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MONASH HEALTHCARE INNOVATION SUMMER SCHOLARSHIPS

Project NEMO



Monash Partners
Academic Health Science Centre



**MONASH
YOUNG
MEDTECH
INNOVATORS**

Current Team:
Clinical Champion:
Affiliations

Executive Summary

Nerve conduction studies are an extension of the clinical examination used to assist in the diagnosis and staging of medical disease¹. In patients with difficult anatomy, usually due to swelling or body fat, the localisation of nerves may be challenging².

In Australia over 470,000 Individual nerves were tested last year leading to over 24.5 million dollars in reimbursement³. Patients with difficult anatomy constitute about 10% of patients seen in the clinic adding 10 – 20 minutes per nerve (according to clinical interviews). Approximately 75% of nerve conduction tests involve testing 4 or more nerves³. This means approximately 2.5 million dollars is lost a year due to time wasted on trying to find nerves due to difficult anatomy.

This means a clinician is required to spend considerable additional time finding a nerve to stimulate which limits the amount of patients they can see and adds complexity to their workflow.

An inability to localise a nerve affects the accuracy and reliability of a study. It may decrease the confidence of a diagnosis and delay beneficial therapy which may harm patient outcomes. The patient may also be subjected to further costly and burdensome investigations and repeated exams¹.

The procedure is uncomfortable, with difficult anatomy requiring a greater intensity of shocks exposing the patient to increased pain. Furthermore, more sites are stimulated to ensure accuracy in this patient population leading to a greater duration of pain.

Our mission is to increase the accuracy of nerve conduction studies in our target population to optimise clinician workflow and decrease the harm experienced by patients.

Our primary current solution is to combine an ultrasound machine with a nerve conduction probe. Other solutions to be prototyped relate to electronically and optically locating the nerve.

Acceptance criteria:

1. Increase the accuracy of nerve conduction tests in patients with difficult anatomy
2. Reduce the time it takes to conduct nerve conduction studies in patients with difficult anatomy by 10 minutes per nerve
3. Reduce the long term cost to the clinic

Gaps analysis

Nerve Conduction Studies are considered an extension of the Neurological exam¹. They are used to support a diagnosis by increasing confidence and building on the information acquired through a clinical history and examination¹. Nerve conduction studies are also part of the diagnostic criteria for some conditions⁴. Nerve conduction studies can be used to differentiate pathology affecting a nerve itself (Neuropathy due to diabetes), the outer insulating layer around the nerve known as myelin (Multiple Sclerosis) or the Neuromuscular junction (Myasthenia Gravis). Nerve conduction studies can be used in the diagnosis of reversible and irreversible disease processes. Thus, improved accuracy has the potential to significantly improve patients clinical course and quality of life. Nerve conduction studies can also be used to observe the progression of a disease over time or justify future procedures¹. For example, a localised disease process - such as carpal tunnel disease - will often be tested in a clinic before a surgeon agrees to operate⁵.

The current gold standard method of conducting a nerve conduction test involves using anatomical guided landmarks to locate and stimulate the nerve¹. According to our interviews, 10% of patients present with difficult anatomy, due to increased fatty tissue or swelling, which makes anatomical guided nerve conduction studies less reliable. From our clinician interviews we found that an inability to stimulate a nerve in patients with difficult anatomy adds approximately 10 – 20 minutes per nerve with around 7 to 8 patients being seen per clinic. This is particularly important as 4 or more nerves are tested in approximately 75% of visits. This adds a lot of wasted time to the consultation³.

About 7,500 additional hours were spent a year on trying to localise nerves in patients with difficult anatomy³. 12,000 patients could have been seen in this time meaning there were 2,500,000 dollars of missed revenue last year.

The current solution used to address this problem in clinic is to use an electrical probe to stimulate an area circumferentially around where a nerve is suspected to be. Additionally the strength of the shock delivered is increased to improve the chance of stimulating the nerve. Various manoeuvres of the limbs may be performed to improve access to the nerve as well. If this is still unsuccessful, clinicians may request assistance from more senior colleagues for advice or guidance. The patient may be rebooked to return at a later date to have the test repeated.

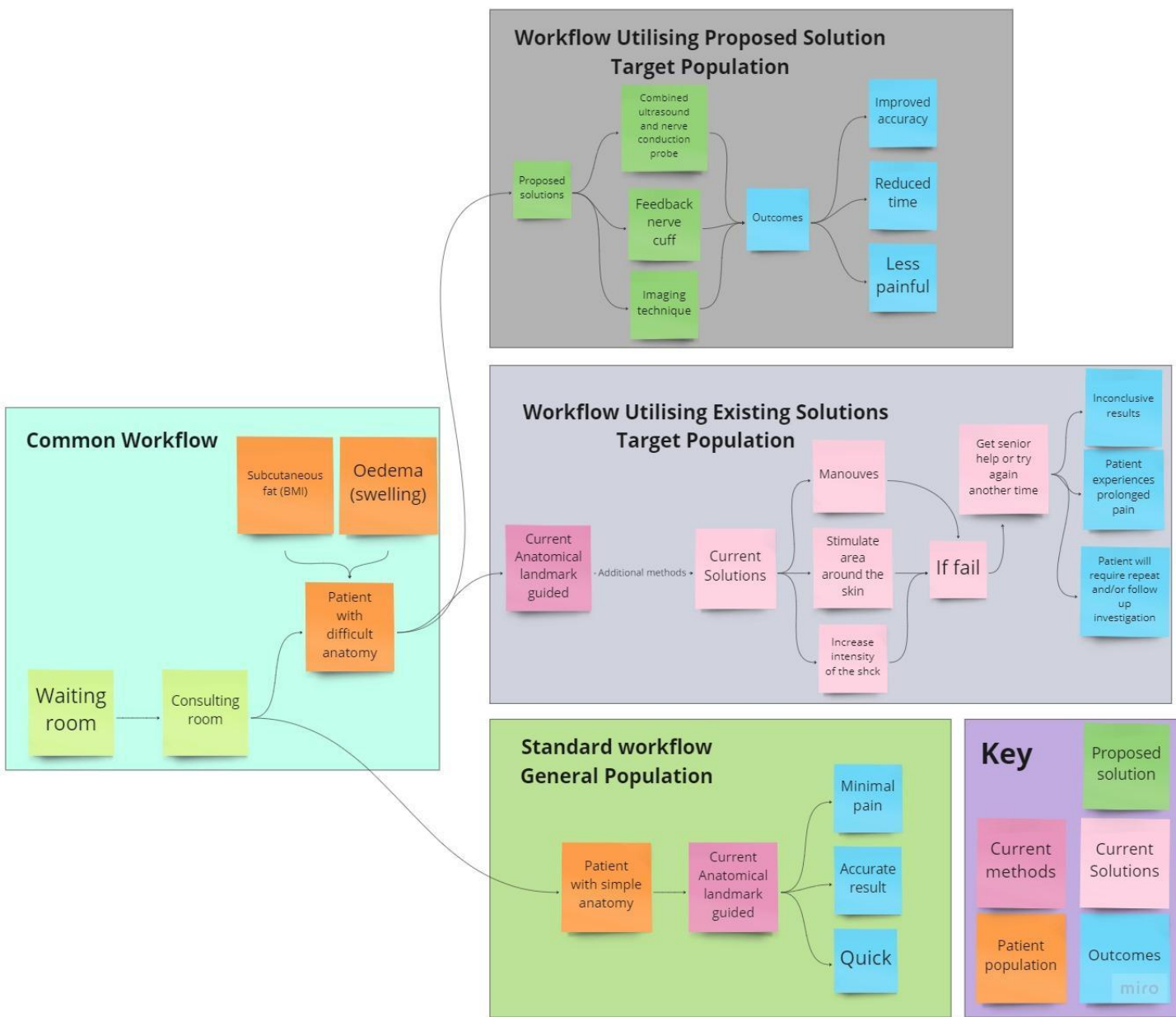
The stimulation of proximal nerves may be guided by palpating for blood vessels that run alongside the nerves. This is less reliable in the distal parts of the limb. Additional factors that may affect accuracy, such as cold limbs, may be addressed by placing the patient's limbs in warm water to maximise the chance of an accurate interpretation.

If uncertainty remains despite all these methods a clinician may write that the nerve conduction test was unreliable or equivocal in the report. This means the patients presentation must be interpreted in the context provided by the history and other examination. Rarely, Invasive procedures such as a biopsy may be need to be performed. This is an invasive procedure associated with risk relating to infection, bleeding and nerve injury.

Systems Map

Figure 1: This diagram maps the workflow in a nerve conduction clinic. It contains the standard workflow in patients with easy-to-locate nerves. It also demonstrates the workflow using current methods in the target population and the workflow using our proposed solution.

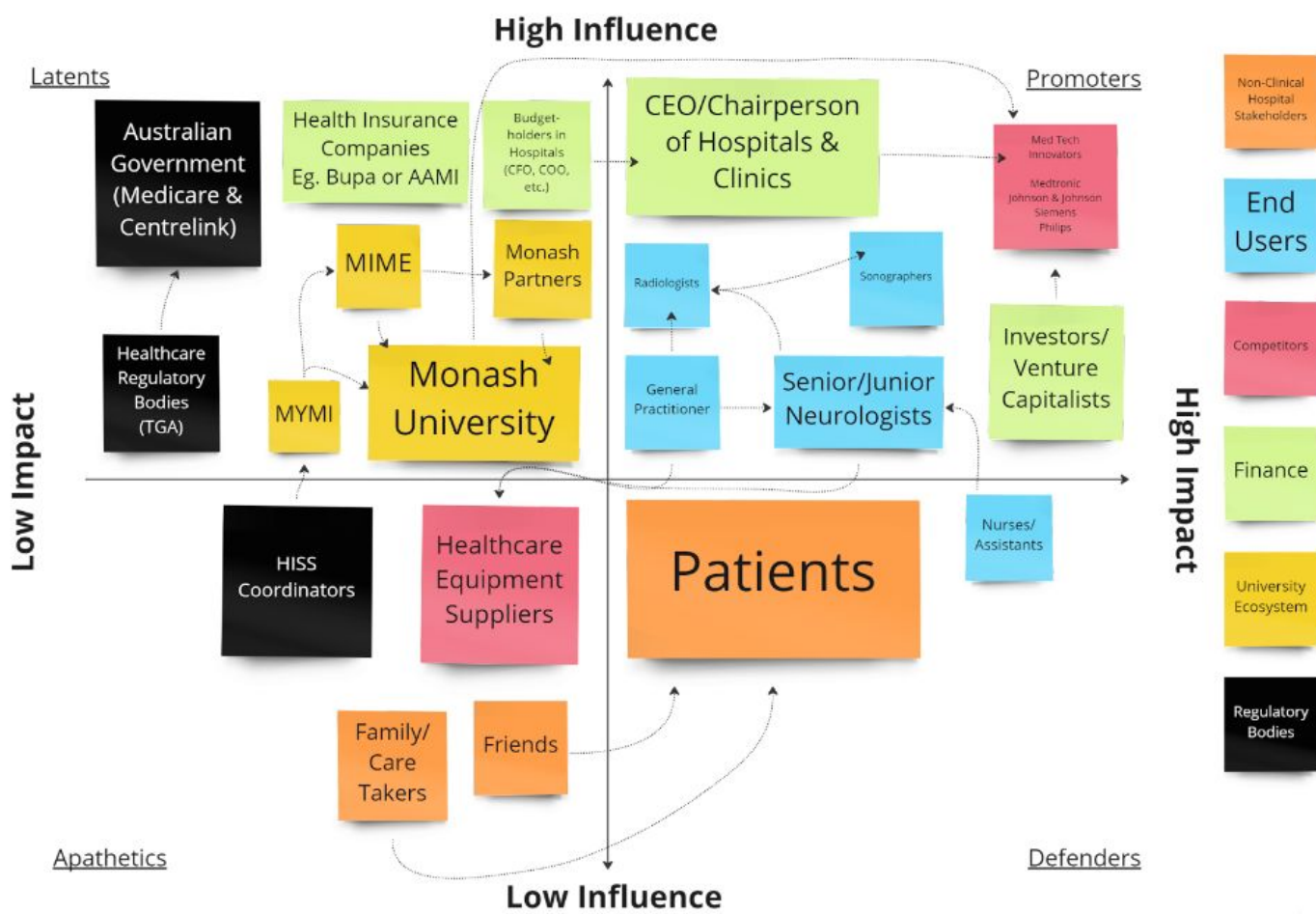
Link for miro board: [HISS 2022/2023, Online Whiteboard for Visual Collaboration \(miro.com\)](#) (1st row 4th column)



Stakeholder Map

Figure 2. Stakeholder Map

This map organises relevant stakeholders based on influence and impact.



Outcomes of Qualitative and Quantitative Research

Title	Author	Number of participants
Ultrasound guidance for sural nerve conduction studies	Cartwright	14
Ultrasound guidance may have advantages over landmark-based guidance for some nerve conduction studies	Wei	30
A hand-held probe for combined ultrasound and electrical impedance tomography		
Risks and Benefits of Ultrasound, Nerve Stimulation, and Their Combination for Guiding Peripheral Nerve Blocks: A Retrospective Registry Analysis	Hagen Bomberg	16
Dual activation: coupling ultrasound to electrochemistry—an overview		
BODY MASS INDEX EFFECT ON COMMON NERVE CONDUCTION STUDY MEASUREMENTS	BUSCHBACHER	253

[Ann R Coll Surg Engl](#), 2011 Apr; 93(3): 236–240.
doi: [10.1308/147870811X566385](#)

PMCID: PMC3291143
PMID: [21477439](#)

Clinic-based nerve conduction studies reduce time to surgery and are cost effective: a comparison with formal electrophysiological testing

[Henry E Bourke](#), [Jeremy Read](#), [Rebecca Kampa](#), [Anthony Hearnden](#), and [Paul A Davey](#)

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Our literature review demonstrated an overall significant increase in accuracy of nerve conduction studies when they were preceded by an ultrasound guided image⁶⁷. This significantly increased the time taken to perform the study (as the ultrasound was performed first, the area to stimulate was marked and then the nerve conduction test took place)⁶⁷.

We also looked at other clinical applications of a hand held device that combined an ultrasound machine and another device in the same probe⁸.

Our literature review supported the use of nerve conduction tests as a cost effective way to reduce time to surgery and improve patient outcomes⁹.

We conducted interviews with five clinicians and had conversations with four patients. All clinicians recognised this as a problem with two saying, “It’s the classic sural nerve” that is hard to stimulate when giving their opinion of the problem. Of the five clinicians four said approximately 10% of the patients they saw had difficult anatomy due to subcutaneous fat or swelling. One clinician said this occurred in 5% of the patients that they saw. On average clinicians stated that difficult anatomy added 10 – 20 minutes to the nerve conduction study.

80% of the clinicians interviewed said they would use the device.

Solution Concept Discussion

- top 3

	Current gold standard	Weight	Solution #1 - NCS Accompanied with Ultrasound	Solution #2 - Stimulator Cuff with Feedback Receptor	Solution #3 - Nerve Finder Pen
Training	Standard NCS Training	1	-	s	S
Accuracy/reliability	Highest Action Potential	3	+	+	+
Patient Comfort	Uncomfortable procedure	2	+	+	+
Time	40 mins	3	+	+	+
Cost (long term)	\$700 (without insurance) - \$4000 (if other tests are required)	2	+	+	+
Is it effective in target population		3	+	+	S
FINAL SCORE			12	13	10

Our primary solution at the moment is a nerve conduction unit combined with an ultrasound in the same probe. While this idea does not have the most points, the combination of two technologies is both realistic and convenient. Ultrasound has already been validated in many clinical trials to find nerves which may improve the ease of development and acceptance by regulatory bodies⁶⁷¹⁰. Ultrasound is portable, requires minimal training, and is cost effective. Therefore, by combining NCS and ultrasound into a single unit, nerves can be localised in a time efficient manner and be accurately stimulated.

The electronic stimulator cuff with feedback receptor had the highest score. Ours would be novel - utilising a positive feedback array with a stimulatory and receptor cuff to identify the position of the nerve using impedance. We would either include multiple electrodes or use an integrated chip to perform math to estimate the nearest position of the nerve.

The utilisation of optics would be a novel, effective and simple technique. However, infrared is unable to penetrate the distances we require so this idea requires more brainstorming and planning.

Final Concept

We plan to prototype three different approaches during the invent phase of the project. These include using imaging techniques (the combined ultrasound device), electronics (the positive feedback array electronic cuff) and optics (using light absorption) to quickly and easily locate the nerve. The exact features and patenting considerations will be largely informed by our prototyping process where we can see what is feasible and what is not. We plan to run a small clinical trial to test the efficacy of our product as well as what features are patentable, what modifications are required and as a result apply appropriate regulatory categories and identify patentable features.

The solution is highly suitable to be incorporated in clinician workflow. It will make nerve conduction studies less tedious and allow clinicians to more effectively utilise their time. As a result the clinic will be able to see more patients and health services will be less burdened with repeated appointments and additional follow up investigations undertaken to confirm equivocal result.

We plan to differentiate ourselves from the market by creating a device that can be used on multiple different parts of the body. We also plan to just make a device that finds the nerve so the clinician can use their initiative to stimulate it as required. We believe this will be highly beneficial to the existing workflow.

Our final solution aims to combine an ultrasound and nerve conduction study probe, into the same probe. This will allow real time visualisation and stimulation of nerves buried deep in the anatomy.

Business Model

Our business structure will likely be a capital equipment model with an ongoing revenue stream through a service fee and potentially low cost disposable electrodes. It would be a B2B model being sold from our business to the relevant hospital bodies.

Our reimbursement strategy would be modelled on the current Medicare codes for nerve conduction studies. The codes involved include code 10112, 10115 and 10118 with larger reimbursement for more nerves tested. Additionally we can model off ultrasound codes for non interventional musculoskeletal ultrasound with Medicare code of 55893.

The health economic profile would see an improvement in a patient's quality of life. There is considerable psychological benefit in a patient receiving a definitive diagnosis which would improve their health and wellbeing by reducing stress and uncertainty and empower them with agency over their health condition¹¹.

We would partner with our clinician who is prominent in this space to advocate for our device. We could focus on one clinic initially and use success in this area to help market to other services. We would initially expand to Monash partners through networks in the university.

For the long term, cooperation with the Australian and New Zealand College of Neurologists will be essential. Our device will require additional training which can be incorporated in the additional nerve conduction study training year. If all future Neurologists are exposed to this device in training they will be more likely to buy it for their future practice or to advocate to their health service to purchase the equipment.

Our exit strategy includes:

1. Selling our stake to a partner or investor
2. Merger and acquisition: Pitch products to medical equipment manufacturers and ask for royalty in return

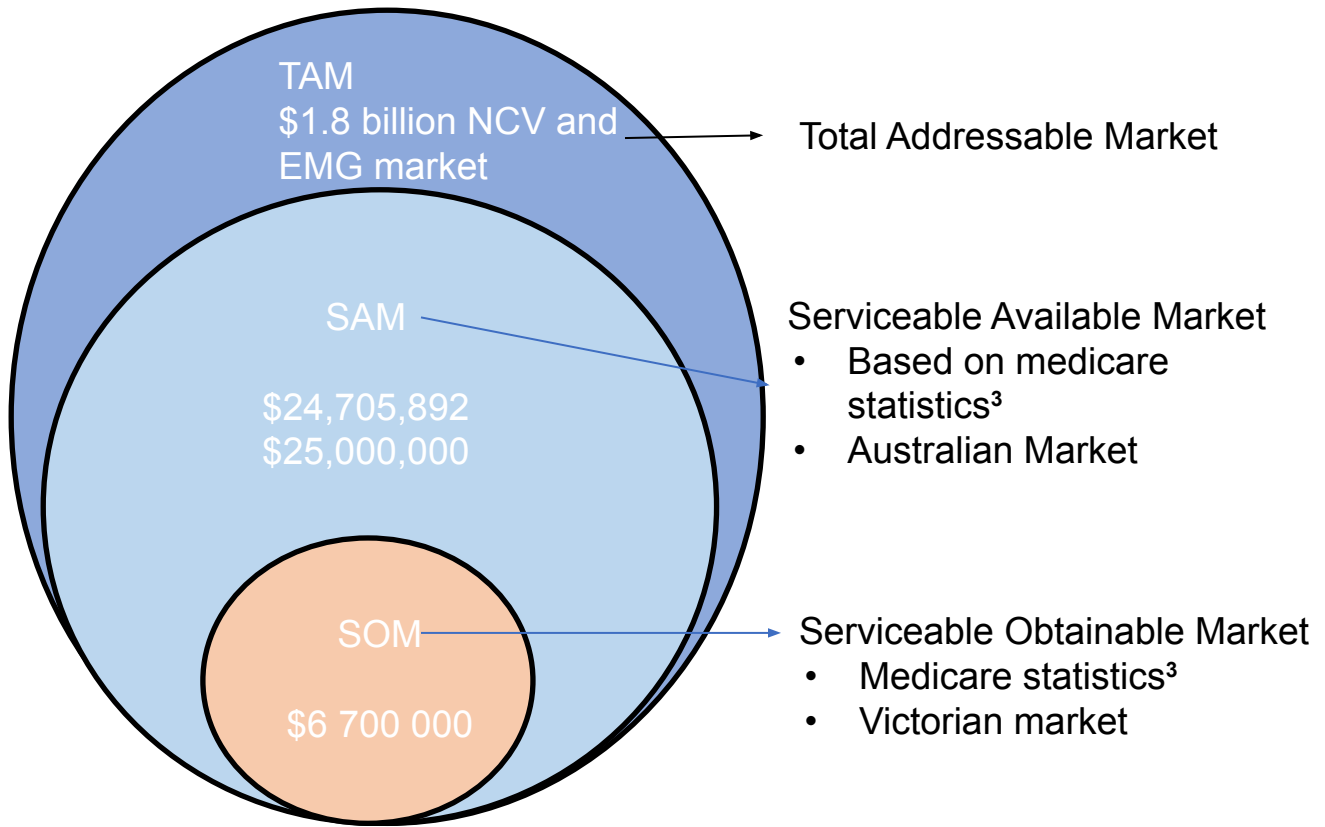
Acquire: Apply for positions at med tech companies by showcasing knowledge and expertise on the basis of this project

Our business model of capital gains with recurring revenue leads us to aim for a margin of about 80%. Our ROI target would be 80%.

At the moment our most significant risk is a lack of a proof of concept. Prototyping to provide a tangible device would significantly decrease risk for investors. Circuit schematics, 3D CAD models and physical prototyping would be an effect de-risking strategy.

Built-in additional safety feature such as surge protectors and circuit breakers would be included to tightly regulate the electrical output.

Market Analysis



These results are likely underestimates. They were retrieved from the medicare statistic database³. This means these calculation do not include private clinics which would be a significant additional market for our device.

There is a potential for market expansion. Accurate localising of nerves is essential for many surgical procedures. A surgeon may have difficulty localising specific nerves in a patient with a history of repeated surgery, burns or difficult anatomy. Therefore a device such as ours may be of benefit in this space.

There are emerging companies looking to digitalise and optimise nerve conduction studies¹². Our segment of the market is to focus on patients with difficult anatomy, particularly due to fat or swelling.

Proposed KPIs

Our solution addresses the KPI of specialist routine referrals seen within 365 days¹³. Our solution would improve clinic efficiency facilitating more patients to be seen with fewer follow ups required.

Clinician workflow will also be simplified and optimised with our solution. The conduction study will be less tedious and time consuming increasing the confidence clinicians have in their diagnosis.

More reliable nerve conduction studies will lead to the early initiation of treatment for conditions such as neuropathy. This will reduce the number of serious injuries associated with falls with is one of the KPIs indices at Alfred Health¹³.

Monash KPIs¹⁴:

Our solution may reduce unplanned hospital readmissions¹⁴. An accurate diagnosis means patients will be able to be started on appropriate treatment early. An unreliable result may require repeated testing over which time a patient's disease may progress. For example, a patient with diabetic neuropathy of the lower limbs may fall. In addition to this, the time saved on trying to locate the difficult anatomical variation may be used to see new patients. These additional patients might be able to be informed of their condition, risks and lifestyle modifications as well as potential treatments which may reduce new hospital admissions due to decreasing flares or deterioration of disease.

Our solution offers to improve patients mental health¹⁴. An accurate diagnosis informs patients of their clinical condition and gives them agency over their own health. A shorter less painful procedure will most likely be better tolerated by patients which may make them more willing to return.

Our solution also offers to reduce the harm patients experience¹⁴. Their discomfort will be minimised with a more accurate and quicker procedure. At the moment equivocal nerve conduction study results may require invasive further investigations, such as a sural nerve biopsy (risk of infection, bleeding and damage to the nerve). Our solution would reduce this risk of harm by providing a more accurate result in patients with difficult anatomy.

Ask and Next Steps

Meet our Team



**Dr Piyush
Ostwal**

Consultant Neurologist



**Vishnu
Sivakumar**

Bachelor of
Engineering (Honours)
Robotics &
Mechatronic (A.I)



David Levitz

Medical Student
Department of Neuroscience
Alfred Health

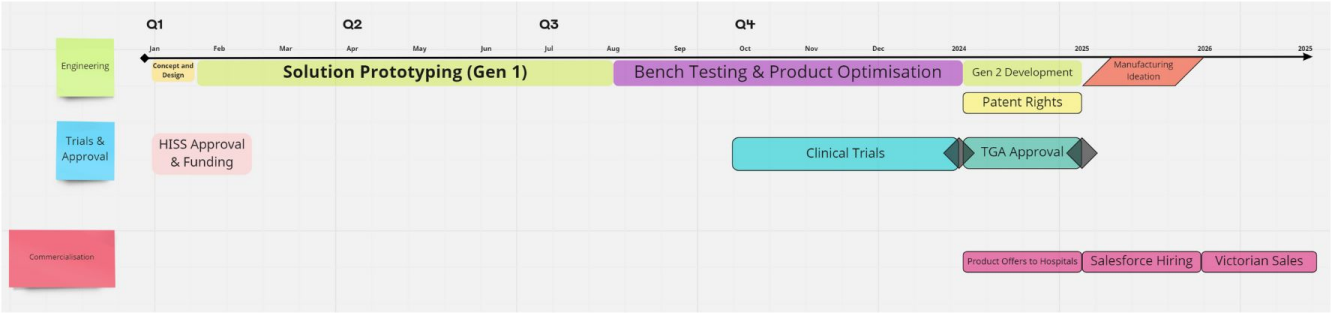
Our next steps are to acquire radiologist input on methods to localise the nerve. We would especially appreciate their expertise with ultrasound.

Additionally we would require technical expertise on imaging, electronics and optics. These are different approaches we plan to prototype.

We would also require funding to prototype our ideas. We are in discussion with the HISS coordinators regarding this.

Timeline

Timeline



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