

**Response to Questions posed to NZAS by Karoline Tuckey
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How is the standard of audiological care in New Zealand regulated?

Audiology in New Zealand is not currently a registered health profession, consequently there is no “name protection” for qualified audiologists, and anyone can call themselves an Audiologist. It is important to distinguish between Audiologists and Audiometrists who are members of the New Zealand Audiological Society (NZAS) and people who refer to themselves as audiologists or audiometrists but who are not members of the NZAS.

The NZAS is a self-regulating body which governs the professional activities of its membership. Rules govern training (including qualification requirements and on-going training), scope of practice, standards of practice and ethics. Therefore, the standards of care for audiometrists and audiologists who are members of the NZAS are regulated by the NZAS, but there are no standards controlling the behaviour of non-members.

The NZAS operates an independent Complaints Board which is responsible for hearing complaints about NZAS Members in relation to any aspect of their professional behaviour. The NZAS complaints process and code of ethics can be accessed via the NZ Audiological Society Website (www.audiology.org.nz).

The NZAS has proposed a quality system to the ACC, Veterans Affairs and the Ministry of Health (MoH) to ensure consistent standards for services provided to their clients. Since the system applies to each service provider, the quality system should ensure quality for all clients. This issue has been discussed for a number of years but to date the NZAS quality audit system has not been adopted by any Government Agency.

Consumer Guarantees Act 1993

Hearing aids are covered by the definition of “goods” in the Consumer Guarantees Act 1993. That Act requires suppliers of goods to ensure the goods they supply are safe and fit for purpose. When an audiologist is directly supplying them to the consumer, the audiologist (or their company) would be the one giving the guarantee of the device’s safety, and that they are fit for purpose. Recourse for an unsafe device would be against the audiologist (or their company).

Moreover, audiologists are considered a supplier under the Act. Audiologists guarantee that their services will be carried out with reasonable care and skill. This aspect of the Act focuses on the services only rather than the hearing aid itself. Recourse for services undertaken without reasonable care and skill would be taken against the audiologist.

The Medicines Act 1981

Guidance and standards as envisaged by the Medicines Act 1981 have not been prescribed, leaving an unregulated market for hearing aids. This means they can be sold by non-regulated persons or online on sites such as TradeMe.

Is there any requirement that a person carrying out a hearing assessment or fitting hearing aids should have a particular qualification or professional registration?

In general no, but the ACC and the Ministry of Health have regulations or legislation which ensures that in some cases work must be carried out by appropriately qualified members of the NZAS.

The ACC requires that only full members of the NZAS (with a current certificate of clinical competence) can carry out hearing services for the ACC. The Ministry of Health, under the Hearing Aid Services Notice 2011 also requires that a full member of the NZAS must provide services (or supervise appropriately qualified members in other membership categories) to people who receive funding from the MoH.

Further the NZAS Code of Ethics requires that Audiologists who are members of the NZAS who delegate work to others, delegate work only to people who are appropriately qualified to carry out that work.

Is there any requirement that someone providing hearing assessments and fitting and dispensing hearing aids be acting in the capacity of a trusted health professional, with the patient/client's interests foremost, rather than a salesperson with financial ties to particular brands?

It is important to distinguish between audiologists and audiometrists who are members of the New Zealand Audiological Society (NZAS) and people who refer to themselves as audiologists or audiometrists but who are not members of the NZAS.

The behaviour of NZAS Members is governed by the NZAS Code of Ethics (COE). Principle four of the COE specifically requires that the all members of the NZAS act independently of commercial pressures. Principal one requires that members hold paramount the interests, and rights of their patients.

A recent amendment to the MOH Section 88 Notice requires the audiology practitioner to tell the patient of any ties to manufacturers, including preferred supplier schemes. In addition, the ACC requires that an audiologist declares (on the ACC 611 form which is filled in for every satisfactory hearing aid fitting) that they "don't work for a hearing aid manufacturer".

There are, however, no corresponding ethical or regulatory requirements governing the behaviour of people who are not members of the NZAS but who sell hearing aids.

Do you think there is confusion for consumers about the roles of people and organisations who supply hearing aids in NZ?

Yes. The public are aware that hearing tests are medical tests and that hearing aids are specialty devices and not general consumer electronics. The public therefore expect that all people who assess hearing, or prescribe, fit and sell hearing aids are suitably trained and accountable - just as pharmacists and opticians are. Most people are completely unaware that someone can adopt a title (such as Audiologist) and provide these services while being completely untrained, unprincipled and essentially unaccountable.

There may be also confusion about the differences between an Audiologist (at least 5 years of University, followed by clinical exams to gain their Certificate of Clinical Competency), and an Audiometrist. The audiologist's scope of practice is broader than hearing aid related activities or basic testing hearing; and includes diagnostic skills and expertise, hearing rehabilitation, tinnitus treatment and counselling, knowledge of paediatric care and other areas such as auditory processing disorders and vestibular disorders.

Do you think this is purposely propagated? (I.E, salespeople/stores presenting themselves in a way that customers could associate with health professionals)?

Yes, by some people. A small number of people selling hearing aids refer to themselves using titles that create a false or misleading impression of their skills, or qualifications. In other cases people with lower levels of training or qualifications use titles applicable to people with more training. We presume that this is done to enhance the person's perceived ability and status as a hearing health professional. People who use this technique to mislead their customers may be subject to prosecution under the Fair Trading Act or other consumer protection laws.

If someone is issued hearing aids they don't need, or that are not set up correctly for them, could these do damage?

People seldom pay for or wear hearing aids that they don't need or that don't benefit them.

In a June 2015 survey undertaken by ACC, 47% of respondents reported using their aids more than 8 hours a day, a further 27% reported they used their aids for between 4 and 8 hours a day and 19% between one and four hours a day. Just 4% reported using their aids for less than one hour per day.

This same survey showed that 86% of clients were satisfied or very satisfied with their new hearing aids. While 5% were dissatisfied.

The ACC quoted from claimants they interviewed one of whom said: *"the hearing aids have made a huge difference in my life. Before I had them, I was always embarrassed by the number of times I asked people to repeat themselves. Now, that rarely happens."*

If someone suspects they have a hearing loss or a hearing problem, which agencies or service providers do you recommend they approach about this?

We recommend that anyone who is worried about their hearing goes to see a member of the New Zealand Audiological Society. There is a list of practicing audiologists on the NZAS website under "Find your nearest MNZAS audiologist".

The public can also see their GP who can refer them to an Audiologist (private or public system) or an ENT surgeon. A hearing therapist or The Hearing Association can also help with listening advice/screening tests and can also refer on to an Audiologist.

Is there any indication of how much New Zealanders spend on hearing aids, or the proportion that are bought through qualified and registered audiologists? (I'm guessing that with an aging proportion of Kiwis this is big business).

The New Zealand Audiological Society does not track how much New Zealanders spend on hearing aids, nor the proportion that are bought through qualified Audiologists.

The Hearing Instruments and Manufacturers Association collect some statistics about wholesale sales, however not all manufacturers in New Zealand participate, thus their data is limited. Through their data it is estimated that approximately 50,000 hearing instruments are sold in New Zealand annually.

The ACC and the Ministry of Health should be able to provide you with some data about the number of hearing instruments that each of them subsidize, and the amount that they contribute towards the cost. In the June 2015 survey, ACC asked claimants how much they paid for new aids. Responses included: 32% said nothing was left to pay, 13% paid less than \$1,000 and 19% less than \$2,000. The amount to pay will reflect the level of technology sought by the claimant.

Has the Society made any moves to raise concerns about the hearing aid industry being unrestricted with the Ministry of Health, the Minister or any other body?

Are you aware of any moves to consider introducing restrictions?

The NZAS has worked with the MoH and the ACC to introduce and monitor standards for many years. The ACC has adopted regulations that require work to be carried out in suitable test rooms and the ACC legislation also restricts who may provide hearing services. The MoH, through the Section 88 Notice imposes a number of conditions on who can provide services to people receiving MoH funding.

The NZAS has investigated and discussed with the MoH how the public can be protected from unqualified people providing hearing health services including restricting who can sell hearing aids. The NZAS believes that such a restriction will not only protect people from untrained and/or unscrupulous salespeople, but will also ensure that only qualified people offer hearing testing services. At present it appears that the best avenue for this is to use the fact that hearing aids are registered medical devices and their supply can be controlled by the Minister of Health.

Referenced:

The "Section 88 Notice" is the Hearing Aid Services Notice 2011 issued by the Crown, pursuant to section 88 of the New Zealand Public Health and Disability Act 2000.

The New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), in its Regulatory Information, defines hearing aids as "Medical Devices" as they are in the category of devices that prevent or interfere with a physiological function and as a therapeutic purposes is claimed for the

device. Furthermore, hearing aids are defined as Therapeutic Products in the Therapeutic Products Advertising Code (Advertising Standards Authority) as they meet the definition of A6. (a) (iv) being a product falling within a class of products the sole or principal use of which is a therapeutic use.

The Medicines Act 1981 could be amended to make hearing aids “restricted devices” in the same way some medicines are classified as “restricted medicines”. This would require an amendment to the Medicines Act 1981 itself and consideration of which types of clinicians should be able to provide and fit hearing aids. The Act could state that restricted devices must be fit by a person described in regulations or by Order in Council. The regulations or Order in Council could then require the clinician to be a full member of the NZAS or other such body as appropriate. Changes such as this have the added benefit of not only controlling the sale and supply of hearing aids but also regulating the profession.



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