Regulation of the Professions of Speech-language Therapy and Clinical Physiology under the Health Practitioners Competence Assurance Act 2003

Consultation Document

September 2007
For Proposal that Speech-language Therapy and Clinical Physiology become regulated professions under the Health Practitioners Competence Assurance Act 2003

1. Introduction
The Ministry of Health has received two proposals for professional regulation:

- one from the New Zealand Speech-language Therapists Association that speech-language therapy be approved as an additional profession for inclusion in the scope of the Health Practitioners Competence Assurance Act 2003;
- one from the Clinical Physiologists Registration Board that clinical physiology be approved as an additional profession for inclusion in the scope of the Health Practitioners Competence Assurance Act 2003.

This document seeks your opinion on either one or both of these proposals.

The Health Practitioners Competence Assurance Act 2003 (the Act) requires that the Minister of Health consult with any organisation that, in the Minister's opinion, has an interest in any proposal to add a profession to those regulated under the Act. This consultation document has, therefore, been produced to obtain your views on these proposals.

This document:
- discusses the relevant provisions of the Act
- discusses the reasons for, and consequences of, regulating a profession under the Act
- asks specific questions to assist you to comment on either or both of these proposals
- sets out the criteria for assessing applications for inclusion under the Act (see Appendix 1)
- provides background material on speech-language therapy (see Appendix 2) and clinical physiology (see Appendix 3).
2. Invitation to comment

You are invited to submit comments on either one or both proposals. In particular, it would be helpful to receive your response to the specific questions listed in section 4 (for speech-language therapy) and / or 5 (for clinical physiology)

Your submissions should be addressed to:

Sandra Cumming
Health and Disability Systems Strategy
Ministry of Health
P O Box 5013
WELLINGTON

Please note that all correspondence and submissions on this matter may be the subject of a request under the Official Information Act 1982. If there is any part of your correspondence that you consider could properly be withheld under that Act, please include comment to that effect and give reasons why you would want it withheld.

The closing date for submissions is 3 December 2007.
3. Health Practitioners Competence Assurance Act 2003

There are currently 16 authorities under the Act charged with registering practitioners of the professions for which they are responsible. These authorities ensure that health practitioners:

• are registered in a 'scope of practice' which describes the health services they can provide
• have the right qualifications for their scope of practice
• have a current practising certificate which has to be renewed each year
• maintain and develop their skills and competence
• have good English language and communication skills
• are physically and mentally able to work.

Why regulate a profession?

The principal purpose of the Act is described in section 3(1) of the Act. That is:

3 Purpose of Act

(1) The principal purpose of this Act is to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions.

It is this element of protecting the health and safety of members of the public that underpins the processes for extending the regulatory cover of the Act to additional professions, and it is the reason to regulate.

The implications of regulation under the Act

Under the Act, the relevant registration authority plays a pivotal role. Authorities have sole responsibility for identifying the parameters of practice for registered practitioners and the qualifications and competencies required for registration.

A key concept under the Act is that of a 'scope of practice'. The Act requires each responsible authority under the Act to describe the profession it regulates in terms of one or more scopes of practice and to prescribe the qualifications that a practitioner needs in order to be eligible to be registered in a scope of practice.

Any practitioner registered under the Act will be required to be registered in a specific scope of practice. Registered health practitioners are not permitted to practise outside their scopes of practice, and responsible authorities are required, through the issuing of an annual practising certificate to certify that the practitioner is competent to practise in their scope of practice. The Act does not prohibit non-registered people from carrying out the activities of a registered profession. However, only health practitioners who are registered under the Act will be able to use the title associated with the profession or scope of practice.

Regulation is not without cost. Under the Act, each registration authority determines the relevant fees for the profession or professions it administers, to provide sufficient revenue to cover the operating costs of the authority. These include fees for registration...
and the issuance of an annual practising certificate and other necessary levies (such as a levy to cover any disciplinary activity). There is no taxpayer subsidy for the operating costs of registration authorities. Fees will differ between authorities and will reflect among other things the level of activity of each authority and the number of practitioners who are registered with it.

Who does the Act currently cover?
At present, some 20 professions are regulated under the Act. These are:

- chiropractors
- dentists, dental technicians, clinical dental technicians, dental therapists and dental hygienists
- dieticians
- dispensing opticians
- medical laboratory scientists and technicians
- medical practitioners (such as GPs, psychiatrists, surgeons and other specialists)
- medical radiation technologists
- midwives
- nurses
- occupational therapists
- optometrists
- osteopaths
- pharmacists
- physiotherapists
- podiatrists
- psychologists
- psychotherapists.

How are additional professions added to the Act?
Section 115 of the Act enables the Governor-General, on the advice of the Minister of Health, to designate health services of a particular kind as a health profession under the Act and to either:

- establish a registration authority to administer the registration of the profession; or
- provide that the designated profession be added to the profession or professions in respect of which an existing authority is appointed – thus creating a “blended authority”.

A protocol has been developed to guide the consideration of proposals for new professions to be added under the Act. The protocol, which discusses the content and assessment of applications, is attached as Appendix 3. Appendix 1 provides background material on speech-language therapy submitted by the New Zealand speech-language therapy profession to assist with consideration of this proposal.
Appendix 2 provides background material on clinical physiology submitted by the New Zealand clinical physiology profession.
4. Proposal to Regulate Speech-language Therapy – Discussion Questions

The Ministry of Health invites your views on the proposal that speech-language therapy becomes a regulated profession under the Health Practitioners Competence Assurance Act 2003.

To assist you to do so, the Ministry has drawn up the following questions that are intended to tease out the elements required, by the protocol, to be established. You may wish to address all or some of these questions.

1. Is the work undertaken by speech-language therapists a health service, as defined by the Act? (NB: the Act defines a health service as “a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals”.)

2. What is the nature of the activities undertaken by members of the profession?

3. Is there a risk of harm to the public from the practices undertaken by speech-language therapists?

4. If so, what is the nature, frequency and severity of the potential risk to the public? What is the likelihood of the risk occurring? [In addressing the risk of harm, are the risks associated with the practice of the proposed profession, as distinct from risks inherent in the area of health care within which the profession operates?]

5. To what extent are the risks mitigated or managed by existing supervisory or other practices?

6. Other than due to risk of harm, is it in the public interest that the profession of speech-language therapy be regulated?

7. Are speech-language therapists generally agreed on the qualifications required for the health services that they provide?

8. What qualifications are generally held by members of the profession and the degree of uniformity in qualifications across members?

9. Are practising speech-language therapists generally agreed on the standards that speech-language therapists are expected to meet?

10. Are practising speech-language therapists generally agreed on the competencies for scopes of practice for this profession?

11. Is the profession regulated overseas, and what risks, if any, have been identified in overseas experience or studies?

12. Does your organisation accord any standing or status to the profession or to practitioners who practise this profession?
5. Proposal to regulate clinical physiology - Discussion questions

The Ministry of Health invites your views on the proposal that clinical physiology becomes a regulated profession under the Health Practitioners Competence Assurance Act 2003.

To assist you to do so, the Ministry has drawn up the following questions that are intended to tease out the ingredients required, by the protocol, to be established. You may wish to address all or some of these questions.

1. Is the work undertaken by clinical physiologists a health service, as defined by the Act? (NB: the Act defines a health service as “a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals”.)

2. What is the nature of the activities undertaken by members of the profession?

3. Is there a risk of harm to the public from the practices undertaken by clinical physiologists?

4. If so, what is the nature, frequency and severity of the potential risk to the public? What is the likelihood of the risk occurring? [In addressing the risk of harm, are the risks associated with the practice of the proposed profession, as distinct from risks inherent in the area of health care within which the profession operates?]

5. To what extent are the risks mitigated or managed by existing supervisory or other practices?

6. Other than due to risk of harm, is it in the public interest that the profession of clinical physiology be regulated?

7. Are clinical physiologists generally agreed on the qualifications required for the health services that they provide?

8. What qualifications are generally held by members of the profession and the degree of uniformity in qualifications across members?

9. Are practising clinical physiologists generally agreed on the standards that clinical physiologists are expected to meet?

10. Are practising clinical physiologists generally agreed on the competencies for scopes of practice for this profession?

11. Is the profession regulated overseas, and what risks, if any, have been identified in overseas experience or studies?

12. Does your organisation accord any standing or status to the profession or to practitioners who practise this profession?
APPENDIX 1

Background material on speech-language therapy

The following material has been provided by the New Zealand Speech-language Therapists Association (NZSTA). NZSTA represents approximately 500 speech-language therapists in New Zealand, comprising around 60 percent of practitioners. The material includes:

- an occupational definition of speech-language therapy
- evidence of the need for regulation, including evidence that the public is at risk of harm by the practice of speech-language therapy
- evidence of general agreement on qualifications standards and competencies to practice speech-language therapy in New Zealand.

The material is provided as background information for those wishing to make a submission and has been provided by the NZSTA. The views expressed are those of the NZSTA and, in providing the material, the Ministry of Health is not endorsing or confirming the contents.

It is important to note that, while NZSTA has developed policy on qualifications and other matters, these will not necessarily be the same as those put in place if the profession becomes regulated under the Act. Under the Act, decisions on scopes of practice, qualifications, and measures of competence will be entirely in the hands of the authority that is given responsibility for regulating the profession.
Definition of speech-language therapy

Speech-language therapists deal with the identification and rehabilitation of communication and swallowing disorders that may be a result of impairment of the respiratory, oesophageal, laryngeal, resonatory, oral, or neurological mechanisms. Such impairment may result from a variety of causes including, but not limited to, factors such as stroke, muscle weakness, progressive disorders (e.g. Alzheimer’s disease, amyotrophic lateral sclerosis), developmental disorders (e.g. Down Syndrome, autism, dyslexia), non-progressive cancers, genetic factors (e.g. stuttering), birth defects (e.g. cleft lip and palate) and unknown etiology. In addition to the treatment of the physical health of individuals, speech-language therapists manage the social and vocational impact of the communication and/or swallowing disorder on an individual’s wellbeing.
Evidence of the need for regulation, including evidence that the public is at risk of harm by the practice of speech-language therapy

The nature and frequency of risk

Specific risks associated with the practice of the speech-language therapy include: failure to identify a disorder or risk of a disorder (e.g. failure to identify impairment in swallowing may lead to pneumonia; failure to identify a child who stutters or is at risk for stuttering may lead to long-term social and emotional difficulties and an impairment at the level of Activity and Participation as described by the World Health Organization (2001)); incorrect diagnosis and cause of the impairment (e.g. incorrect diagnosis of the cause of a voice disorder may lead to long-term impairment to the larynx); inappropriate intervention (e.g. a child who is not provided with appropriate treatment for developmental verbal dyspraxia may have long-term difficulties in school, be delayed in communicating with peers and may suffer social and emotional difficulties due to the impairment; an adult with a head injury who is not given appropriate intervention may engage in costly long-term treatment programs with no progress and be unable to return to work).

The frequency and severity of the risk and the harm is difficult to measure as the profession of speech-language therapy in New Zealand as there is currently no requirement to report risk or harm. However, due to the large portion of the population who will present with a communication disorder, the risk of harm to the public is great.

The severity of harm varies depending on the nature of the communication disorder. In many cases the harm would be reversible; however there are instances where the harm may be irreversible. For instance, it has been shown that when children receive early diagnosis and appropriate treatment, stuttering can be eliminated; otherwise approximately 24 percent of preschool children who stutter that are not treated will stutter as adults and the stutter will be managed but not eliminated. Children and adults with feeding and swallowing disorders are at risk for aspiration pneumonia. Children and adults with vocal nodules who do not receive appropriate treatment may require surgical intervention.

The following table provides examples of potential harm caused by unqualified or incompetent speech-language therapists. However, it should be noted that the speech-language profession has advised the Ministry that it is not aware of any data currently available regarding the frequency of incidents of harm either in New Zealand or internationally.

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## Examples of Potential Harm caused by Unqualified or Incompetent Speech-language Therapists

<table>
<thead>
<tr>
<th>Speech-language therapist error</th>
<th>Potential harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation of feeding too soon or inserting objects into the mouth for thermal stimulation during dysphagia treatment</td>
<td>Patient choking and/or aspirating leading to aspiration pneumonia and possible death</td>
</tr>
<tr>
<td>Improper placement, adjustment or monitoring of oral prostheses such as palatal lifts or obturators</td>
<td>Tissue breakdown secondary to pressure. Or the device could weaken over time, break and fall into the airway</td>
</tr>
<tr>
<td>Improper insertion of speaking devices for patients on respirators</td>
<td>Reduction in airflow</td>
</tr>
<tr>
<td>Incorrect choice of augmentative devices for non-verbal patient</td>
<td>Limitation of communication competence if choice is below the patient’s abilities. Frustration, withdrawal, decreased motivation to attempt communication or rejection of subsequent devices if choice is above the patient’s abilities. Inappropriate educational and vocational placements</td>
</tr>
<tr>
<td>Providing therapeutic services to an individual with a perceived voice problem without first referring to an otolaryngologist</td>
<td>Overlooking possible cancer of the larynx, resulting in surgical removal of larynx and possible death</td>
</tr>
<tr>
<td>Inability to successfully perform a Fiberoptic Endoscopic Examination of Swallowing (FEES)</td>
<td>Damage to vocal tract and larynx due to improper insertion of the endoscope. Improper interpretation of the FEES results leading to aspiration and/or death</td>
</tr>
<tr>
<td>Improper usage of facilitating techniques in the treatment of voice disorders</td>
<td>Development of vocal nodules</td>
</tr>
<tr>
<td>Failure to identify seizure activity in speech disordered clients, such as those with Traumatic Brain Injury or Cerebral Palsy</td>
<td>Permanent brain damage, coma, death</td>
</tr>
<tr>
<td>Failure to identify conditions of chronic otitis media in preschool children with speech and language difficulties</td>
<td>Permanent sensorineural hearing loss, poor educational achievement</td>
</tr>
<tr>
<td>Failure to identify conditions indicative of motor neurone disease (for example), in adults who present with deteriorating speech articulation difficulties</td>
<td>Delayed medical treatment, resulting in short life span, reduced quality of lie</td>
</tr>
<tr>
<td>Failure to provide necessary environmental support for communicatively impaired patients who have demonstrated physical weakness (stroke, paralysis)</td>
<td>Injury due to fall</td>
</tr>
</tbody>
</table>
Existing public safety concerns resulting from unregulated activities
Specific safety concerns that have been identified include: individuals practicing below the recommended standard of competence; individuals failing to continue professional development in order to maintain the recommended standard of competence; individuals operating in a manner contrary to the code of professional ethics of the profession. Concerns have arisen from the public, speech-language therapists and other health professionals. Service providers, such as District Health Boards and Group Special Education (GSE), have also indicated a concern that the profession remains unregulated.

Regulation of speech-language therapy in other countries
Speech-language therapy is regulated in 47 of the 50 States in the United States of America, six provinces in Canada, the United Kingdom, Ireland and South Africa.

In Australia, speech-language therapy is regulated in Queensland, and the professional association, Speech Pathology Australia, has agreed to pursue registration of speech-language therapy across Australia.

Evidence of general agreement on qualifications standards and competencies to practice speech-language therapy in New Zealand
Consultation and Feedback
The following organisations and individuals were consulted in the preparation of the application to regulate speech-language therapy under the Act:
- Members of NZSTA
- Members of the Profession
- Allied Health Professionals Association Forum (AHPAF)
- New Zealand Association for Occupational Therapy (NZAOT)
- Service Providers
- Speech Pathology Australia (SPA)
- Tertiary institutions (University of Canterbury, University of Auckland, Massey University).

Members of the speech-language therapy profession were consulted through written and verbal consultation including presentations and a teleconference. Members of NZSTA have been consulted on the application through presentations, information printed in the quarterly newsletters and discussion at area meetings. Feedback has been received via written responses, email correspondence, through area representatives and verbally at presentations. Non-members of the profession were consulted through written information and a survey sent to workplaces in New Zealand and through a teleconference held in August 2005. Over 200 professionals took part in the teleconference and 139 written submissions regarding speech-language therapy and the Act were received.

Of the 139 written submissions, 85 percent were members of NZSTA and 15 percent were not. The respondents represented a broad spectrum of work situations with most
being employed through a DHB or Group Special Education. The views expressed were in favour of regulation of the profession with 83 percent supporting the inclusion of speech-language therapy in the Act.

The primary concerns raised were with regard to cost and definition of scopes of practice. Cost of the annual practicing certificate was of particular concern for private practitioners; however there was general agreement that regulation was favourable (116 in favour of regulation, 12 against and 11 did not know). Definition of scopes of practice was a concern primarily because of the broad range of activities and fields in which a speech-language therapist can practice. For instance, a speech-language therapist may be employed primarily to work in the area of swallowing, while another may be employed to work in the area of stuttering or cleft-lip and palate. A second concern expressed is that someone who has practiced for many years in one area (e.g. child language) who wishes to practice in another area (e.g. swallowing disorders) may not be competent to do so because of lack of knowledge or experience. There were questions as to how this might be reflected on an annual practicing certificate.

Speech-language qualifications

There is general agreement in the profession that speech-language therapists are expected to have either a Bachelor's degree in Speech-Language Therapy or equivalent, or a Masters degree in Speech-Language Therapy or equivalent. It is generally agreed that a first degree (i.e., a Bachelor’s degree or equivalent) would take a minimum of 115 weeks of full-time study (or its equivalent part-time) preferably distributed over four years. A post-graduate qualification in speech-language therapy would be expected to take a minimum of 80 weeks full-time study (or its equivalent part-time) over at least two extended years. It is expected that individuals entering a post-graduate degree in speech-language therapy would have as a major in their first degree, an area of study that is related to speech-language therapy. Clinical requirements for all degree programmes are a maximum of 25 direct contact hours of supervised clinical observation and a minimum of 275 contact hours of direct clinical practice of which at least 25 percent must be supervised. The standards of academic and clinical education were developed from the IALP guidelines for initial education in logopedics (1995). In addition, a comparison of international qualifications indicated similarities across countries. For instance, the Royal College of Speech-Language Therapists (RCSLT) indicated that the Joint Accreditation Council for Professions Supplementary to Medicine follow the IALP (1995) guidelines.

The establishment of a Bachelor’s degree in Speech-Language Therapy was not in place in New Zealand until 1989. Prior to 1989, training was conducted at the Christchurch Teacher’s College and involved a combination of teacher training and training in speech-language therapy. NZSTA recognises training prior to 1989 as equivalent to a Bachelor’s degree in speech and language therapy.

Individuals who are applying from overseas to practise as a speech-language therapist must have their qualifications approved by NZSTA. The qualifications approval process involves examining the individual's transcripts and ensuring they meet minimum course and clinical requirements. In addition, individuals seeking membership to NZSTA must also show they were members in good standing of their national associations.
Standards and Competencies

It is expected that all speech-language therapists will demonstrate competency in paediatric speech and language therapy practice and adult speech and language therapy practice in the areas of speech, language, swallowing, voice, and fluency. Within those areas, speech-language therapists should demonstrate competency in: assessment, analysis and interpretation, planning and carrying out of speech and language therapy intervention, service delivery, and professional, group, and community education. In addition, all speech-language therapists have a responsibility for continuing professional development.

Standing and status of Profession and qualifications among service providers and education authorities

The qualifications, standards, and competencies outlined by NZSTA have been accepted by tertiary institutions and service providers such as DHBs and GSE. The three tertiary institutions in New Zealand: the University of Canterbury, University of Auckland, and Massey University, have all pursued and achieved accreditation. Employers such as DHBs and GSE state that their employees must be eligible to be members of NZSTA. Only individuals who have graduated from an accredited New Zealand programme or individuals who have their overseas qualifications approved are eligible to be members of NZSTA.
APPENDIX 2

Background material on clinical physiology

The following material has been provided by the Clinical Physiologists Registration Board (the Board). The Board represents the professions of cardiac, respiratory and sleep physiology. The Board represents approximately 220 clinical physiologists in New Zealand. The material includes:

- an occupational definition of clinical physiology
- evidence of the need for regulation, including evidence that the public is at risk of harm by the practice of clinical physiology
- evidence of general agreement on qualifications standards and competencies to practice clinical physiology in New Zealand.

The material is provided as background information for those wishing to make a submission and has been provided by the Clinical Physiologists Registration Board. The views expressed are those of the Board and, in providing the material, the Ministry of Health is not endorsing or confirming the contents.

It is important to note that, while the Board has developed policy on qualifications and other matters, these will not necessarily be the same as those put in place if the profession becomes regulated under the Act. Under the Act, decisions on scopes of practice, qualifications, and measures of competence will be entirely in the hands of the authority that is given responsibility for regulating the profession.
Definition of clinical physiology

Clinical physiology includes the following three groups:

- Cardiac physiology
- Respiratory physiology
- Sleep physiology.

Cardiac physiology

Cardiac physiology services are provided for the purpose of diagnostic assessment, intervention and treatment of patients with heart conditions. The services are also involved in the improvement of the lives of patients with heart problems and with the provision of services aimed at preventing and protecting patients from severe complications related to heart conditions.

Respiratory physiology

Respiratory physiology services are provided for the purpose of diagnostic assessment, intervention and treatment of patients with respiratory illness and respiratory-related conditions. The services are also involved in the education and long-term assessment and treatment of patients with chronic respiratory disorders.

Sleep physiology

Sleep physiology services are provided for the purpose of diagnostic assessment, intervention and treatment of patients with sleep-related breathing disorders. The services are also involved in the education and long-term assessment of patients with chronic sleep-related breathing disorders.
Evidence of the need for regulation, including evidence that the public is at risk of harm by the practice of clinical physiology

Risks posed to the public from the professional practice of the clinical physiologist are physical (ergonomic), drug related and mental. During the performance of their professional duties the clinical physiologist has the primary responsibility for the care, wellbeing, and health and safety of the public.

Cardiac physiology

Cardiac technologists are involved in the invasive and non-invasive assessment of the human heart in patients with suspected or known heart conditions.

Potential harm

Many patients attending the cardiac physiology department for diagnostic testing or intervention services are at high risk from potentially fatal cardiac events. Many of the procedures used by the clinical cardiac physiologist increase the risk of a cardiac event, which placed the patient at increased risk. It is the cardiac physiologist who takes responsibility for the health and safety of the patient during many of the cardiac diagnostic procedures performed.

During some procedures the cardiac physiologist monitors the patient’s ECG, blood pressure, oxygen saturation and cardiac pressures. In other procedures such as pacemaker implants, electrophysiology studies the clinical physiologist monitors the electrical activity in the heart. During these procedures it is imperative for the data collected (and often instantly interpreted) to be accurate. This requires the clinical cardiac physiologist to be competent in the calibration and troubleshooting of all equipment used. They have to be competent in the knowledge of limitations of equipment used. Misdiagnosis from poor data collection techniques or poor interpretation of data will have an immediate effect on the patient and the decisions made regarding choice of treatment. They also need to know when to refer to other health practitioners when a patient presents with a dangerous heart condition or poor clinical condition.

Significant potential risks include the following:

- Death – incorrect recognition of or data collected from a Holter monitor or an event recorder, failure to recognise and act on a patient in poor clinical condition during a device clinic, failure to recognise or act on data obtained from an implanted device during a device clinic, incorrect programming of a pacemaker or Internal Cardioverter Defibrillator.

- Cardiac arrest – failure to report or misdiagnosis of a dangerous heart rhythm or poor clinical condition during a procedure or test, incorrect pacemaker or Internal Cardioverter Defibrillator programming, failure to recognise that equipment is electrically safe to operate.

- Increased frequency of procedures, unnecessary procedures performed or inappropriate treatment or medication chosen due to substandard equipment calibration or failure to recognise adequate standard of data collection during all procedures and tests, inappropriate programming of a pacemaker or Internal Cardioverter Defibrillator.
Cardioverter Defibrillator, failure to recognise alternative programming options of a pacemaker or Internal Cardioverter Defibrillator.

- Severely compromised circulation could result in shortness of breath or recurrence of original symptoms such as dizziness or blackouts due to incorrect pacemaker programming.

**Evidence of harm**

A United States Food and Drug Administration (FDA) audit performed a few years ago identified that approximately 12 patients had died as a result of implanted cardiac devices being left disabled after surgery.\(^5\)

In New Zealand, deactivation and reactivation of these devices is the responsibility of the cardiac physiologist. Although there is no evidence that patients have died in New Zealand due to non-reactivation of their devices, there is anecdotal evidence in Australia and Wellington that there have been a number of incidents where patients’ cardiac devices have not been reactivated post surgery.

A study looking at a remote monitoring database showed a number of instances where devices were left disabled. The study was not directed to look at the outcome for patients.\(^6\) Again, it is the cardiac physiologist who is responsible for monitoring implantable cardiac devices.

**Specific instances of harm internationally include:**

- The technologist ignored or did not realise there was an increasing pacing threshold on a patient who was completely dependent on his pacemaker, this resulted in loss of capture and the patient died, this case was referred to the police as a manslaughter case.
- The senior chief technologist did not arrange the required follow-up checks for pacemaker patients resulting in undetected battery depletion, the technologist responsible was fired.
- A trainee acquired the 24 hour ECG recording from a patient on to the computer under another patient’s name, following analysis and reporting the incorrect patient had a pacemaker implanted unnecessarily.
- Several instances of a pacemaker being temporarily re-programmed to perform tests and not being re-set to the normal programme – resulted in breathing difficulties and / or symptoms of heart failure.
- A patient was given a rapid burst of ventricular pacing rather than the requested atrial burst pacing, as a result the patient required external defibrillation and resuscitation.
- The function of a region of the heart wall was not detected, resulting in the patient being inappropriately treated (by prescribed medication) for 24 hours.

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\(^5\) Hauser R G and Kallinen L Deaths associated with implantable cardioverter defibrillator failure and deactivation reported in the United States Food and Drug Administration manufacturer and user facility device experience database Heart Rhythm 2004 4 pages 399-405

\(^6\) Lazarus A Remote, wireless, ambulatory monitoring of implantable pacemakers, cardioverter defibrillators and cardiac resynchronization therapy systems: Analysis of a worldwide database Pace 2007 30 Suppl 1S2-S12
• A patient with aortic valve stenosis was reported by an echo scan as being moderately severe when it should have been severe, resulting in delayed surgery.

• Thrombus in the ventricle was not detected by echo and although there was no adverse effect in this case, there was the risk of stroke.

Respiratory physiology
Clinical respiratory physiologists (respiratory scientists) are involved in the non-invasive and invasive assessment of the human respiratory (lungs) and cardiopulmonary (heart and lungs) systems of patients with suspected or known respiratory and cardio-respiratory conditions.

Potential harm
Physical (ergonomic) – stress of performing spirometry, particularly for older people and those with significant respiratory impairment, can cause syncope, particularly with expiration lasting up to 15 seconds. In addition, many patients perform a range of exercise-based diagnostic tests ranging from simple six-minute walk tests to incremental cardiopulmonary exercise tests. The risk of physical injury from the performance of these tests range from low to very high. Sustainable injuries range from sprains and bruising to broken bones. There is also a significant risk of both respiratory and cardiac adverse events during these tests as the patient’s cardio-respiratory system is under stress. Bronchial challenge using eucapnic hyperventilation technique is a potent stimulant for inducing bronchial constriction leading to significantly reduced ability to breathe.

Drug-related – drugs are used by the respiratory physiologist for a range of diagnostic tests from bronchodilator therapy which risks adverse reaction (increased heart rate and occasional bronchoconstriction), to bronchial provocation testing where nebulised or dry powder preparations of drugs (methacholine, histamine, hyper-tonic saline, manitol) are used to induce a controlled airway bronchoconstriction in the suspected asthmatic patient. Airway bronchial challenge testing with these potent drugs carries the risk of severe airway obstruction. The respiratory physiologist must be able to recognise this condition and use appropriate bronchodilator therapy to reverse the airflow limitation. The need for injection of local anaesthetic and arterial puncture for blood gas sampling and testing can lead to adverse reactions such as lignocaine allergy, vaso-vagal response to needles, artery trauma and haemotoma.

Evidence of harm
Anecdotal drug therapy related incidents include:

• adverse reactions to Bricanyl – several incidents of adverse reactions to Bricanyl – resulting in patients being monitored in emergency department for up to two hours

• incidence of severe bronchospasm during bronchial challenge testing requiring medical intervention

• significant Bronchoconstriction leading to severe airflow limitation in a paediatric patient – paediatric team called.

Anecdotal evidence of vaso-vagal attacks and black-outs include:

• vaso-vagal responses from skin prick testing requiring patient to be monitored
• multiple instances of vaso-vagal reactions to arterial blood gas sampling
• a patient blacked out and sustained minor abrasions from convulsing and knocking himself on his wheelchair
• a patient felt light-headed during spirometry and fell forward in his wheelchair badly grazing his leg, caught by staff and prevented hitting his head on a table
• two episodes of patients collapsing in body plethysmograph (during diagnostic testing), both patients were unresponsive and were placed in the recovery position on the floor with supplemental oxygen therapy, cardiac arrest team called.

Anecdotal evidence of injury from an invasive procedure include:
• respiratory scientist did an invasive arterial blood sample and hit the radial nerve causing injury and pain that lasted several weeks, the patient made an ACC claim.

Reported evidence of cardiac events include:
• myocardial infarcts during and post routine testing – crash teams called and patients admitted for further care
• S-T segment depression during cardiopulmonary exercise testing
• hypertensive response to cardiopulmonary exercise testing
• vomic ECG changes during cardiopulmonary exercise testing.

In New Zealand there has recently been a case where the staff using a piece of equipment were not specifically trained in the test, and did not follow defined protocols for the calibration of the equipment or performance of the procedure. The equipment concerned is used to test respiratory function in a population of people who practice in high-risk environments (eg pilots, fire fighters, scuba divers).

International evidence includes similar events to those in New Zealand (as outlined above). Two events are noteworthy:

• United Kingdom – a patient undergoing a test to measure lung volumes using the technique of helium gas dilution was reported to have passed out and collapsed during the test. The collapse did not cause serious injury. The investigation of the event revealed that the person performing the test was unfamiliar with the technique where the patient is connected to a closed circuit and rebreathes on this circuit for up to ten minutes. During the test the patient’s exhaled carbon dioxide collects in the rebreathing system and oxygen is depleted. Oxygen is fed into the system at a controlled rate for patient safety and comfort. In the reported case the operator neglected to add oxygen to the circuit.
• United States – a puncture of the brachial artery to obtain a sample for blood-gas analysis resulted in damage to the median nerve with a persisting neuropathy and apparent loss of function. Errors of judgement and contributions to possible negligence included: 1) inappropriate choice of sampling site; 2) lack of knowledge of precautions and possible complications; 3) incomplete / inadequate description of
optimal procedure in department procedure manual; 4) arbitrary selection of the
dominant hand.  

**Sleep physiology**

Sleep technologists are involved in the collection of data for diagnosis and treatment of
sleep / wake disorders.

**Potential harm**

Data collection is required to be of a high technical standard and the ability to recognise
life-threatening events such as heart problems or a cessation of breathing is imperative.
The quality of data can also influence the final diagnosis which will most likely affect the
patient for the rest of their life and can have a significant effect on their ability to work /
drive. For example people diagnosed with Obstructive Sleep Apnoea (OSA) or
Narcolepsy are required to be on active treatment to be able to hold a commercial
drivers license. Misdiagnosis from poor data collection techniques or poor interpretation
of data could have significant life long effects on these patients as well as potential
deleterious effects in others (i.e. the general public) who come into contact with these
patients while driving vehicles, in their work or social environment. Finally inappropriate
or misuse of actual monitoring equipment may pose risks to patients in terms of
electrical safety.

One of the most common treatment devices for obstructive sleep apnoea syndrome (a
sleep breathing disorder) is nasal Continuous Positive Airway Pressure (CPAP).
Although CPAP is usually prescribed by a medical practitioner, it is often implemented
by a technologist. This device has a number of contraindications and can be potentially
life threatening if used in an incorrect manner. For example people administering the
device must be aware of the exhalation ports and valves and ensure that the patient is
aware that these are not to be blocked as doing so could result in the patient
suffocating. Patients who are haemodynamically unstable are not suitable for this
device as acute application could induce a reduction in the amount of blood the heart
pumps out, reducing blood pressure and resulting in a cardiac arrest. Those with
existing respiratory failure or insufficiency must be closely monitored during application
of the device due to possible worsening respiratory failure. It is contra-indicated in
those with perforated eardrums, pneumothorax and recent trauma or surgery, which
may have produced cranio-nasopharyngeal fistula – this could lead to air within the
cranial cavity.

**Evidence of harm**

- Type II respiratory failure following the discovery that the exhalation vent on an oro-
nasal mask had been blocked by hospital staff who thought the mask was leaking.
- Patient supplied with an autoCPAP through a commercial entity supplying CPAP
  services, when this device was contra-indicated for the patient.
- Unaccredited service without suitable staff management sent results of diagnostic
testing to patient without physician involvement 12 months after study, by which time

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7 Watson M E Median nerve damage from brachial artery puncture: A case report *Respir Care* 1995
40(11) pages 1141-1143
the patient had died – evidence of poor policy and procedure documentation, not following accreditation guidelines for reporting.

- CPAP services being set up by members of the public without any physiology or medical input – leading to inappropriate treatment options, also conflict of interest / ethical concerns as company profits from sale of CPAP devices to patients.

- Patient with Duchennes Muscular Dystrophy in ICU on a ventilator, exturbation and placed on Non-Invasive ventilation in Spontaneous mode. This is contra-indicated as it results in worsening respiratory failure.

- Commercial truck driver with severe OSA and on CPAP treatment, CPAP device broke, sought assistance from a health care provider was given a Hudson mask, which is incompatible with CPAP.

- GP failed to recognise skin breakdown and infection on bridge of nose could be caused by CPAP mask, prescribed oral antibiotics then placed on IV when face swollen and eyes swollen shut, patient eventually contacted a sleep lab – mask was changed and problem was resolved.

- Patient with known severe OSA was in Coronary Care Unit following a MI, patient audibly obstructing – CPAP had been left on the windowsill unused.

**Other than due to harm, is it in the public interest for clinical physiology to be regulated**

The clinical physiology professions apply their clinical knowledge and use advanced medical technology in the performance of their professional duties. The level and complexity of the medical technology used and its application in health care is key to the provision of successful and cost-effective diagnostic investigations. An in-depth knowledge of human physiology, technology and the uses and risks of the medical technology in relation to the well-being and health and safety of the public and patient are paramount if the clinical physiologist is to be able to practice safely.

The three professions believe it is in the public interest that the clinical physiology professions be regulated as there is evidence and multiple examples within New Zealand of persons with no qualifications and little or no training in the clinical physiology disciplines, no continuing professional development and no professional supervision performing diagnostic tests, interpreting results and providing patient information and education. These examples show that the public are at risk and do nothing to promote standards of performance, conduct or patient safety in environments where this is allowed to happen.

**Regulation of clinical physiology in other countries**

In the United Kingdom the Health Professions Council (HPC) has recognised the need for regulation of the clinical physiologist professions, including respiratory physiology and cardiac physiology and has recommended the professions for regulation to the Secretary of State for Health. Other clinical physiology professions recognised by the HPC as needing regulation are neurophysiology, audiology and gastrointestinal physiology.

In the United States of America professionals practicing in clinical respiratory physiology, clinical cardiac physiology and clinical sleep physiology are required to hold membership of appropriate professional societies, to pass certification and registration
examinations and to hold State Registration in the federal state in which the clinical physiologist wishes to practice.

In Australia (primarily in the federal states of ACT and NSW) there are discussions relating to the regulation of professionals employed in the fields of clinical cardiac physiology, clinical respiratory physiology and clinical sleep physiology.
Evidence of general agreement on qualifications standards and competencies to practice clinical physiology in New Zealand

Consultation and Feedback

The process of voluntary registration and the question of regulation of the professions of clinical physiology under the Act have been addressed to the professionals concerned via their professional societies.

The Australian and New Zealand Society of Respiratory Science (ANZSRS), Australian Sleep Technologists Association (ASTA) and Society of Cardiopulmonary Technologists (SCT) have been intimately involved in the process of developing voluntary registration, training, education and continuing professional development for the three professional groups. The societies, through their boards / councils, have been involved in the decision making and the formation of the Clinical Physiologists Registration Board to represent the three professions in their joint application for regulation under Act.

The New Zealand based membership of all three professions has been consulted and asked to comment on the documentation through their professional societies. The members of the three professions have also been consulted and asked to vote on the following:

1. Do you support the Clinical Physiologists Registration Board in its application to the Ministry of Health asking that the professions of cardiac, respiratory and sleep physiology and related professions be regulated under the Health Practitioners Competence Assurance Act 2003?
2. Do you support the Clinical Physiologists Registration Board as the registration board for purposes under the HPCA Act?

It was the decision of the membership and their respective professional societies that the Clinical Physiologists Registration Board go ahead with the application for proposed regulation of the professions under the Act.

Professional societies and numbers

The Society of Cardiopulmonary Technologists (SCT) is the primary professional society for cardiac physiologists and cardiac technology in New Zealand. In New Zealand there are 150 cardiac physiologists, cardiac technologists and cardiac technicians registered with the SCT. It is estimated that there may be as many as 50 non-registered people practicing in the field of clinical cardiac physiology in smaller centres and private institutions in New Zealand.

The Australian and New Zealand Society for Respiratory Science (ANZSRS) is the primary professional society for respiratory scientists (which include clinical respiratory physiologists) in New Zealand and Australia. Respiratory scientists who are currently practicing at the level of clinical respiratory physiologists are also eligible to be members of the Thoracic Society of Australia and New Zealand (TSANZ) and the Asia Pacific Society of Respirology (APSR). In New Zealand there are 40 professionals practicing in the field of respiratory physiology who are members of ANZSRS. There is uncertainty about the total number of people practising respiratory physiology throughout New Zealand as there is cross-over of other staff into the field.
The Australasian Sleep Technologists Association (ASTA) is the primary professional society for sleep technologists (which include clinical sleep physiologists). Those sleep physiologists who hold a degree and appropriate post graduate training may also be members of the Australasian Sleep Association. In New Zealand there are approximately 30 technicians / technologists working in the field of sleep medicine. The number is an approximate as in smaller centres some technologists will cover several roles including sleep.

**Standards and competencies**

In order to define standards of practice that are in line with international standards in the professional fields the Board, in partnership with the professional societies and with the assistance of the Health Professions Council (UK) and ACT Health (Australia), has developed the following:

- standards of conduct, performance and ethics
- general standards of proficiency
- requirements for continuing professional development.

These standards have been ratified by the professional societies and accepted by the Board as minimum practice standards for all professionals registered with the Board.

The competencies required by the clinical cardiac, respiratory and sleep physiologist are clearly defined and documented, and are directly linked into the educational requirements and on-the-job training for each of the professional fields. The competencies have been developed in partnership with the professional societies and with the assistance of the Association of Clinical Scientists (UK). The competency documents set out the minimum requirements for professional registration under a scope of practice, and also for on-going professional development. Each of the competencies is also linked back to the general standards of proficiency ensuring that competency to practice is measured with proficiency to practice.

Clinical physiology recognises the primacy of the patient in all patient / professional health care encounters, and recognises the ‘need to listen to the patient, communicate with the patient, protect the patient, offer the patient the best healthcare within resources, and bravely confront colleagues if standards slip…’ (Judge Cartwright). The standard of conduct, performance and ethics document was developed in partnership with the professional societies and with the assistance of the Health Professions Council (UK) to provide a minimum standard for clinical physiologists.

**Qualifications**

The three professions represented under this proposal for regulation all have stated entry level education requirements, training and educational requirements for practitioners working as either physiologists or technicians. The table below sets out the required qualifications.
<table>
<thead>
<tr>
<th>Scope of Practice</th>
<th>Qualification / Certification</th>
<th>Work Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac physiologist</td>
<td>Completion of Post Graduate Diploma in Cardiac Technology, and SCT certification of cardiac physiologists programme or Qualifications and experience assessed by the board as equivalent SCT membership</td>
<td>Minimum of 2 years relevant full-time work experience in a recognised training establishment</td>
</tr>
<tr>
<td>Respiratory physiologist</td>
<td>Completion of recognised tertiary qualification in respiratory science ANZSRS certification / registration examination ANZSRS membership</td>
<td>Minimum of 2 years relevant full-time work experience in an accredited training establishment</td>
</tr>
<tr>
<td>Sleep physiologist</td>
<td>Completion of recognised tertiary qualification in sleep science Certification / registration examination (BRPT or other) ASTA membership</td>
<td>Minimum of 2 years relevant full-time work experience in a recognised training establishment</td>
</tr>
<tr>
<td>Provisional cardiac physiologist</td>
<td>Bachelor Degree in Science Studying towards Post Graduate Diploma in Cardiac Technology, as provided by an accredited education provider in NZ SCT membership</td>
<td>Enrolled in the certification of cardiac physiologists programme</td>
</tr>
<tr>
<td>Provisional respiratory physiologist</td>
<td>Bachelor Degree in Science Studying for a recognised Post Graduate level qualification in respiratory science ANZSRS membership</td>
<td>Employed as a trainee respiratory physiologist following recognised on-the-job training</td>
</tr>
<tr>
<td>Provisional sleep physiologist</td>
<td>Bachelor Degree in Science Studying for a recognised tertiary level qualification in sleep science ASTA membership</td>
<td>Employed as a trainee sleep physiologist following recognised on-the-job training</td>
</tr>
</tbody>
</table>
Overseas qualifications

Overseas qualifications and experience will be assessed against the standard set for the clinical physiology specialty scope of practice applied for.

Overseas applicants who hold current registration and a practicing certificate from a recognised overseas registration board will be offered registration in New Zealand and an equivalent scope of practice. Where there is any question as to qualifications or competence to practice, limitations to the scope of practice and the requirement for supervision will be considered where appropriate.

Status of the Professions

The status of the professions has been acknowledged by educational institutions in New Zealand, Australia, the United Kingdom, Canada and the United States of America. In all of these countries the education of the clinical physiologists is provided for through university level education at either Baccalaureate or postgraduate level depending on the educational status of the clinical physiology candidate.

For cardiac and sleep physiology the education is provided for at postgraduate level through Otago University Medical School, Wellington.

For respiratory physiology the education is provided for through the Charles Sturt University (AUS) postgraduate and undergraduate courses in respiratory science and Griffith University (AUS) postgraduate courses in Clinical Physiology. And Monash University, Melbourne, Biotechnology.

Paediatric respiratory physiology education is provided for through the Graduate Certificate in Paediatric Respiratory Science, University of Western Australia.

The qualifications for clinical physiology have been recognised by the following District Health Boards during the APEX national collective agreement negotiations for cardiopulmonary technologists, scientists and technicians agreed in 2006: Auckland DHB, Counties Manakau DHB, Waikato DHB, Hutt Valley DHB, Midcentral DHB, Capital and Coast DHB, Nelson Marlborough DHB, Canterbury DHB, Otago DHB and Southland DHB.
Appendix 3

New Professions under the Health Practitioners Competence Assurance Act 2003:

Criteria for Assessing Applications for Inclusion in the Act

Introduction

At the time of its enactment, the Health Practitioners Competence Assurance Act 2003 applied to 15 registration authorities. At the same time, the Act contained provisions enabling the scope of the Act to be extended to cover other practitioners and professions that provide health services. Section 115 of the Act enables the Governor-General, on the advice of the Minister of Health, to designate health services of a particular kind as a health profession under the Act.

Criteria for regulation

Purpose of Act Paramount

Any application to come within the Act must show consistency with the purpose of the Act; the principal purpose of which is to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions (s 3(1)).

Implicit in the Act is the protection of the public interest through ensuring that the public can readily find out what services a health practitioner is competent and entitled to provide. This will enable the public to know what health services can be expected from their chosen practitioner, and to know that that practitioner is competent and safe. The concept of providing the public with clear information on the nature of a profession, and the scope of practice and competencies of its practitioners, is reflected in the requirements set out below.

The development of these steps is also guided by the policy framework for regulating occupations. The framework (Cabinet Office Circular No (99) 6) includes that:

- intervention by the government in occupations should generally be used only when there is a problem or potential problem that is either unlikely to be solved in any other way or inefficient or ineffective to solve in any other way;
- the level of intervention should be the minimum to solve the problem;
- the benefits of intervening must exceed the costs.

The following process and evidence requirements under the Act help ensure compliance with this framework.
Section 116 of the Act

Section 116 of the Act requires that, before recommending a health service be regulated as a health profession, the Minister of Health be satisfied that the health service poses a risk of harm to the public or that it is in the public interest that the health service be regulated.

The Minister must also be satisfied that the providers of health services are generally agreed on the:
- qualifications for any class of providers of those health services
- standards that any class of service providers are expected to meet
- the competencies for scopes of practice for those health services.

Section 116 of the Act also requires that the Minister of Health consult with any organisation that, in the Minister’s opinion, has an interest in the recommendations. The relevant text of section 116 follows:

Evidence of need to regulate

Applications must establish the following elements.

1. The application relates to the provision of a health service as defined by the Act. That is: “a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals”.

2. The profession must be identifiable.
   - What is the nature of the activities undertaken by members of that profession?
   - How many practitioners are participating in the profession?
   - Are there any current professional organisations to which members of the profession belong or are eligible to join?
   - Does the public see the members of the profession as an identifiable group?
   - Evidence provided by the profession should state how the profession considers itself different from other professions which practice in similar areas (i.e. identifying what the profession does that is not within the training and/or competence of another profession)

3. There is evidence of need for regulation. Provide evidence that goes to the purpose of the Act. Specifically, applications should identify:
   - the nature, frequency and severity of the potential risk to the public
   - the likelihood of the risk occurring
   - the nature, frequency and severity of the harm to, or the consequences for, the public
   - whether there are existing public safety concerns resulting from the activities of unregulated practitioners
   - whether it is otherwise in the public interest to regulate the profession and why.
In addressing the risk of harm in this context you should endeavour to identify that risk which is associated with the practice of the proposed profession, as distinct from risks inherent in the area of health care within which the profession operates.

Supporting evidence should identify if the profession is regulated overseas, and what risks (especially those to the public) have been identified in overseas experience or studies.

The profession must be generally agreed on the need for regulation.

The application must include a list of the organisations and individuals consulted on the regulation of this health service together with a summary of issues and concerns raised, agreements reached and any other matters.

**Evidence of general agreement on qualifications, standards and competencies**

1. Identify how the profession has been consulted on the application and what views were expressed. [NB: the Ministry will then be able to use this information during the decision-making process as well as background for further discussions]

2. Identify what qualifications are generally held by members of the profession and the degree of uniformity in qualifications across members.

3. Identify what sorts of courses or training are currently offered for members of the profession.

4. List the agreed qualifications, standards and competencies expected of practitioners once regulated. [NB in assessing the list of qualifications expected of providers the Minister will be guided by the requirements in section 11 and 12 of the Act. These sections are contained in the Appendices to this Protocol].

5. Provide evidence of how the qualifications, standards and competencies expected of practitioners reduce the public’s risk of harm or help achieve the public interest.

6. Provide evidence of general agreement among the profession or representatives of the profession on the qualifications, standards and competencies expected of health practitioners of that profession.

7. Identify the relationship between the generally agreed qualifications, standards and competencies of the profession proposed to be regulated, and the current scope(s) of practice of existing responsible registration authorities. Where possible this analysis should specify the similarities and differences in the qualifications, standards and competencies; at what educational level; whether at an accredited institution; and whether continuing competency is a requirement of the profession (with details of the programmes and auditing processes).

8. Identify if service providers (such as District Health Boards) and the New Zealand Quality Authority/universities accord any standing or status to the profession and the qualifications.
The Ministry of Health will advise the Minister of Health on decisions to be taken on any applications received. This will require the Ministry to independently assess whether the public is at risk of harm or whether it would be in the interest of the public to regulate the health service.

This will involve:

1. reviewing the evidence provided in the application (including undertaking separate investigation into overseas experience and evidence);
2. consulting internally, drawing on available Ministry clinical expertise and if necessary, engaging independent clinical advisors to advise the Ministry;
3. consulting with any organisation that, in the Minister’s opinion has an interest in the recommendations. This may include consulting with DHBs, registration authorities and individuals or organisations within the practitioner group.

**New authority or addition of profession to existing authority?**

The starting premise when it comes to this decision is whether an existing authority agrees with the proposal or not and, if it does not, whether there is an overwhelming reason to override that authority.

To assist in this decision, applicants may be required to provide further information. This may include the following factors.

- Estimated establishment costs.
- Estimated ongoing costs – including estimated compliance costs for service providers, employers and self-employed practitioners.
- Evidence that the benefits of regulation under the Act exceed the costs.
- Whether there are any similarities with scopes of practice, qualifications, training and competencies of other registered practitioners.
- Whether the proposed new profession works closely with, or maintains close professional links with, any current authority.
- Whether the proposed new profession wishes to establish a new authority or to form part of a current authority.
- If it wishes to form part of a current authority, what the current authority thinks about the proposal and what expectations there are, if any, over representation of the proposed profession on the current authority.
- If a blended authority is suggested, is a name change required.

If a decision is taken to recommend that the health services in the application be designated as a health profession, a separate decision will be required on whether to create a new authority or to add that profession to the ambit of an existing authority.

The Ministry will:

1. consider the information provided by the applicant on the establishment of a new authority or the joining with an existing authority
2. if a blended authority is going to be considered, arrange a discussion between the Ministry, the new profession and the existing authority to talk through issues (including whether the proposed new profession should be represented on the authority)

3. if agreement is reached, go ahead with the rest of the process

4. if agreement is not reached, look at why not and see if any of those issues can be dealt with.

**Appointment of Authority and Requirement to Register**

The Minister, if satisfied that the requirements of the Act are met, will give effect to any decisions by recommending to the Governor-General an Order in Council. Any such Order in Council will prescribe the date that the decisions come into effect. It is likely that that date will take into account the time required to appoint authority members. Board members are appointed by the Minister. The appointment process (which includes calling for nominations) can take some months.

The new authority (or any existing authority to which a profession has been added) will be required by the Act to gazette the necessary scopes of practice for that profession. Once that is done, practitioners undertaking the services described in the scopes of practice will be required to be registered with that authority.

**Role of registration authorities under the Act**

**Health Practitioners Competence Assurance Act 2003 - Sections 11 and 12**

**11 Authorities must specify Scopes of Practice**

(1) Each authority appointed in respect of a profession must, by notice published in the Gazette, describe the contents of the profession in terms of 1 or more scopes of practice.

(2) A scope of practice may be described in any way the authority thinks fit, including, without limitation, in any 1 or more of the following ways:

(a) by reference to a name or form of words that is commonly understood by persons who work in the health sector:

(b) by reference to an area of science or learning:

(c) by reference to tasks commonly performed:

(d) by reference to illnesses or conditions to be diagnosed, treated, or managed.

**12 Qualifications must be prescribed**

(1) Each authority must, by notice published in the Gazette, prescribe the qualification or qualifications for every scope of practice that the authority describes under section 11.

(2) In prescribing qualifications under subsection (1), an authority may designate 1 or more of the following as qualifications for any scope of practice that the authority describes under section 11:

(a) a degree or diploma of a stated kind from an educational institution accredited by the authority, whether in New
Zealand or abroad, or an educational institution of a stated class, whether in New Zealand or abroad:

(b) the successful completion of a degree, course of studies, or programme accredited by the authority:

(c) a pass in a specified examination or any other assessment set by the authority or by another organisation approved by the authority:

(d) registration with an overseas organisation that performs functions that correspond wholly or partly to those performed by the authority:

(e) experience in the provision of health services of a particular kind, including, without limitation, the provision of such services at a nominated institution or class of institution, or under the supervision or oversight of a nominated health practitioner or class of health practitioner.

(3) A notice under subsection (1) may state that 1 or more qualifications or experience of 1 or more kinds, or both, is required for each scope of practice that the authority describes under section 11.

(4) An authority must monitor every New Zealand educational institution that it accredits for the purpose of subsection (2)(a), and may monitor any overseas educational institution that it accredits for that purpose.