

Epilepsy Waikato Charitable Trust (EWCT)

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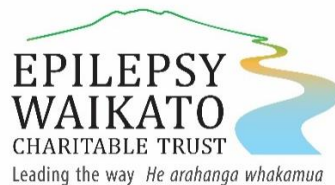
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29 July 2023

N.B. EWCT is a stand-alone charitable trust not associated with Epilepsy New Zealand



RE: Petition by Maria Lowe on behalf of the Epilepsy Waikato Charitable Trust (EWCT) and our request to fully fund the vagal nerve stimulator (VNS) for adults with intractable, medication-resistant epilepsy as an adjunct therapy

To the Select Health Committee

Thank you for considering our petition and reading why the vagus nerve stimulator (VNS) could be an important treatment tool for all New Zealanders who have no seizure control with conventional medications. At least 30% of people living with epilepsy have no seizure control with conventional medications (references 1–3). The vagus nerve stimulator has been proven overseas to provide relief for most of those living with partial-onset and generalised seizures. To date, the VNS is an established treatment option overseas but it is not readily available for adults living with intractable epilepsy in Aotearoa New Zealand, hence the urgency of this petition.

We begin with a short introduction to the VNS and what it is and can do for our most burdened by this debilitating condition. We will then outline the costs of implementing the VNS here in Aotearoa New Zealand, iterating the support from fellow epilepsy professionals in Australia who have helped our organisation in recent years.

Epilepsy affects at least 50,000 New Zealanders (ref. 1). Most people have seizures that are well controlled by conventional anti-seizure medications but, unfortunately, approximately 30% of people are deemed to have intractable epilepsy and have no seizure control whilst using them (refs. 2, 3). Despite advances in medical and surgical therapies over the past two decades, and with more than 15 new anti-seizure medications being available, poorly controlled seizures continue to be a significant health problem and burden for those who have intractable epilepsy.

The Epilepsy Waikato Charitable Trust (EWCT) therefore proposes that the vagal nerve stimulator (VNS) be available as an adjunct therapy to those adults who have tried at least two anti-seizure medications to control seizures, but which have failed. Although the VNS will not cure epilepsy, it will reduce the number, length and severity of seizures and improve the mood in most people. It is a safe and effective treatment for focal and generalized seizures in both children and adults (ref. 4).

Always at the forefront of our role as a charitable trust is our concern for the wellbeing of New Zealanders facing the challenges of having epilepsy. EWCT aims to provide information, advice, and support to individuals with epilepsy, and their families, friends, and work mates, to enable them to improve their physical, physiological, and psychological well-being, and also to promote a better understanding of epilepsy in the wider community (see www.ewct.org.nz). Even though our organisation is based in and largely works with clients in the Waikato region, EWCT has been involved with several previous significant national petitions or commentaries over the past five years. These include (a) the use of the ketogenic diet to help people with intractable epilepsy (<https://ewct.org.nz/ewct-keto-diet-petition/>), (b) the Accessibility Bill for New Zealanders (<https://ewct.org.nz/submission-to-parliament-for-the-accessibility-bill/>), and (c) speaking out in response to the ill-considered lamotrigine–logem medicinal switch (<https://ewct.org.nz/lamotrogine-funding-switch-our-response-to-the-change/>) that had a profound effect on 10,000 New Zealanders.

What is the vagus nerve stimulator (VNS)?

The VNS is a small device that is implanted under the skin in the chest and is connected to the left vagus nerve in the neck (Fig. 1) (refs. 5, 6). VNS delivers mild pulses (doses) to the brain through the left vagus nerve to help prevent seizures before they start and help stop them if they do occur. The basic components of the dose are the output current (intensity or charge), pulse width (length of pulse measured in microseconds), and the signal frequency (hertz, number of pulses per second). The “duty cycle” looks at the frequency of the dose, i.e., percentage of the time is the device on/active.

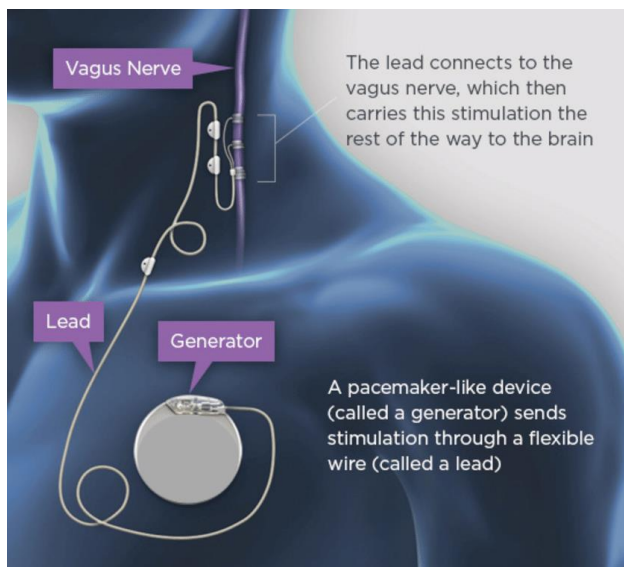


Figure 1. An illustration showing the various parts of the VNS and how it sits on the body. Image: Epilepsy Society (UK) (ref. 5).

A VNS implant is a one-and-a-half-hour operation and is performed by a neurosurgeon. The cost of the full VNS unit (as at 10 May 2023) is \$30,103; that of a replacement unit is \$25,458 (Appendices 1 & 2). These costs do not include the medical costs associated with the implantation. As with all treatments there can be side effects with a VNS implant. These can include voice changes (for example, hoarseness), throat pain, coughing, headaches, shortness of breath, difficulty swallowing, a tingling or prickling of the skin, insomnia, and potentially a worsening of sleep apnoea.

For most people, however, the side effects are tolerable given the alternative. The side effects may lessen over time, but some may remain bothersome for as long as implanted vagus nerve stimulation is used by the client. Adjusting the electrical impulses (doses) can help minimize these effects. If side effects do become intolerable, the device can be shut off temporarily or permanently and removed with no lasting consequences for the client.

The vagus nerve patient magnet

A temporary increase in the amount of electrical stimulation can be made by sweeping a patient magnet over the generator (Fig. 2). In some instances, this sweep can prevent a seizure if a person feels one coming on, or it can stop a seizure that is already happening. Applying an extra dose of stimulation in this way may (a) stop the seizure, (b) shorten the seizure, (c) decrease the intensity of the seizure, and (d) shorten the recovery period following the seizure.

The magnet is swiped downwards slowly from the left shoulder blade across the VNS implant for up to 3 seconds (Fig. 2). The magnet can be used again after 1 minute if the seizure has not stopped. Using the magnet more than once will not harm the patient or the generator.



Figure 2. Using the patient magnet. Image: Liva Nova (ref. 7)

Development and efficacy of VNS

The VNS was developed 30 years ago and was approved as a treatment option in the mid-1990s in the USA, Europe, Canada, and Australia. It is an adjunct therapy used alongside anti-seizure medications and it has been deemed safe for long term use. In close dialogue with our Australian counterparts, they have generously shared with us their knowledge of the VNS and how it has been received in Australia since its implementation as a nationally recognised treatment.

According to Australian-based studies (ref. 8):

- a) More than 65% of people have experienced a reduction in seizures by 55%, and it shortens recovery time
- b) A total of 73.7% of people said that the VNS was beneficial
- c) Nearly 15% of people have become seizure-free
- d) A total of 88% of people have retained long-term therapy
- e) The device lasts between 7 to 9 years
- f) The VNS is well tolerated and with most reported adverse effects improving over time
- g) The device has reduced the prevalence of SUDEP (Sudden Unexpected Death by Epilepsy)
- h) It has improved the mood and memory of those living with intractable epilepsy. (Depression is a frequently encountered co-morbidity and, according to a recent report from Denmark (ref. 9), people with epilepsy have triple the risk of an attempted suicide and at least double the risk of death by suicide, compared with the risks of the general population.)

Research findings from Norway (ref. 10) and the USA (refs. 11, 12) have reiterated the benefits of the VNS on adults and children and showed that:

- a) Patients with focal or temporal lobe epilepsy experienced the most robust response at 68.9%
- b) Those with multi-focal and generalised seizures had a 56.2% reduction in seizures
- c) There is a significant reduction in seizures in all groups by 60% with many experiencing a 50% reduction in seizures
- d) Patients without intellectual ability had a higher chance of achieving 75% or more seizure reduction or seizure freedom
- e) There is no significant difference between the efficacy of the VNS between children and adults.

When the VNS was compared with the ketogenic diet as a treatment option for intractable epilepsy, the VNS was seen as being more cost effective after two years (ref. 13). However, the quality of life for those living with intractable epilepsy needs to be factored into the economic equation. Currently the status quo of re-jigging already trialled anti-seizure medications to control seizures is not working and approximately 15,000 New Zealanders at least are living with a significant epilepsy burden [i.e., 30% of ~50,000 people].

Mitigating the burden of intractable epilepsy internationally *cf.* lack of support in Aotearoa New Zealand

In 2015, Aotearoa New Zealand signed a resolution of the World Health Organisation which was aimed at ensuring that people living with epilepsy would experience improved social and health outcomes free from stigma and discrimination (ref. 14). By 2020, at least 80% of those countries that signed the resolution were also improving legislation with a view of promoting and protecting the human rights of people with epilepsy.

New Zealanders living with epilepsy are not only affected by the condition itself, but also are subject to other risks in our society. The World Health Organisation compiled a list of risks for those living with epilepsy (ref. 15), all of which our organisation has dealt with since EWCT became established as a charitable trust in the Waikato in 2011 (e.g., see ref. 1). This list includes:

- a) Injury, drowning or suffering from burns as a result of seizures
- b) Road traffic accidents
- c) Hospitalisation for seizures or status epilepticus

- d) Sudden unexpected death (SUDEP) (~60 people die annually in Aotearoa New Zealand from SUDEP: ref. 16)
- e) Depression, suicide and other mental health conditions
- f) Neurological, cardiovascular and respiratory disorders
- g) Socio-economic marginalization, which affects professional status and personal relationships
- h) Being victims of sexual violence and abuse
- i) Food insecurity and malnutrition

Clients also face reduced prospects of:

- a) Completing schooling and accessing higher education
- b) Marrying or sustaining relationships
- c) Securing employment
- d) Obtaining a driving licence

By its own admission, the New Zealand Ministry of Health's "Epilepsy Consumer Survey 2018" (ref. 16) recognised that 'Epilepsy is a hidden burden with a low profile in the health system. It does not feature in long-term conditions or burden of disease reporting, and many people including health professionals have little to no understanding of how epilepsy affects people.' In 2019, the Ministry of Health recognised three treatment options (medications, brain surgery, and the ketogenic diet) but it did not recognise the VNS despite it being widely used in Australia and beyond (ref. 16). This seems a deliberate omission in treatment option availability in Aotearoa New Zealand when for the past 30 years there has been ongoing research (e.g., refs. 9, 10) looking into ways in which to improve the quality of life for those living with epilepsy. Moreover, in its draft report (ref. 14), the Ministry of Health stated (p. 34), "Given the proven benefit in around 60 percent of cases, it is recommended that the Auckland epilepsy centre consider requirements to develop the capability to provide this treatment [VNS] over the next five years". This recommendation, unfortunately, is missing from the final report (ref. 16). Why?

The economic burden of epilepsy in Aotearoa New Zealand has not been measured but a very detailed economic study by Deloitte's in Australia 2019-2020 (ref. 17) estimated that the cost to that nation of people living with active epilepsy is \$12.3 billion/year. Using that figure, the estimated cost in Aotearoa New Zealand pro rata would therefore be about \$4.14 billion/year. The Deloitte study (ref. 17) looked at (a) the medical costs of epilepsy, e.g., hospital costs (pathology and imaging) and medication; (b) financial costs to the individual carer and society as a whole in productivity losses (absenteeism and premature mortality), transport, welfare costs, deadweight loss of taxation; and (c) the burden of epilepsy itself.

Thank you for considering our proposal. We look forward to hearing from you.

Maria Lowe

Epilepsy advisor on behalf of EWCT Trust Board

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