported that a 30-year-old miner had tested positive for COVID-19 following his death.

This prompted a massive heath department response, which required the entire populace to be placed in quarantine and tested. The miner’s samples were retested and subsequently found to be negative 2 days after the lockdown began, on the 29th May 2020, but authorities did not release the residents or the results for 4 more days [113].

*"There are two potential answers here. One is that it was a false positive. The other is that it was a true positive and we won't know which it was,"* ***Dr Jenette Young, Chief Health Officer, Queensland. 2.6.20***

This is not the first time there has been a high profile analytical error involving pathology laboratories in Australia [114].

The published material for the disease process of this novel coronavirus states that the average time until symptoms appear is between 4.9 – 7 days. The accepted testing regime means that a number of tests are required to completely ensure that an individual is not positive for the virus over a 14-day period of quarantine [115]. This level of testing has a direct impact on laboratory Turn around Time’s (TaT) as the testing throughput is limited by the platforms maximum number of tests available.

It has been reported in the USA some results are not being provided until late into the proposed isolation period of 14 days, during which time patients may be out in the community. At this level testing becomes irrelevant as the person could be unknowingly infecting many other people.

In Australia, the average reported turnaround time is 2-3 days and until most of the population is vaccinated by the recent Government program. The best tools we have for limiting the spread and preventing overloading the country's ability to treat infected patients are:

1. Quarantine of infected individuals
2. Social distancing
3. Rapid and robust testing.
4. Effective handwashing

These strategies have been shown to be effective in Australia and around the world but require compliance from a large section of the community to be effective, which would possibly explain the difficulties facing the USA and other nations. Unfortunately, it appears that in America the health of the citizens has been politicised with reports that the federal government shelved a national testing program on political party lines [116].


Figure 9- Donald Trump tweet

*"It's the Wild, Wild West, there's been no national testing strategy, so states are duking it out for supply chains. That's a problem."* ***Blair Holladay, CEO of American Society for Clinical Pathology USA Today 16.7.20***

Many other nations have recognised the importance of testing during the global pandemic.

*"These lab staff are working tirelessly to ensure we know the true scale of the outbreak, and to ensure those with COVID-19 know, and get the appropriate care. I want to say on behalf of New Zealand, thank you for your work."*

***Jacinda Ardern, Prime Minister of New Zealand addressing the nation on 27.3.20.***

**The Australian Response**

The Australian Government established AHPRA in 2010 to regulate healthcare professions in Australia. This was the culmination of a 5-year process involving an extensive examination of the Australian healthcare workforce, the decision was made the despite Medical Scientists being more numerous than Dentists, Medical Imaging workers and Ambulance officers/Paramedics they would not be included. The exclusion of Medical Scientist assumed that their lack of patient contact and that Medical Scientists are overseen by a registered professional i.e. a Pathologist meant it was unnecessary [117].

*"Currently, Pathologists in Victoria can process up to 18,000 tests a day"* ***Mr. Daniel Andrews, Premier of the State of Victoria, 25.6.20***

It would appear from this quote that the leaders in the pathology industry have failed in their role by acknowledging those workers who are responsible for conducting the testing. Pathologists are not responsible for the processing of pathology testing; the technical staff perform the tests and are just as integral to the formation of a robust strategy and this has been demonstrated without argument during the global pandemic.

"*It has brought pathology labs to the fore, but we still need to emphasize the difference between Pathologists and scientists in the public perception."* **Laboratory Manager with more than 20 years' experience**

This is not unique however in a recent Centres for Disease Control and Prevention (CDC) Advisory Committee on Immunisation practices (ACIP) document the following clarification was made regarding which Healthcare providers should be the first to receive the COVID-19 vaccine,

"*Healthcare Personnel does not include dental healthcare personnel, autopsy personnel, and laboratory personnel*" [118].

Highly trained laboratory professionals are involved in the daily testing of community and hospital members. Citizens that rely on these healthcare professionals to provide an appropriate specimen for testing. The collection of cells required for COVID testing with a nasopharyngeal swab is invasive and reasonably unpleasant process and must be conducted by appropriately trained medical personnel.

*"Workers in the labs are encountering and handling thousands of samples that have active live virus in them... They truly are front line workers and often are forgotten*," ***Amy Karger, MD, Medical Director of MHealth Fairview Point-of-Care Testing. 9/12/20***

Considering the recent nature of the outbreak and the incredible level of testing that has been required, it would be reasonable to assume that the various Pathology organisations have necessarily been required to recruit new staff, upskill current staff, adjust staff schedules or sequester staff from other departments. This training will be required to be reviewed by the NATA inspection teams at the laboratories next scheduled inspection to ensure compliance with ISO 15189 regulations for staff training and competency.

*"More work, in an already stressed system, that has insufficient staff and 'distancing roster'."* **Laboratory Supervisor with more than 20 years' experience**

On the 18th January 2021 the RCPA were quoted in an article published by the Australian Broadcasting Corporation (ABC) discussing the fact that Australia has recorded 12 million COVID tests, equivalent to almost half the population.

"*Australia's current position of having effectively suppressed the virus to intermittent outbreaks owes much to the year-long dedication and ingenuity of 35,000 Pathologists, Medical Scientists, lab technicians, couriers, phlebotomists and ancillary personnel, who've worked tirelessly every day to keep us safe*." [119].

This was addressed in a workplace survey of Medical Scientists with a question about the effect of the pandemic on the pathology industry in Australia which provide some contrasting insight.

*"Exhaustion, and a complete silence in the media about any role of Medical Scientists in the process. Research into vaccines gets coverage. People shoving swabs up noses get coverage. 'Frontline workers' get coverage. All deserved. But the swabs don't turn magically red or green. The role of laboratories in testing (and everything else) has been overlooked"*

**Laboratory Supervisor more than 20 years' experience**

The ABC article describes several inaccurate statements regarding the impact of pathology testing worldwide beginning with the exposition that there are 35,000 people working in the industry. Due to the lack of any register, there is no accurate method to ascertain the actual number of pathology workers in Australia. This number is based on the previous census data which is inaccurate because it is not detailed enough.

*"We have experienced periods of 1000% increase in workload during outbreaks… recession has meant staffing is sparse and global outbreak has meant laboratory supplies are difficult to source often requiring sharing among many locations."* **Medical Scientist with less than 5-year experience**

The ABC article also quotes that the clinical impact of pathology testing in the treatment of patients stating that "*Seventy per cent of all medical diagnoses are based on a pathology test, as are all cancer diagnoses*" [119].

Historically the healthcare community has reported that pathology testing is performed for approximately 70% of all patients. However, there is little evidence to this claim which has been described in Chapter 4 of this thesis [120].

"*An effective public health response requires information from pathology testing to support decision making in every setting. This information was required by epidemiologists, hospitals, community doctors — the list goes on*." [119].

In this statement the RCPA is publicly recognising the contribution testing provides to the wider healthcare community. Therefore, as leaders in the pathology industry are responsible for the promotion and recognition of all members, perhaps their strategies may need review, with the results of the survey may be demonstrating a workforce which is underappreciated.

*"Staff burn out and increased stress due to decisions made for and about pathology by clinical teams who sit outside of pathology…tension between Pathologists and scientists due to disagreements between testing methods for COVID…the scientists understand the testing a lot better as are the ones performing them with the Pathologists only signing off at the end."*

**Lab Supervisor with less than 5 years in the role.**

The lack of recognition of Medical Scientists has meant that they are ignored by other healthcare professions in decisions that directly impact their work.

*"Staff burn out and increased stress due to decisions made for and about pathology by clinical teams who sit outside of pathology."* **Lab Supervisor with less than 5 years' experience**

Of the thirty-one responses received in the survey only 3/31 (9.6%) were positive, describing the introduction of new analysers and increased staffing levels to assist staff with the increased level of testing. Both of which would have been welcomed by employees however, considering the amount of work required to validate a new platform or to ensure staff competency this would merely add pressure to an already stressed environment.

"*Never before has pathology testing made such a clear contribution to the wellbeing of the community as during this pandemic*" [119].

Laboratory testing is the **only definitive** method of ascertaining a patients COVID status and this virus has the capacity to be fatal or cause chronic ongoing health problems. It would be fair to argue that the work of Medical Scientists has a direct impact on the level of care that may be required. The leaders of our profession have missed a once in a lifetime opportunity to increase recognition of the work of medical science in the face of an international crisis.

This is a perfect juncture for the Medical profession and the Australian Government to rethink its stance on regulation of Medical Scientists and recognise the critical work conducted by the highly educated and skilled practitioners. This work is providing the public and the entire healthcare framework with the critical information to manage this pandemic. It can no longer be dismissed as not being as critical to patient outcomes as the work of their colleagues.

The scientists, technicians and phlebotomists deserve appropriate recognition for their contribution to the health and wellbeing of the Australian public not only during the pandemic but beyond. The whole structure governing the "profession" from the occupational descriptions provided by NPAAC and a comprehensive career framework through to national recognition by AHPRA alongside their colleagues. The societies which provide professional leadership must provide a unified platform for the benefit of the entire "profession" and patient healthcare.

The pandemic has provided a once in a lifetime opportunity to make a positive change and lay the foundations of a professional registration framework to govern a critical part of the healthcare community which is currently absent in Australia. The leaders of the pathology industry such as NPAAC seem to be avoiding the commitments made to support pathology in Australia. This is detrimental to the workers who remain unrecognised in their own country and reduce their professional currency internationally, an unnecessary position and one that should not exist in a proud developed nation like Australia.

*"The biggest impact I can see is that the deregulation and shortage of scientific staff has been highlighted through the inconsistency in pathology response times from public vs private companies. Having a centralised Victorian Pathology Service would improve service and oversight of pathology companies. Highlighted the importance of Medical Scientists (although being called Pathologists by the Federal Minister for Health)."*

**Medical Scientist with 15-10 years' experience**

Table 27: What has been the impact on the industry due to the level of testing during the COVID-19 pandemic?

*(Responses from second survey question regarding the impact of the pandemic on the pathology industry in Australia symbols in () indicate a positive or negative response)*

| |
|---|
| High workloads, separating different teams in case any staff pick up the virus, increased employment, deployment of staff for COVID-19 testing. (-) |
| More work, in an already stressed system, that has insufficient staff and 'distancing roster. (-) |
| Increased workflow due to increased sample numbers. (-) |
| The industry has been stretched to the limit with many groups unable to function due to lack of trained, qualified personal. (-) |
| Exhaustion mainly. It has brought pathology labs to the fore, but we still need to emphasise the difference between Pathologists and scientists in the public perception. (-) |
| Work harder with less people for longer hours. Be happy that you have a job as lots of people don't. (-) |
| Exhaustion, and a complete silence in the media about any role of Medical Scientists in the process. Research into vaccines gets coverage. People shoving swabs up noses get coverage. ‘Frontline workers’ get coverage. All deserved. But the swabs don’t turn magically red or green. The role of laboratories in testing (and everything else) has been overlooked. (-) |
| It appears to have adapted, with new technology and testing. however, I have seen increased stress on employees. (-) |
| Huge and varied-stressful since no extra staff provided. (-) |
| Switch to higher throughput PCR analysers and quick adaptation to new testing methods and diversification. (+) |

| |
|---|
| Burnout and increased pressure to perform. (-) |
| Staff burn out and increased stress due to decisions made for and about pathology by clinical teams who sit outside of pathology. Scientists understand the testing because they are the ones performing them with the Pathologists only signing off. (-) |
| Overall, the impact of COVID-19 has been minimal except for them hiring extra staff to help with COVID-19 testing. (+) |
| Minimal. We had reduced work for about a month. We are now back to normal workload but are short staffed. (-) |
| Increased workload increased operational hours; increased call outs have led to more fatigue in the industry it has also impacted on the infection risks of some workers. (-) |
| Higher workload mainly and I still see scientists with a relaxed view on PPE. (-) |
| Long hours. (-) |
| We have experienced periods of increase in workload understaffed, lack of supplies. (-) |
| Increased demand on pathology services (-) |
| Requirement to greatly accelerate available testing, but also greater opportunities to show importance of Medical Laboratory Scientists. (-) |
| Wild fluctuations in workload which have been coped with and many more positions for new scientists. (+) |
| Longer shifts, pathology is the unseen hero that the public has little knowledge of. (-) |
| Our lab has seen increases in testing across all areas. (-) |
| Increased workloads and demands on existing manpower, industry infrastructure, and procedures. (-) |
| Microbiology have been extremely busy over lockdown with the number of swabs being processed. (-) |

| |
|---|
| More jobs (not secure ones), more shift-work, more overtime, less opportunity to take ADO's and leave, less input into what shifts you work (whether you are assigned additional shifts at late notice), more technician roles in the laboratory to allow for a rapid influx of workers. (-) |
| In our lab there was a massive influx of COVID-19 PCR testing, so Microbiology has more vacancies due to increased workload. (-). |
| Our lab has increased the volume of testing by over 150%. It has meant work is busier and we have needed staff later in the evening to process the workload. (-) |
| The impact on our industry has been extreme. We have never seen total test numbers so high, nor have we ever had so much pressure to expand our capability of testing so rapidly. Staff have been under immense pressure, with many working large amounts of overtime when test numbers spike. It has also impacted on our routine testing, as our specimen reception areas have been flooded with swabs, making it more difficult to maintain turnaround times. (-) |
| The biggest impact I can see (I don't work in microbiology) is that the deregulation and shortage of scientific staff has been highlighted through the inconsistency in pathology response times from public vs private companies. Having a centralised Victorian Pathology Service would improve service and oversight of pathology companies. Highlighted the importance of Medical Scientists (although being called Pathologists by the Federal Minister for Health). (-) |

# 10 Discussion and Recommendations

## 10.1 Discussion

*A **Profession** is defined as a paid occupation especially one that involves prolonged training and formal qualifications [121].*

***A Regulation** is a rule or directive made and maintained by an authority* [122].

Internationally, Medical Scientists are required to hold a practicing license to be employed in clinical laboratories. This license provides recognition as a profession, and protection to the public. The Governmental Regulatory bodies in countries such as the UK or New Zealand maintain a register of practitioners, monitor Continuing Professional Development, and provide disciplinary measures if required. A fundamental activity of any profession is the maintenance of a register of practitioners which allows regulators and industry alike to make strategic decisions. Registers are commonly available to the public and they also form the foundation of occupational Scopes of Practice.

In Australia, AHPRA provides regulation to a large group of medical professionals including Dentists, Doctors and Nurses; however, this group does not include medical laboratory staff. AIMS has federal authority in Australia to assess the skills of medical laboratory workers immigrating to Australia through ANZSCO regulations 234611 and 311213. These regulations detail the skills and duties of an occupation in Australia and are used to aid policy development and human resources management. Critically, this assessment of skills and duties does not apply to those Medical Scientists who graduate from Australian Universities.

Over the last decade the AIMS has highlighted many times the lack of professional recognition of its members. In this context, in 2010 AHPRA was established but ruled that the role of Medical Scientists were sufficiently controlled by a Pathologist registered with the Medical Council and NATA accreditation of a testing laboratory. This led AHPRA to advise AIMS that Medical Scientists should remain self-regulated due to a perceived lack of clinical influence and patient contact.

Due to the fractured nature of the pathology workforce in Australia with none of the cohesion provided by other countries frameworks the drive to become a recognised profession has lacked impetus. There are many competing aspects both inter and intra state which have prevented this and although the current pandemic has highlighted some of these there are many issues to resolve and the reason for this dissertation is to perhaps provide solutions by providing information and data to support a change.

The first chapter of this thesis provided a background of the development of registration in the United Kingdom and Ireland, The United States of America and Canada, Australia and New Zealand and Qatar. Pointing out that each country recognised Medical Scientists as a healthcare profession, with governmental regulation involving registration and maintenance of a practicing license, except in Australia. In most cases this had been in response to an incident which had cause harm to members of the public.

Australia had not been immune to this type of incident, with the Melbourne Pathology cytology incident occurring in the early in the new millennium and then the South Australia Pathology

PSA incident in 2016. Whereas in New Zealand similar incidents caused a Ministerial enquiry and subsequent formation of the current registration for Medical Scientists in New Zealand, the Australia Government decided that nothing so far reaching was required. The Society of Cytologists developed their own licensing system as a result and the investigation of SA Pathology was kept largely inhouse.

This led to the hypothesis that without comprehensive clinical leadership involved in day-to-day output of laboratories, there is risk of harm to the public and that a comprehensive regulation framework provides additional oversight. To examine this the aims of this document were to initially describe the development of regulation of pathology laboratories around the world. This review then provided the scaffolding for the document as identified the most appropriate course for the research to follow

Beginning with critically defining the direct influence of pathology in patients by quantifying the amount of input pathology has in the diagnosis and addressing the criteria used by AHPRA to define a healthcare profession in Australia, which informed recommendations for Medical Scientist licensing in Australia based on current practice and workforce data provided by a workforce survey of Medical Scientist employed in Australia and internationally.

Historically the healthcare community has reported that pathology testing is performed for approximately 70% of all patients. In Chapter 4 the CVD clinical guidelines were analysed to identify the contribution of laboratory medicine to the diagnosis and maintenance of the largest group of diseases in the world today. This analysis showed that an average of 78% of proposed

diagnoses recommended pathology testing internationally while this jumped to 94% in Australia. The conclusion here is that the role of Medical Scientists has a significant clinical influence, albeit largely hidden from public view.

The Australia Government cite that Medical Scientist do not have enough patient contact to warrant registration, however the definition of "patient contact" is ambiguous. Does it only mean contact with a person receiving medical attention, or can it include contact with samples/specimens taken from patients as well.

If it is the former, then a study of two large Sydney teaching hospitals showed that the average Nurse spent 37% of their shift interacting directly with patients as opposed to phlebotomists who spend almost their entire day extracting samples. To include the second part of the definition means that 9 out of 10 heart disease patients, all cancer patients, and everyone who receives a blood transfusion, have been in contact with a Medical Scientist.

The pathology chain-of-care in Australia requires a Pathologist to maintain a license to practice through their registration with the Medical Council. This license enables a Pathologist to have clinical oversight of all testing conducted in a laboratory. Their clinical oversight occurs in an environment of increasing technical sophistication and automation with an increasing reliance on the skills and competence of Medical Scientists.

The increasing complexity of testing compared with the last decade including advancements in automation and advanced testing strategies for genetics and clinical chemistry, means that the

workforce also needs to be agile, competent and well educated in order to respond quickly to an emergent event such as a novel virus.

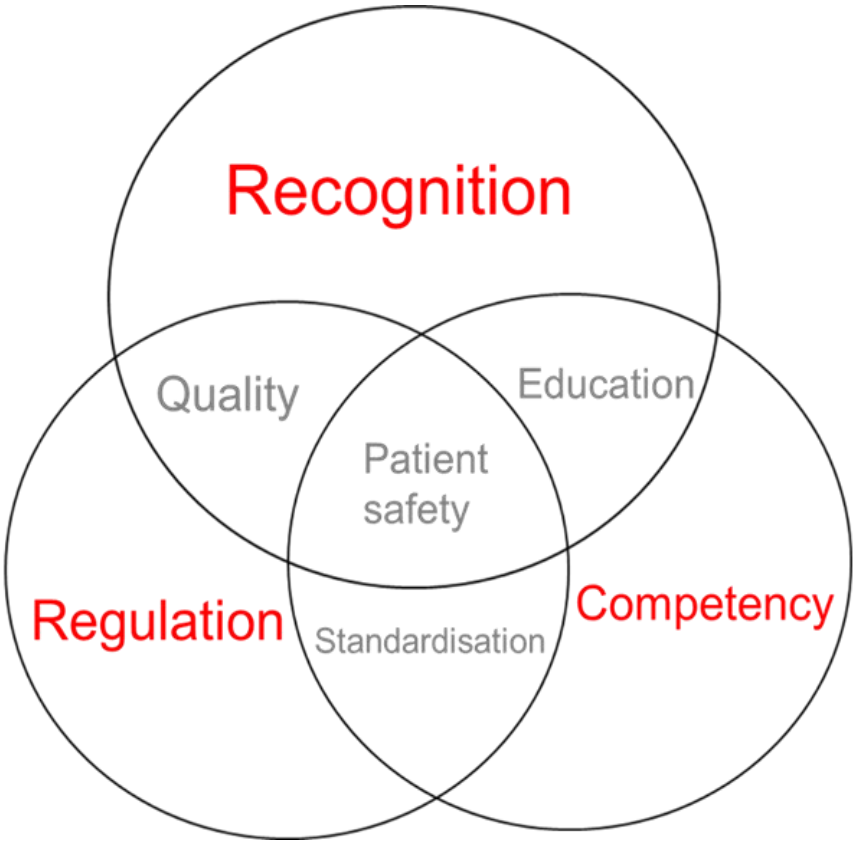
Against this backdrop, much of the responsibility for maintaining the quality of pathology services in Australia falls to NATA. This organisation is responsible for providing assurance of technical competence for many industries including pathology laboratories. As an ISO compliant body, they are required to maintain the international quality standards including competency and training in pathology labs.

In Chapter 5 a review of significant incidents from pathology laboratories highlighted real life examples of risk to patients. In the UK and New Zealand there have been several incidents which have been fully investigated and resulted in fundamental changes to those countries pathology services.

However, in Australia, the similar incidents have provided no impetus for change. The twin controls of the Registered Pathologist and NATA accreditation, accepted by the Australian Government, have been exposed twice since the turn of the century with no appreciable changes to the requirements. In both incidents their impact was brought into question and despite a recent independent review identifying that laboratory staff lack clinical understanding, no recommendation addressing this shortcoming was made.

Chapter 6 provides the analysis of the workforce surveys of an international group (the technical staff of the Pathology department at Sidra Medicine, Qatar) and several Australian respondents.

These findings can be expressed in the following diagram, this demonstrates the interconnectivity of the thematic analysis. Patient safety is always at the core of any healthcare profession and the practitioners surveyed have agreed with this sentiment. By placing this at the centre and the major themes of Recognition, Regulation and Competency we begin to understand the connections between the themes that were brought out of the analysis.




Thus, Recognition is underpinned by quality of service and the education of the practitioners supporting greater patient care. In a dynamic field like pathology continuing professional education is an important tool to maintain staff morale and knowledge. This has a direct effect on the quality of work produced and more efficient reporting of results.

Likewise, Regulation which promotes better quality and standardisation within the profession leads to reduced errors and greater protection for the patient. Standardisation of laboratory practice not only makes economic sense as it allows the business model to be more efficient, it also removes confusion over, not only products but clinical facets such as units of measure. This practice standardisation reflects in quality measures with regulatory oversight becoming more transparent.

Finally, higher individual competency driven by better education and standardisation of procedures means that patient outcomes are maximised. Laboratory Technologists provided with the appropriate information will be able to make better, more informed decisions about the most efficient and safe way to provide the best information to the Pathologist. By standardising these processes each of the links in the pathology chain of care are recognised for their contribution in the welfare of a patient. Something which, is perhaps missing in the current scheme.

A second survey which focused on the personal implication and professional impact of registration in Australia. The respondents highlighted personal issues with extra time required to complete the CPD or the cost for maintaining their license. The responses were more positive regarding the professional impact identifying the benefits of increased recognition and patient safety. The addition of a question regarding the impact on the industry due to the COVID pandemic found a workforce suffering burnout and fatigue with little recognition of the critical role that pathology testing plays.

To be considered a profession in Australia six stipulations are applied by AHPRA, which are as follows:

- *It is appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?*
- *Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?*
- *Do existing regulatory or other mechanisms fail to address health and safety issues?*
- *Is regulation possible to implement for the occupation in question?*
- *Is regulation practical to implement for the occupation in question?*
- *Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?[5].*

Chapter 7 provides evidence as to why medical science meets each of these stipulations. The pathology service is certainly governed by the Ministry of Health and it is both practical and possible for Medical Scientists to be included in the AHPRA framework. Not only does their work pose significant risk to the public there are concrete benefits to a form of registration that may address gaps in the current system.

Externally monitored professional registration of some form is as a public protection, for without it an employee is only held to a code of conduct, which is a document that has no legal backing. As Medical Scientists provide accurate results of the most personal nature regarding the health

of members of the population then a code of conduct does not provide any protection to the public. The threat of legal action should be a realistic deterrent to any member of a modern society.

In other countries with a recognised Medical Scientist profession, the possibility of legal sanctions is an important function. Given that there have been more than 150 disciplinary hearings in the UK and four in New Zealand in the last 5 years, then based on a population ratio, there could have been 20 incidents in Australia over the same period. Unfortunately, there is no way of knowing if these incidents have occurred because there is no transparency in reporting them.

In 2018, NPAAC released a new edition of the *Requirements for Medical Pathology Services* and *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories"[65].* At the same time, AIMS highlighted the fact that these new documents removed any provision for Medical Scientists to manage pathology laboratories in Australia. Thus, the NPAAC decision effectively removed professional progression of Medical Scientist to management roles and a semblance of a transparent career pathway for experienced Medical Scientists.

NPAAC is also responsible for documents that provide the occupational definitions for technicians, scientists, and clinical scientists, which have changed significantly from the previous editions. Most concerning is the removal of the Supervising Scientist role and the credentialing ability of professional societies. In the current edition, NPAAC allows credentialing of individual

staff members to be performed by each individual laboratory management to address their own specific needs and the professional society's only role is to provide equivalence against immigration occupational standards.

To be effective these NPAAC documents need to accompany a modern Scope of Practice for Medical Scientists. However, the only endorsed scope of practice is ten years old and is rendered ineffective by the lack of any requirement to uniformly apply this due to the absence of any comprehensive governing body. AIMS is the obvious choice to take this role, but it must be recognised by industry and regulators alike.

While AIMS is the largest recognised professional body for Medical Scientists in Australia, there are several smaller, more specialised, groups with their own fellowship programs. The fellowship requirements range from written and oral exams for the AACB through to the ASM's three-part process involving exams, essays, and publications. This is unnecessarily complex for the size of the workforce, with larger countries such as the UK and Canada adopting a single entity and postgraduate qualifications framework.

A consistent framework could easily be developed with AIMS administering the educational component, perhaps in partnership with educational organisations and the relevant society convening a panel of members to examine each candidate in their specialist subject, thus providing a clear, consistent pathway to higher recognition.

For the fellowship to be truly recognised it needs the support of industry and must be defined in the career progression of the profession. This would add intrinsic value to a qualification which is then acknowledged sufficiently in the workplace. As in other countries, fellowship needs to be a requirement for laboratory management as it involves a higher level of proficiency and ancillary skills.

In a post made on the AIMS website in May of 2017 the board issued a statement entitled "Certification of Medical Scientists" which contained the following statement: *"A formal application for registration of Medical Scientists was made to the Federal Government in May 2008. Unfortunately our case was rejected as medical laboratory scientists were not seen to directly influence patient outcomes"* [123]. A renewed application was developed, led by AIMS and the AACB, with QUPP support from the Ministry, commissioning the HCA to develop a certification program for Medical Scientists.

A certification framework is an important and valuable contribution to professional licensing. Through several stakeholder's meetings, a program developed and implemented in 2020, currently certifies 241 practitioners across Australian laboratories. The major flaw in the scheme, which has been highlighted by the developers, is that the lack of legal backing prevents many aspects that would ensure the success of the program. Not only are they unable to effectively apply sanctions, but membership is also not mandatory which limits its potential and means that the certification need not be recognised by employers.

In the latest proposal several errors have been made regarding the NPAAC occupation definitions and workforce data. In addition to reduced entry qualification requirements which are not equivalent to the ANZSCO international standards, which effectively removes the need for vocational degrees. This appears to be a retrograde step which will be detrimental to a profession which is striving for recognition.

Added to this is the assertion that an additional body needs to be formed in an already crowded system to manage the framework. A new organisation that requires staff and administrators and finance provided by the membership. Considering that there are several established administrative bodies an additional organisation seems unnecessary, particularly if they are responsible for processes that are already available, such as CPD with APACE.

The simpler method of achieving the desired outcomes of legal support, mandatory regulation, and professional recognition of Medical Scientists, considering that AHPRA refuse to admit the profession to the existing framework, would be to use a blockchain based credentialing system similar to that used by the University of Melbourne and RMIT [96]. The inherent open source nature of this type of platform with the backing of industry would provide valuable workforce data and provide a robust method of monitoring competency with the ability to identify and sanction practitioners, a function unavailable in the current framework.

The use of the emerging blockchain technology would have reduced the costs of implementing the tradition framework utilised by the project. The secure and transparent nature of a blockchain credentialing scheme would have provided real-time human resources data to the industry. The

industry partners adopting the scheme would remove the need to rely on support from the workers base which currently sits at approximately >1% of the estimated Australian workforce.

There is an immediate need for a review of the pathology framework in Australia, this document highlights systemic flaws. All the appropriate pieces are available; however, they are disjointed which has no benefit to the current workforce. NPAAC and the professional bodies need to come together and revise the scope of practice and occupational definitions to assist employers and provide a transparent career framework for Medical Scientists.

The professional societies will also need to agree on a standardised Fellowship pathway which is industry relevant. The certification initiative has provided an appropriate means of self-regulation and with a closer relationship with industry and utilisation of a blockchain credentialling would be able to provide as robust a framework as AHPRA albeit independently governed.

## 10.2 Recommendations

1. **The Australian Government should review its suggestion that Medical Scientist should be self-regulated and recognise that their role is critical to patient outcomes**.

   The evidence presented here provides arguments that the assumptions regarding Medical Scientists are incorrect with respect to patient contact and influence being at least equivalent to other AHPRA-recognised professions. Adopting this recommendation would allow appropriate recognition of laboratory workers and allow legal sanctions to be applied for misadventure by any practitioner.

2. **NPAAC must review the occupational definitions for laboratory workers.**

   The current documents are inaccurate and confusing and need to be consistent with international best practice. The restriction of senior Medical Scientists to non-supervisory roles suffocates the talents of experienced staff. The occupational definitions need to be aligned with ANZSCO definitions for consistency and clarity. The role of a credentialing body must be returned to the professional body as the current definition removes any possibility of standard qualification verification or scope of practice application. An up to date and industry relevant Scope of Practice must be designed and implemented.

**3. A single authority must govern the medical science profession in Australia.**

The new certification company may be uniquely placed to become the sole body governing the medical science profession in Australia or an existing member must be given overall authority. The scheme is designed to provide CPD audits, but this should be expanded to include single source verification of qualifications and supervisory educational courses. The current system of granting individual laboratories authority for acceptance of an individual's qualification is valueless. International best practice demands a single source of qualification by subject matter experts in the field, which is unachievable in the current framework.

This framework should be built to be ISO 15189 compliant as the recognised international standard. This would allow for NPAAC support which would mandate its use across Australia deeming competency and compliance with NATA accreditation requirements. A blockchain based credentialling program would provide an opensource platform that could be financially supported by the industry, removing any fee from the individual members. This online solution would provide valuable workforce data to the human resources departments and through manipulation to the certification authority which would provide a practicing certificate and reports to accreditation teams.

4. **A new transparent career progression model must be developed and endorsed by industry**

With the assistance of NPAAC, supervisory roles should be reinstated for experienced Medical Scientists that require a transparent career progression pathway involving recognised qualifications. This would require all supervisors to undertake managerial education that could be provided online by the certification provider. This approach would address significant gaps in general laboratory functions such as quality and training along with general financial and human resource allocations. In addition to this, a laboratory manager should pursue a master's degree qualification.

Currently there is little recognition of higher learning, but it is an important step in career progression. This could be an MBA, MSc or MPhil depending on the career aspirations of the individual and the relevance of the academic program. Managerial progression could be complemented by Fellowship following an oral exam conducted by experienced members of AIMS. This way a Fellow is recognised by his colleagues in the field and the pathway is consistent.

A PhD should remain the province of a clinical scientist, who should work under the supervision of a Pathologist or another more experienced Clinical Scientist to develop the skills necessary to assist clinical staff. These highly skilled scientists should be considered equivalent of Pathologists. Providing a valuable resource in an increasingly demanding healthcare environment. This is along the same lines as the AACB career pathway but needs to be universally applied [124].

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**Appendices**

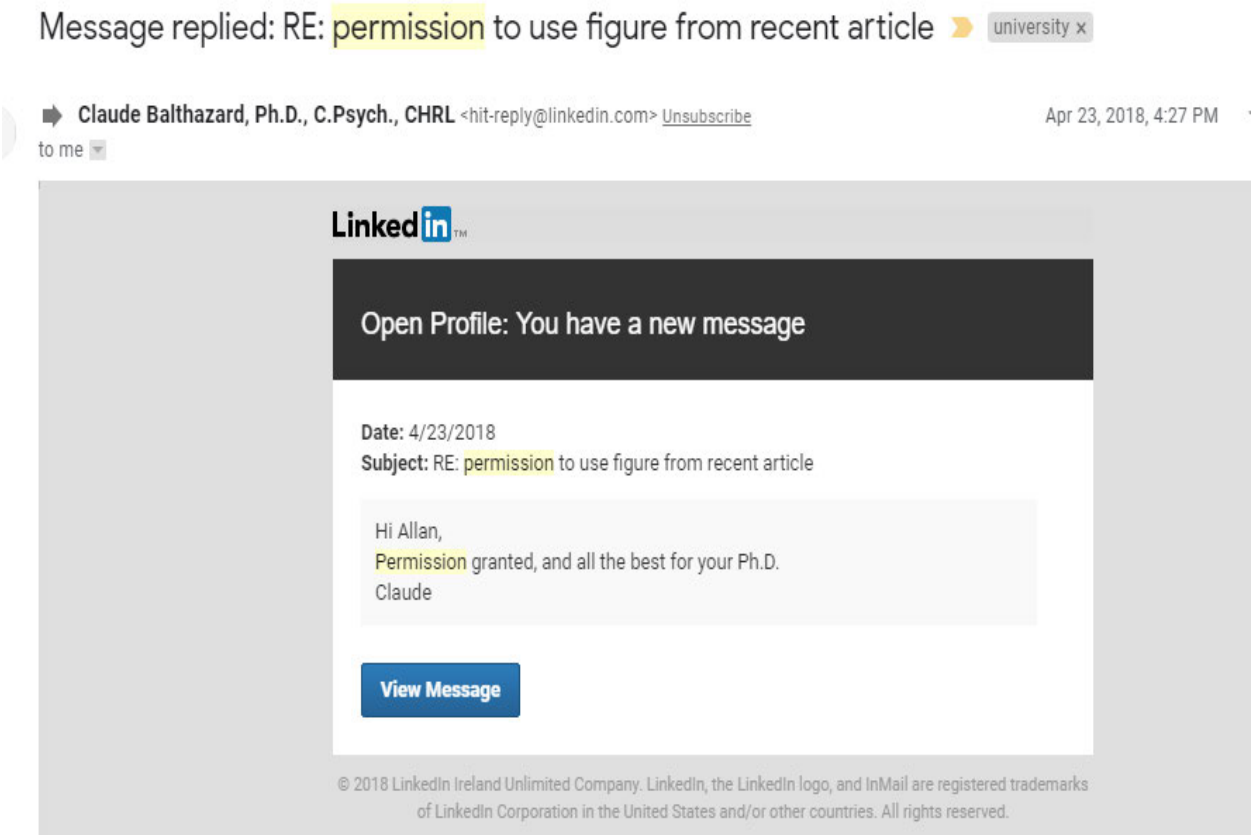


Figure 10- Permission to use "4 types of Professional Organization" diagram

سدرة للطب
Sidra Medicine

16th July 2018

Dear Dr. Allan James Hicks,

This letter will serve as a follow-up to previously sent communication on 1st May 2018 from Peter Morris and Dr. Christof Von Kalle, **Ref: CEO 2018-073**, suspending research activities under the purview of Sidra's Institutional Review Board (IRB).

In this regard, your study entitled "**Is there any benefit in Governmental Regulation of the Medical Laboratory profession?**" **[Protocol n#1804023942]** is exempted from IRB review. As a result, the above suspension will not affect this protocol and all corresponding activities may resume accordingly.

Kind Regards,

سدرة للطب
Sidra Medicine
Member of Qatar Foundation

**IRB Office**
PO BOX 26999 Doha, Qatar
sidra.org

PO Box 26999
Doha - Qatar
Sidra.org

Figure 11 – Ethics approval from Sidra Medicine

**From:** rims@griffith.edu.au <rims@griffith.edu.au>
**Sent:** Tuesday, April 2, 2019 2:51:08 AM
**To:** Allan Hicks; a.kundur@griffith.edu.au; i.singh@griffith.edu.au
**Cc:** research-ethics@griffith.edu.au; k.madison@griffith.edu.au
**Subject:** Full Research Ethics Clearance 2018/724

GRIFFITH UNIVERSITY HUMAN RESEARCH ETHICS REVIEW

Dear APro Indu Singh

I write further to the additional information provided in relation to the provisional approval granted to your applicatic for ethical clearance for your project "Is there any benefit in governmental regulation of the medical laboratory profession in Australia?" (GU Ref No: 2018/724).

This is to confirm that this response has addressed the comments and concerns of the HREC.

The ethics reviewers resolved to grant your application a clearance status of "Fully Approved".

Consequently, you are authorised to immediately commence this research on this basis.

Regards

Kim Madison | Human Research Ethics

Office for Research
Griffith University | Nathan | QLD 4111 | Level 0, Bray Centre
T +61 7 373 58043 | email k.madison@griffith.edu.au

Figure 12- Griffith University ethics approval 2018/724

Sun 21/04/2019 9:54 AM

Haytham Makki

Survey to ascertain the overall opinion of practicing Medical Scientists to the need and/or benefits of registration.

To ⊞ **Pathology Dept**

Volunteers needed

In many countries, Medical Scientists are required to hold a practicing license in order to be employed in clinical laboratories.

The Australian Government believe that registration for Medical Scientist is unnecessary as it is already sufficiently controlled by a Pathologist and laboratory accreditation, inferring that laboratory staff do not have enough direct patient contact and suggested that they remain self-regulated.

However, with the increasing use of technology and the changing role of the Scientist, clinical oversight is increasingly not required or provided.

The hypothesis is that without comprehensive clinical leadership involved in day to day output of laboratories, there is risk of harm to public that would be reduced by formal registration of Medical Scientists.

The aim of this survey is to ascertain the overall opinion of practicing Medical Scientists to the need and/or benefits of registration.

There are no foreseeable risks associated with participation in this research and there are no direct benefits to you for your participation.

However, it will aid research into this area and may benefit the Medical Scientist working in Australia in future for making a proposal for inclusion of Medical Scientists in AHPRA.

This survey should only take 15 mins and can be saved at any time.

Griffith University conducts research in accordance with the National Statement on Ethical Conduct in Human Research.
If you have any concerns or complaints about the ethical conduct of the research project, you should contact the Manager, Research Ethics on 3735 5585 or research-ethics@griffith.edu.au
Griffith University Ethics Reference Number: 2018/724

If you are interested the survey can be found here:
https://www.surveymonkey.com/r/medicalscientistregulation

Thank you

**Kindest Regards**

سدرة للطب
Sidra Medicine
Member of Qatar Foundation

**Haythem Makki** ***FIBMS, MBA, CMgrCMI***
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Figure 13- Invitation to complete survey sent by Laboratory Director

**Allan Hicks**

**From:** Allan Hicks
**Sent:** Wednesday, April 17, 2019 12:54 PM
**To:** AIMS Administration (contact@aims.org.au)
**Subject:** Request for survey to be sent to AIMS membership

Good Day,

I would like to ask if it would be possible to send the following survey invitation and web link out to your membership please, it would help me immensely in my PhD research.

## Volunteers needed

In many countries, Medical Scientists are required to hold a practicing license in order to be employed in clinical laboratories.

The Australian Government believe that registration for Medical Scientist is unnecessary as it is already sufficiently controlled by a Pathologist and laboratory accreditation, inferring that laboratory staff do not have enough direct patient contact and suggested that they remain self-regulated.

However, with the increasing use of technology and the changing role of the Scientist, clinical oversight is increasingly not required or provided.

My hypothesis is that without comprehensive clinical leadership involved in day to day output of laboratories, there is risk of harm to public that would be reduced by formal registration of Medical Scientists.

The aim of this survey is to ascertain the overall opinion of practicing Medical Scientists to the need and/or benefits of registration.

There are no foreseeable risks associated with participation in this research and there are no direct benefits to you for your participation.

However, it will aid research into this area and may benefit the Medical Scientist working in Australia in future for making a proposal for inclusion of Medical Scientists in AHPRA.

This survey should only take 15 mins and can be saved at any time.

Griffith University conducts research in accordance with the National Statement on Ethical Conduct in Human Research.
If you have any concerns or complaints about the ethical conduct of the research project, you should contact the Manager, Research Ethics on 3735 5585 or **research-ethics@griffith.edu.au**
**Griffith University Ethics Reference Number: 2018/724**

If you are interested the survey can be found here:
https://www.surveymonkey.com/r/medicalscientistregulation

Kind Regards

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sidra.org

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Figure 14-Invitation to complete survey sent to AIMS

Table 28 - First survey questions

| Questions | Answers |
|---|---|
| How old are you? | 20-29, 30-39, 40-49, 50-59, >60 |
| What is your Gender | Male, Female |
| What type of Lab do you work in? | Public, Private, Research, University, Industrial, Other |
| Do you currently work in Australia | Yes/No |
| What is your designation? | Technician, Technologist, Senior Scientist, Manager, Other |
| How long have you worked in the field? | 1-5, 5-10, 10-15, 15-20, >20 years |
| Which undergraduate degree do you hold? | Bachelor of Science, Bachelor of Medical science, Bachelor of Medical Laboratory science, Bachelor of Biomedical science, Other |
| What is your highest degree? | Bachelors, Masters, Doctorate |
| Which title do you prefer? | Biomedical Scientist, Medical Scientist, Medical Technologist, Medical Laboratory Scientist |
| Are you a member of a Professional society? | No/Yes, which one |
| Which level of membership do you hold? | Member, Fellow, Student, Affiliate, Graduate, Intermediate, Chartered Scientist, Specialist, Technologist, Technician, Other |
| Do you think of Medical Science as a Profession? | Yes/No/Don't Know |
| Do you think your work is recognised (defined as "Acknowledge the existence, validity or legality of") by the public? | Yes/No/Don't Know |
| Do you think your work is recognised by other healthcare professionals? | Yes/No/Don't Know |
| Do you feel your work is respected by the public? | Yes/No/Don't Know |
| Do you feel your work is respected by other healthcare professionals? | Yes/No/Don't Know |
| Do you think Continuing Professional development (CPD) is important? | Yes/No/Don't Know |
| How many hours of CPD are required for you to maintain your membership/license in a year? | 0, <20, 20-30, 30-40, >40 |
| Does your workplace provide CPD? | Yes/No/Don't Know |
| Does your workplace provide protected time to do CPD? | Yes/No/Don't Know |
| Does your laboratory conduct annual competency assessments? | Yes/No/Don't Know |
| Do you think there are promotional opportunities within the profession? | Yes/No/Don't Know |
| Do you think governmental regulation or registration will improve the profession? | Yes/No/Don't Know |
| Do you think that pathology testing has a direct impact on patient care? | Yes/No/Don't Know |
| What do you think the benefits of registration of Medical Scientists would have on your career or on a country's healthcare? | |
| If regulation of Medical Scientists existed what impact do you see that having on a country's healthcare? | |

Table 29- Personal Benefit v Professional impact statements from the first survey

| Personal benefit (Australian respondents) | Code | Exp (years) | Designation | Education |
|---|---|---|---|---|
| restrict the Medical Scientist role to people who have an approved qualification (not just any old science degree) +<br><br>Every other health professional must be registered except for pathology. It would be nice to be recognised as an actual profession and not just someone who 'puts a specimen on a machine' we make clinical decisions every day which affect patient treatment and outcomes. (31) + | Recognition | 10-15 | Senior Scientist | Bachelors |
| Become a more recognised and respected profession with more credibility to reflect our education and knowledge (30) + | Recognition | 1-5 | Senior Scientist | Bachelors |
| more drive for people to advance in their career, currently being a Medical Scientist is a great career for working families as you can use shift work to your advantage and still look after your family (32) + | Regulation | 1-5 | Technologist | Masters |

| | | | | |
|---|---|---|---|---|
| improving engagement and keeping people interested (43) + | Competency | >20 | Senior Scientist | Bachelors |
| **Personal benefit (International respondents)** | **Code** | **Exp (years)** | **Designation** | **Education** |
| This would give me more respect as a trained professional. (9) + | Recognition, | 10-15 | Technologist | Bachelors |
| For me registration gives you privilege (21) + | Recognition, | 10-15 | Technologist | Bachelors |
| Registration is a form of recognition and of professional standing (63) + | Recognition | 10-15 | Senior scientist | Doctorate |
| It credits my educational qualification and permits me to practice my job (65) + | Recognition | 10-15 | Technician | Diploma |
| None for career, but for personal standing I believe it would have a positive influence on those holding registration (67) + | Recognition | >20 | Supervisor | Masters |
| Belongingness in your career it will be recognised more by the country and other healthcare professional (72) + | Recognition | 5-10 | Technologist | Bachelors |
| We can get full entitlement of the organisation's benefits (74) + | Recognition, | 10-15 | Technologist | Bachelors |
| Improve advocacy for the profession and increase the respect of the profession (77) | Recognition | >20 | Manager | Masters |
| More Responsibility (80) + | Recognition | 1-5 | Technologist | Masters |
| It enhances CPD and update the current developments (55) + | Competency, | 10-15 | Technologist | Masters |

| | | | | |
|---|---|---|---|---|
| The benefits are that; I have complied with any conditions of my scope of practice, maintained the standard of competence required for my scope of practice, fit to practice and competent (57) + | Competency | >20 | Senior Scientist | Masters |
| It guaranties that staff have the relevant education to work within the industry (58) + | Education | 15-20 | Supervisor | Masters |
| improve my knowledge (64) + | Education | 1-5 | Technician | Bachelors |
| Recognised profession means scientists will have to demonstrate their competence through accredited pathways into the profession. This will benefit staff by improving pay and giving them recognition (60) + | Competency | 15-20 | Senior Scientist | Masters |
| It will ensure staff are competent (68) + | Competency | >20 | Manager | Masters |
| Registration is important; it ensures you don't get lazy or complacent in the care you deliver. Scientific professions progress at a fast pace and it is vital to the healthcare system and patients it serves that all practitioners are consistent and responsive to progress, whilst adhering to recognised standards of proficiency and competence (13) + | Standardisation | 10-15 | Clinical scientist | Doctorate |
| There should be a regulation within the medical science profession itself to maintain its own credibility as an existing profession (16) + | Regulation | 5-10 | Technologist | Bachelors |

| Personal benefit (Australian respondents) | Code | Exp (years) | Designation | Education |
|---|---|---|---|---|
| The plan to draw Medical Scientists into AHPRA (or other similar body) is a construct by people who have little to contribute in science and medicine and instead are focused on making time wasting petty rules and duties for everyone else. (28) | Recognition | 1-5 | Manager | Doctorate |
| Current oversight by laboratory executive is enough (29) - | Recognition | >20 | Technologist | Bachelors |
| If ongoing professional education was required to maintain registration, then employers should be obliged to provide paid time to do such activities. With increasing pressure on all staff this is unlikely to happen. (2) - | Education | 15-20 | Manager | Bachelors |
| Just another fee for us, the current private pathology system revolves around scientists following document laboratory procedures and work instructions. I don't see how being certified improves my ability to read them and then follow them (39) - | Regulation | 10-15 | Technologist | Bachelors |
| **Personal benefit (International respondents)** | **Code** | **Exp (years)** | **Designation** | **Education** |

| | | | | |
|---|---|---|---|---|
| It is waste of money and time to spend just for CPD points which many of the staff attend these seminars, classes, and conferences irrelevant to their specific profession. (15) - | Waste, | 10=15 | Technician | Diploma |
| It will help develop a real career pathway, there is no recognition or understanding by the public of the role that Scientists play. The Medical profession take credit for the results or distribute blame to the Laboratory whichever is most convenient. I feel Scientists are completely undervalued for the work, underpaid for the responsibility and stress that is inherent in the work. The role in Healthcare is totally under recognised (44) - | Recognition | >20 | Senior Scientist | Bachelors |
| The profession in my opinion lacks recognition in the public eye. The technologist/Biomedical Scientist is not seen as playing a critical role in providing care to the patient (53) - | Recognition | 5-10 | Technologist | Masters |
| **Professional impact (Australian respondents)** | **Code** | **Exp (years)** | **Designation** | **Education** |

| | | | | |
|---|---|---|---|---|
| It would better protect the line between scientist and lab tech/assistant positions, but would also increase fees, waste time on administration/bureaucracy, which could otherwise be better spent on CPD (28) + | Recognition | 1-5 | Manager | Doctorate |
| I think it would improve standards as it would protect the industry's professionalism and longevity. Keep standards high or push them higher. (45) + | Regulation | 1-5 | Technician | Bachelors |
| Increased standardisation of protocols in pathology labs in Australia. Registration is a good idea to maintain high standards in the industry. It does also provide a governing body that can provides some guidance and direction to pathology practices such as an agreed single plate form that can negotiate, discuss, etc. with NATA NPAAC and so forth. (27) + | Regulation | 5-10 | Technologist | Bachelors |
| Poor quality scientists cannot simply go from lab to lab using very selective referees, it would also provide a basis for campaigning for scientists to have a recognised role in laboratory supervision (34) + | Regulation | 15-20 | Manager | Doctorate |
| It would make scientists accountable and keep their knowledge up to date and provide a consistent standard of performance and improve the standard of results we provide (43) + | Competency | >20 | Senior Scientist | Bachelors |

| | | | | |
|---|---|---|---|---|
| Better standard of scientists, more consistent results. (4) + | Competency | 10-15 | Senior Scientist | Bachelors |
| Better knowledge and conscientious effort behind the results given out. (32) + | Competency | 1-5 | Technologist | Masters |
| It would make pathology testing more reliable as it would force people to do CPD which would mean that the quality and reliability would improve (31) | Education | 10-15 | Technologist | Masters |
| Improved knowledge currency across all departments. (2) + | Education | 15-20 | Manager | Bachelor |
| More reliable results. Less idiots hired due to lack of applicants (41) + | Quality | 15-20 | Manager | Masters |
| Improved service to patients. (29) + | Patient safety | >20 | Technologist | Bachelors |
| **Professional impact (International respondents)** | **Code** | **Exp (years)** | **Designation** | **Education** |
| It would improve quality and patient outcomes (5) + | Recognition | >20 | Supervisor | Masters |
| The profession will gain greater respect from other healthcare professionals and the public leading to improved quality in the country's healthcare. (8) + | Recognition | 10-15 | Technologist | Masters |
| It may give more legitimacy to the field in the view of the other healthcare employees and the public. (9) + | Recognition, | 10-15 | Technologist | Bachelors |

| | | | | |
|---|---|---|---|---|
| I believe that it would provide employees of a standard competency they must meet and ensure that they maintain this level or even encourage continued development. This would ensure that the country's healthcare, regardless of location, would meet this minimum standard giving equal healthcare across the country. I think this would lead to a better monitoring of technologists/scientists to identify non-competent employees at a more standard level. (9) + | Regulation, Competency | 10-15 | Technologist | Bachelors |
| Benefit to standard of practice to achieve healthcare goals. (15) + | Recognition | 10-15 | Technician | Diploma |
| Almost all countries have regulations, rules and restrictions governing the practice of Medical Technology. The impact of this is on how easily you can find work and find opportunities. It would be easier if you already have one from your own country and that would be good enough for a different country. This would mean there is continuity of work and shortage is addressed, thereby quality healthcare is not thwarted. (21) + | Recognition, | 10-15 | Technologist | Bachelors |
| Registration provides you with recognition and code of ethics, encouraging a high standard of work and general improved Healthcare (25) + | Recognition | >20 | Technologist | Masters |

| | | | | |
|---|---|---|---|---|
| A regulated workforce would encourage further education, recognition and would add value to the profession increasing recognition of the role that Scientists have in Healthcare (44) + | Recognition | >20 | Senior Scientist | Bachelors |
| Gain recognition and make public aware of the profession, will improve the quality of care provided. (53) + | Recognition | 5-10 | Technologist | Masters |
| I think the Australian system is out of kilter with international best practice and needs overhauling to reflect the professional standing of Medical Laboratory Scientists. It can only serve to have a positive impact and to provide confidence regarding the professionalism of Medical Scientists. (63) + | Recognition | 10-15 | Senior Scientist | Doctorate |
| We can have equal treatment and consistent rules not just changing it when they want it (74) + | Recognition | 5-10 | Technologist | Bachelors |
| Better recognition of the profession (76) + | Recognition | >20 | Manager | Masters |
| A protected profession where specially trained staff can only work in the profession, this will ensure that staff have the right knowledge and background training and will hopefully decrease errors, having worked in multiple countries, including Australia, I feel registration of lab staff is important (68) + | Competency, Regulation | >20 | Manager | Masters |

| | | | | |
|---|---|---|---|---|
| It provides assurance that healthcare professionals meet certain requirements and holds them accountable for their actions, improving safety for patients. Diagnostic laboratory plays a huge part in the patient journey providing diagnostic testing on which diagnosis and monitoring are usually based. It would provide better and safer healthcare within the laboratory and make people more accountable for their actions. Provides a means of assessing a suitable candidate for the job knowing they have met minimum requirements (60) + | Competency, Regulation, Patient safety | 15-20 | Senior Scientist | Masters |
| Staff are tracked where they work which ensures that when there is an incident, those involved are documented and if necessary, struck off register from working again. it also ensures that the work that is produced from the laboratory that they work at is to the highest level. (58) + | Regulation | 15-20 | Supervisor | Masters |
| It will regulate the profession to create laws and order on the practice to provide quality result and a general enhancement of quality and precision of reports (19) + | Regulation | 10-15 | Technologist | Bachelors |
| The most important investment to scientists and health professional is to be part of an official body that add to the academic and work records different level and reflect their | Competency, Regulation | >20 | Senior Scientist | Masters |

| | | | | |
|---|---|---|---|---|
| commitment to both development and career. Because medical malpractice occurs when a health care professional or provider neglects or been neglected (57) + | | | | |
| I totally support the idea of regulation of medical science profession for it will be advantageous to the career and country. Regulation of Medical Scientist will uphold professionalism and integrity of the profession (72) + | Regulation | 5-10 | Technologist | Bachelors |
| we should have freedom and choice to work (65) + | Regulation | 10-15 | Technician | Diploma |
| Improve regulation and accreditation leads to improved quality of patient care, increased collaboration, and standardisation of the practice (77) + | Regulation | >20 | Manager | Masters |
| A registration body empowers the healthcare practitioners with more people being attracted to the profession due to the awareness of the Medical Scientists and their role and importance in healthcare. It will help to understand the healthcare practitioners about their role, code of conduct and professionalism. (55) + | Competency, Regulation | 10-15 | Technologist | Masters |
| A countries health system would benefit as training, qualifications and CPD would hopefully increase competency and standards. Leading to an increased profile of profession, personal standards and conduct of those practicing in profession, (67) + | Competency | >20 | Supervisor | Masters |

| | | | | |
|---|---|---|---|---|
| Improved quality of work will be confident and a good step towards patient safety (59) + | Patient safety | 5-10 | Technologist | Bachelors |
| Quality care and patient safety (80) + | Patient safety | 1-5 | Technologist | Masters |
| Ensuring quality outcomes with improve quality of people and thus results, but will cost more (61) + | Competency | 15-20 | Senior Scientist | Masters |
| Provide assurance this is good for the profession, the quality of scientist and helps to protect patients/ public (35) + | Patient safety | >20 | Senior Scientist | Masters |
| Patients can be confident that result is accurate and performed by a competent person who understands the results (+),<br>Better monitoring of diseases and better management of treatment and lifestyle is also improved. (10) + | Quality | 15-20 | Senior Scientist | Masters |
| There will be uniform QC for every laboratory and the quality of healthcare will be more outstanding (48) + | Quality | 5-10 | Technologist | Bachelors |
| If regulation of Medical Scientist existed, the impact on country's healthcare will be more consistent and efficient. (73) + | Quality | 10-15 | Technologist | Bachelors |

| | | | | |
|---|---|---|---|---|
| standardised training, less risk of near misses in lab and reduction in near misses/harm to patient (79) + | Standardisation, Patient safety | 5-10 | Technologist | Bachelors |
| Registration provides a framework in which standards are known and adhered to. (+) Improve the consistency and standard of care, as well as ensuring practitioners are adhering to the appropriate guidance and evidence base. (13) + | Standardisation | 10-15 | Clinical scientist | Doctorate |
| Those who are highly trained and qualified scientists only should be allowed to perform laboratory procedures (16) + | Education | 5-10 | Technologist | Bachelors |
| This could lead to a better structure and help protect, promote, and maintain the health and safety of the public by ensuring proper standards in the practice are met. Possibility of streamlining certain trials and having the data used to offer treatments earlier to the public. (54) + | Standardisation, Patient care | 5-10 | Technologist | Bachelors |
| public are better protected against malpractices lab and professionals should be protected against exploitation, leading to an overall improvement of services (22) + | Patient care | >20 | Technologist | Diploma |
| **Professional impact (Australian respondents)** | **Code** | **Exp (years)** | **Designation** | **Education** |
| Probably minimal impact on whole system (2) - | Regulation | 15-20 | Manager | Bachelors |

| | | | | |
|---|---|---|---|---|
| Extra burden on scientists for no reward resulting in more scientists leaving the industry thus having a negative impact on services, but a positive result for the universities who get to educate more customers (students). I would like to see a way to allow certified scientists to run their own labs (39) - | Regulation | 10-15 | Technologist | Bachelors |
| **Professional impact (International respondents)** | **Code** | **Exp (years)** | **Designation** | **Education** |
| Until government and employers acknowledge scientists are necessary registration is irrelevant (5) - | Recognition | >20 | Supervisor | Masters |
| all health organisations are accredited and have other standard policies and regulations then it is enough for the management and Pathologist to have registrations rather on Medical Scientists or lab techs. (15) - | Recognition | 10-15 | Technician | Bachelors |
| No impact as the public perception is limited (56) - | Recognition | >20 | Manager | Masters |
| Pressure on individuals to get points without understanding the material read. Waste of taxpayer's money. (37) - | Waste | >20 | Technologist | Masters |

Good Day,

I would like to request if it would be possible to send the following survey invitation and web link out to your members/employees please, it would assist me greatly in finishing the research for my PhD thesis.

**Volunteers needed**

In many countries, Medical Scientists are required to hold a practicing license in order to be employed in clinical laboratories. The Australian Government believes that registration for Medical Scientists is unnecessary as it is already sufficiently controlled by a Pathologist and Laboratory Accreditation, inferring that laboratory staff do not influence patient outcomes enough and suggest that they remain self-regulated. However, with the increasing use of technology and the changing role of scientists, clinical oversight is increasingly not required or provided.

The aim of this survey is to ascertain the overall opinion of practising Medical Scientists regarding the personal implications and professional impact of registration in Australia.

There are no foreseeable risks or direct personal benefits associated with participation in this research. However, it will aid research into this area and possibly increase recognition of Medical Scientists working in Australia. This anonymous online survey is voluntary, should only take 15 minutes and can be saved at any time.

Griffith University conducts research in accordance with the National Statement on Ethical Conduct in Human Research.

If potential participants have any concerns or complaints about the ethical conduct of the research project, they should contact the Manager, Research Ethics on **3735 4375** or **research-ethics@griffith.edu.au**. [**GU ref no: 2020/793**]

If you are interested the survey can be found via the link below;

**https://prodsurvey.rcs.griffith.edu.au/registration_impact_on_medical_scientists_in_Australia**

Figure 15-Invitation to join 2nd survey to Pathology laboratory's and State health providers

Table 30- Second survey questions

| Question | Answer |
|---|---|
| What qualification do you hold? | Diploma, Bachelors, Master, Doctorate |
| What is your designation? | Technician, Technologist, Supervisor, Manager |
| How much experience do you have? | <5, 5-10, 10-15, 15-20 >20 |
| What would the personal implications be if AHPRA registration existed in Australia? | Free text |
| What would the professional impact on Medical Scientists if AHPRA registration existed in Australia? | Free text |
| What has been the impact on the industry due to the level of testing due to the COVID-19 pandemic? | Free text |
| What is your gender? | Male, Female, Other |
| Are you a member of a Professional Society in Australia? | AIMS, AACB, ASM, ASC, HGSA other |
| Which type of Laboratory do you work in? | Public, Private, Mixed |
| Do you think that Medical Scientists are recognised by other healthcare professionals in Australia? | Free text |
| Do you think that Medical Scientists are recognised by the Australian public? | Free text |
| "Medical Scientist should hold an approved degree"<br>"Registration is a form of recognition and of professional standing"<br>"The current oversight by laboratory executive is enough"<br>"Employers should provide paid time for CPD, with increasing pressure on all staff this does not happen"<br>"Registration would just be another fee to pay"<br>"The Medical profession takes credit for the results or distribute blame to the Laboratory whichever is most convenient"<br>"It would better protect the line between scientist and lab tech/assistant positions"<br>"Registration provides a single governing body that provides guidance and direction to pathology practices"<br>"Regulation prevents poor quality scientist moving from lab to lab with no control"<br>"Registration will improve the service to patients"<br>"The profession will gain greater respect from other healthcare professionals and the public"<br>"Registration would make minimal impact on the Australian healthcare system"<br>"Registration could lead to a better structure and help protect, promote and maintain the health and safety of the public"<br>"Standardised training, qualifications and CPD would lead to increased competency and standards"<br>"It is waste of money and time for CPD points if the education is irrelevant to their specific profession"<br>"The Medical Scientist is not seen as playing a critical role in providing care to the patient" | Strongly agree, Agree, Neutral, Disagree, Strongly Disagree |

Figure 16- Griffith University Ethics approval 2020/793

GRIFFITH UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

Dear APro Indu Singh

I write in relation to your application for ethical clearance for your project "NR: Would professional registration impact medical scientists in Australia?" (GU Ref No: 2020/793). Thank you for providing responses to the conditions outlined in my previous email.
The research ethics reviewers resolved to grant your application a clearance status of "Conditionally Approved".

This decision is subject to:

Condition 04: Please provide an estimate of the total number of participants that are expected to take part in the research.

Condition 08: If data collection is anonymous, it is not necessary to include a privacy statement in the informed consent materials.

Response: None received

Condition 08b: This was not removed from the informed consent materials. Please ensure that it is removed from the Participant Information Sheet.

Condition 10: Please provide your response to the conditions/concerns raised by the Committee in the body of an e-mail to research-ethics@griffith.edu.au or in a separate document forwarded by e-mail (please do not try to amend the RIMS application). Please ensure you respond directly to each condition/concern raised. Section 5.2.23 of the National Statement (2007) specifies that all documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the review body, prior to their use.

However, you are authorised to immediately commence this research on the strict understanding that these matters are addressed and that you provide details of how they were addressed.

Please note that failure to provide a timely response to these matters may result in this authorisation being suspended or withdrawn.

It would be appreciated if you could give your urgent attention to the issues raised by the Committee so that we can finalise the ethical clearance for your protocol promptly.

Regards

Gynelle Murray| Ethics Systems and Support Officer
Office for Research
Griffith University | Nathan | QLD 4111 | Bray Centre (N54) Room 0.10
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