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MONASH HEALTHCARE INNOVATION SUMMER SCHOLARSHIPS

Project Sentinel



Monash Partners
Academic Health Science Centre



**MONASH
YOUNG
MEDTECH
INNOVATORS**

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Clinical Champion: Dr Thanh Phan
Affiliations: Monash Health

Executive Summary

1 in 4 people will suffer a stroke in their lifetime, with almost 80% of all strokes being ischaemic (caused by blood clot) [1]. The severity and effect of a stroke differs from person to person, but for a third of the population, their strokes are severe enough to warrant a long term stay at a hospital. Unfortunately, stroke victims staying in hospitals in Australia have a 15% mortality rate within 90 days of their initial admittance [2]. Deaths are commonly caused by an unforeseen and sudden occurrence of a follow up stroke. We seek to lower the 15% mortality rate of stroke patients in hospitals by solving one of the key problems in the current hospital system, which is the slow response time to the recurrent strokes. The slow response time is caused by a lack of continuous monitoring. Thus, we have devised a monitoring software to observe patients recovering from ischaemic strokes without the presence of medical staff over a long period of time, that is able to update doctors and nurses of the condition of the patient over the duration of the monitoring session in an easy-to-read format, so that help can be provided in an efficient manner.

Acceptance Criteria

- Does not cause discomfort within the patient
- Offers continuous independently-functioning surveillance of the patient's neuronal activity over a period between 30 minutes and 24 hours
- Offers a rapid response signal of ischaemic stroke occurring within a patient

Gaps analysis

Gold Standard Pain Points - NIHSS

The current gold standard of care for monitoring ischaemic stroke patients for repeated blood clots is to use the National Institute of Health Stroke Scale. It is a physical test done by neurologists to determine the state and health of a patient post stroke [3]. The test involves 11 main checks for:

Level of consciousness	Limb Ataxia
Horizontal extraocular movements	Sensation
Visual fields	Language/aphasia
Facial palsy	Dysarthria
Arm motor drift	Extinction/inattention
Leg motor drift	

These tests have been optimised to be as objective as possible, but subjective errors may still occur.

The only equipment needed for these tests are some images of words to test for aphasia, which is completely free and easy to obtain. It is expected for patients to be on a bed while this test is being conducted, which restricts patient mobility. Furthermore, the nature of the test requires the patient to be conscious while the examination is being conducted. This may prove difficult in more severe ischaemic stroke cases, as extensive haemorrhage can lead to the patients being admitted while unconscious. This test can be done at any time and does not require any preparation, but it takes up to 30 minutes to conduct, thus neurologists only check each stroke patient up to twice a day. Currently, the National Skills Commission has declared a nationwide shortage of neurologists, suggesting that time restrictions may prove important, as the number of specialists that can receive patients is limited [4]. The current golden standard also does not possess predictive or immediate-response power.

Existing solutions

Electroencephalography (EEG)

Overview

A method used to measure the electrical activity of the brain by applying electrodes to the scalp. The procedure is completely non-invasive and is currently used to diagnose multiple conditions, including epilepsy and sleep disorders [5].

Clinical Solution Profile

The operating principle relies on capturing electrical signal frequencies and quantifying them by rate and intensity, Abnormal results may indicate the presence of particular neurological disorders [5]. EEG has been determined to be safe for the operator and the patient, however, exposure to electrical current has been listed as a potential risk. Appropriate training in regards to equipment setup, and continuous maintenance of the device are known to minimise patient exposure to current [6].

Damaged sections of the brain should not be producing any signals and thus will show up as a dark spot. Brain activity recovery should be seen in real time using this method. An EEG specialist is needed to read the output.

The patient journey for this method involves the patient coming into the hospital and getting initial treatment first before getting placed into a hospital bed for recovery where an EEG cap can be placed onto the patient to monitor them. This cap will be left on until either the patient is fully recovered and no longer needs monitoring, or for temporary durations for cleaning purposes [7].

Economic Profile

A prolonged recording costs the patient \$260 - \$300 AUD, depending on benefits. Without benefits, the service costs \$345 AUD [8]. The price of the equipment ranges from \$1500 - \$2000 AUD, depending on the number of channels used in the configuration [9].

Solution Alignment

- Does not cause discomfort within the patient
- Offers continuous, but not independently-functioning, surveillance of the patient's neuronal activity over a period between 30 minutes and 24 hours

Solution Gaps

- Low resolution.
- Current algorithms create a some signal localisation error.
- Is a new solution that will need time and resources to develop.

Computerised tomography (CT)

Overview

Multiple x-rays of the patient are taken from different angles and spliced together to create a cross section of the bones, blood vessels and soft tissue within the body [10].

Clinical Solution Profile

Due to the usage of x-rays, CT scans have a limited number of safe uses per day for each patient (usually 3).

Some CT scans require the patient to ingest or inject dye to improve the quality of the scan.

The patient's journey, without needing dye, is very quick; they change into a hospital, take the scan, and are then free to go.

If a patient needs dye, then they need to take a drink or IV half an hour before the scan, and must not eat up to 4 hours before the scan.

The imaging takes up to 30 minutes and image processing/analysis can take up to a day at the fastest [10].

Economic Profile

The procedure costs the patient \$175 - \$200 AUD [11], depending on Medicare cover. The cost of the procedure without Medicare benefits is \$234 AUD [11].

Solution Alignment

The CT scan has limited capabilities of solution alignment, however, is one of the most commonly used imaging techniques.

Solution Gaps

- Only provides static images of the brain.
- Some patients may experience side effects from the dye
- Limited number of recommended uses per day.

Magnetic resonance imaging (MRI)

Overview

Large magnets are used to create strong magnetic fields which temporarily realigns water molecules in the patient's body; radio waves are then used to cause the aligned atoms to generate signals [12].

Clinical Solution Profile

MRI scans do not use any radiation and are usually non invasive and painless, however some specific scans may require an injection of dye to increase the quality of the scan.

MRI specifically scans soft tissue such as the brain, heart and bone marrow, and is commonly used to detect soft tissue damage and organ damage, such as those created by a stroke.

Specialists are required to run the MRI scan and also to process the images afterwards.

The patient journey is as follows: patients have to change into a hospital gown and make sure they have nothing metallic on them before entering the machine. After the scan, patients are free to leave.

An MRI scan takes up to two hours to take, followed by a day minimum to process and analyse the images [12].

Economic Profile

An MRI scan can cost the patient anywhere from \$300 to \$1000 AUD. The Medicare benefits scheme can bring the fee down to approximately \$350 [13].

Solution Alignment

The MRI has limited capabilities of solution alignment, however, is one of the most commonly used imaging techniques.

Solution Gaps

- Patients are confined in a small space which may be uncomfortable and trigger claustrophobia.
- MRI scans take a lot of time to run, process, then analyse.
- Only provides static images of the brain.

Systems Map

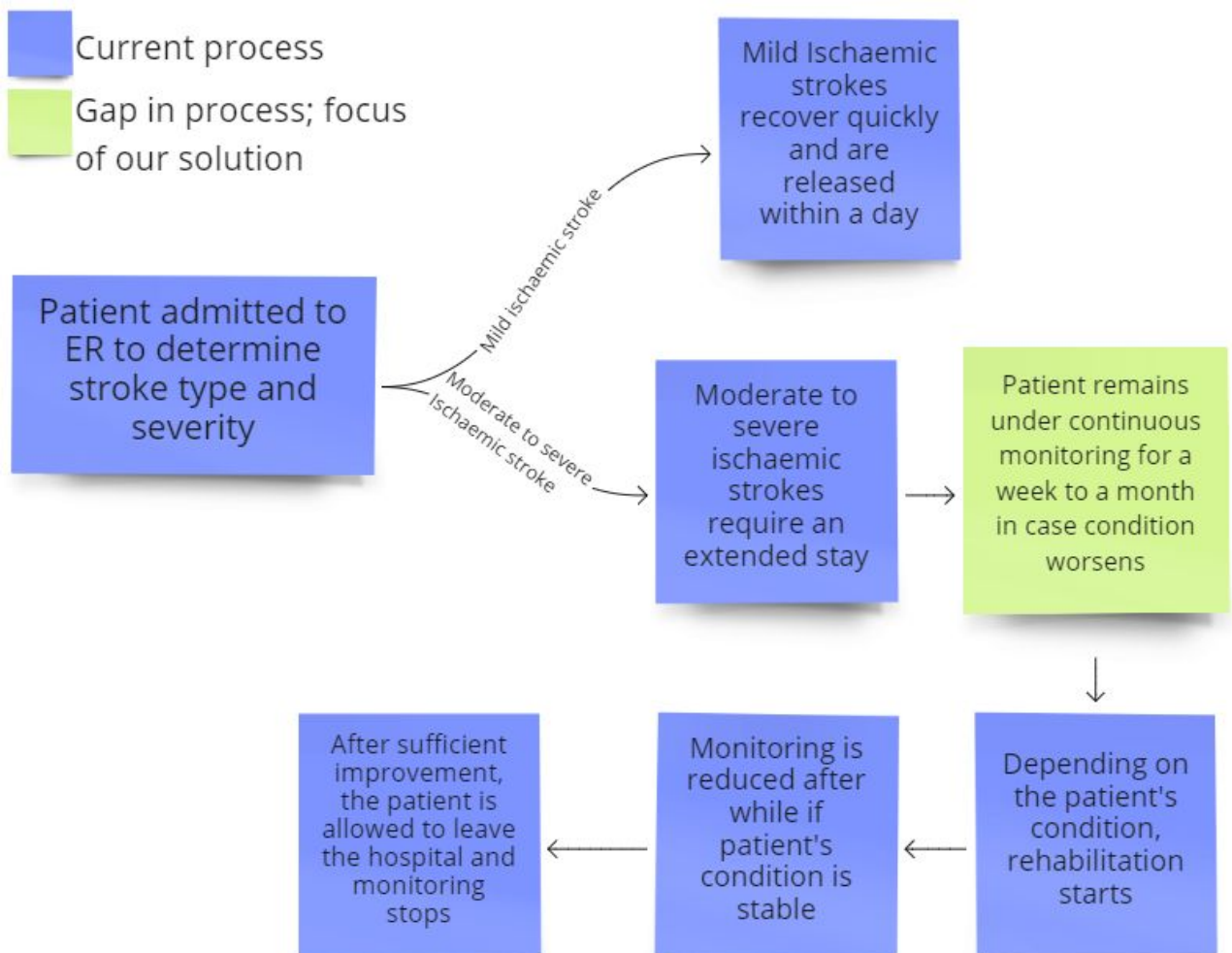


Figure 1: This simplified patient diagram maps the progression from admittance to the hospital due to stroke to the rehabilitation process and future release. Our solution fits into the gap within the process shown by the green box.

Link to full patient journey on miro board:

https://miro.com/app/board/uXjVP7z7TJ0=/?share_link_id=565607384525

Stakeholder Map

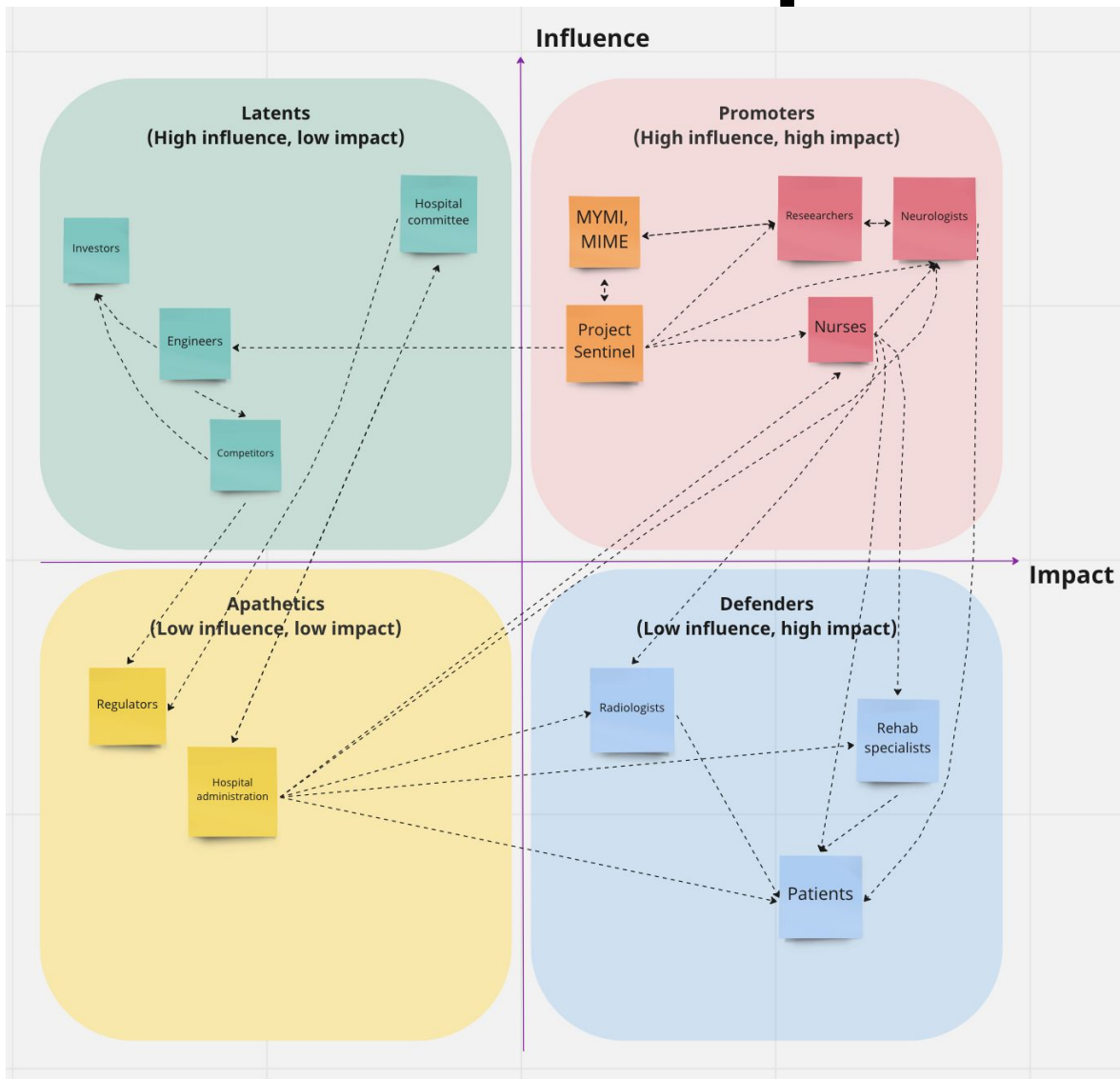


Figure 2. Stakeholder Map:

Depicts the range of stakeholders and the position they hold in terms of the direct influence they have on the project, and the impact the project will have on them. There are four major stakeholder categories: latents, who have high influence and low impact on the solution; promoters, who exercise high influence and high impact; apathetics, which have low influence and low impact, and defenders, with low influence and high impact.

Stakeholder titles are arranged on the coordinate system according to their level of influence and impact on the project. Neurologists are shown to be the most influential stakeholders, who are also impacted the greatest by the implementation of the solution.

Link for miro board: https://miro.com/app/board/uXjVP6luSc8=

Outcomes of Qualitative and Quantitative Research

1 in 4 people will suffer a stroke in their lifetime, with almost 80% of all strokes being ischaemic (caused by blood clot) [1]. The severity and effect of a stroke differs from person to person, but for a third of the population, their strokes are severe enough to warrant a long term stay at a hospital. Unfortunately, stroke victims staying in hospitals in Australia have a 15% mortality rate within 90 days of their initial admittance [2]. Deaths are commonly caused by an unforeseen and sudden occurrence of a follow up stroke.

The reason that repeated ischaemic strokes have such a high occurrence rate is because after the first blood clot is treated, it may have already damaged the blood vessel, or it may not have been fully removed, which are both situations that can easily cause a follow up blood clot and thus a second stroke.

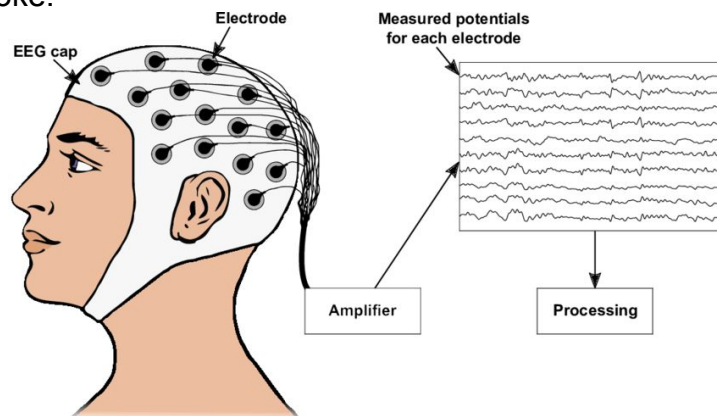
The current gold standard is for a neurologist to conduct a physical examination called the National Institutes of Health Stroke Score to determine the current health of the patient. This exam takes between 5 to 10 minutes to conduct, according to the clinicians we interviewed, and only determines the damage that the patient has suffered, not the patient's condition, whether it's deteriorating or if they're likely to have a second stroke soon. Additionally, according to the majority of neurologists that were interviewed, Each stroke patient at the hospital is given a physical test only once a day. Blood clots in the brain take on average between 1 hour and 8 hours to form; since patients are only checked once every 24 hours, there is a large gap of time where the patient's stroke won't be detected.

A third of the clinicians interviewed did not believe that the lack of continuous monitoring was an issue as there are obvious signs if a patient is having a stroke, however the other two thirds disagreed as by that time damage has already occurred which may be fatal or further impact the patient's quality of life.

Solution Concept Discussion

Electroencephalogram with Inverse Problem Mapping

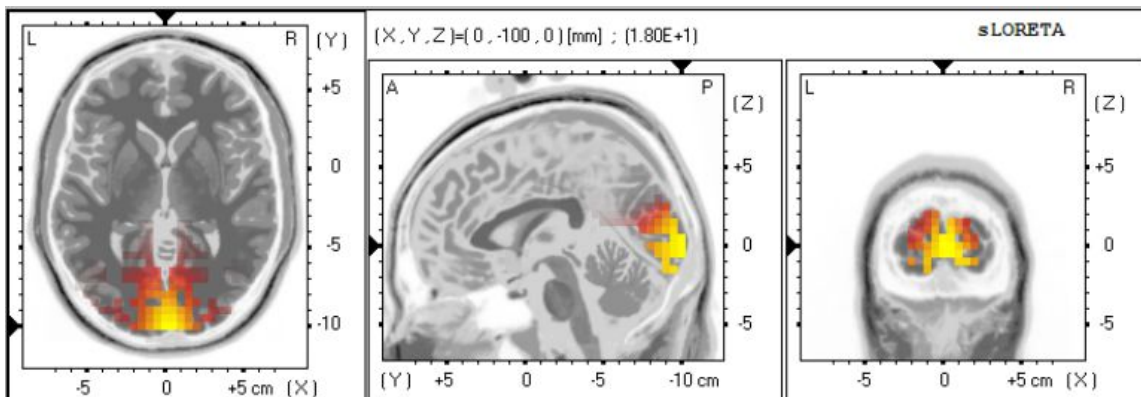
This method attaches an electrode cap onto the patient to measure the electrical signals generated by their neuronal activity. An algorithm is implemented to recognise patterns within the brain activity and to raise an alert instantly if the recorded signal changes and differs from the base signal of a stable brain. A destabilisation of brain activity should signify the occurrence of another stroke. An inverse solution, which is a type of algorithm, is used to then convert the recorded electrical signals into a 3 dimensional model where the source of electrical potential within the brain is localised. This information will be useful for a neurologist to determine the state of the stroke and the potential location of the blood clot; this will aid in determining the type of treatment to use in curing the ischaemic stroke.



EEG electrode cap

The process should be fully automatic and continuous as the electrode cap is not too restrictive and the EEG can be placed by the bedside of a patient with no supervision. EEGs are relatively affordable, averaging around \$1,500 for one machine [9].

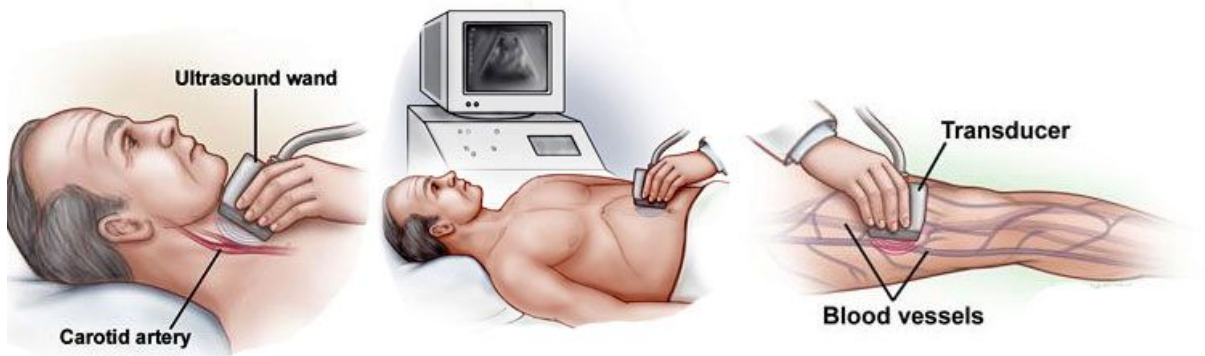
Current gold standard inverse solutions that may be implemented in this system include sLORETA (Standardized Low Resolution brain Electromagnetic Tomography Algorithm), eLORETA (Exact Low Resolution brain Electromagnetic Tomography Algorithm), and density spectral array [14, 15] .



LORETA visualisation

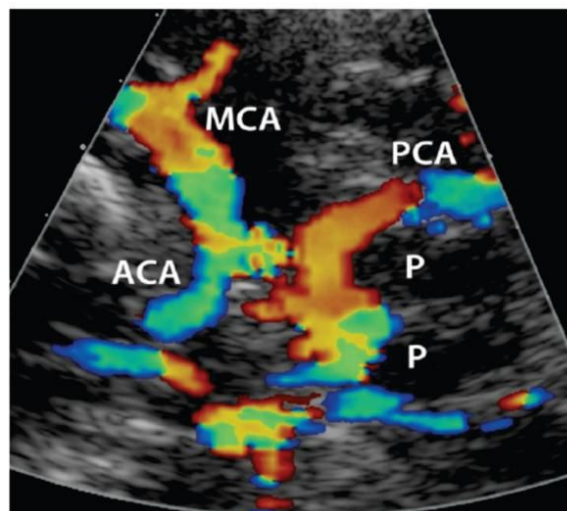
Duplex Ultrasonography (Doppler + B-mode)

Duplex ultrasonography uses waves of high frequency to map bloodflow. The device consists of two parts: a B-mode transducer, which uses sound to map the outline of the blood vessel, and a Doppler probe, which evaluates the velocity of the blood within the vessel. Using this technique, the location of occlusions blocking the blood vessels can be plotted [16].



Duplex ultrasonography procedure

Currently, the technology is mainly used to detect obstructions in the major vessels of the arms and legs, however some clinical trials on patients with ischaemic stroke have also been conducted. The procedure is not currently included in the standard stroke imaging protocol [17].



Doppler visualisation of the Circle of Willis

The cost of the equipment is relatively high, averaging \$3500 AUD per Duplex device [17].

Furthermore, despite being non-invasive and minimising patient discomfort, it may be difficult to automate the process. The device cannot be placed directly over the skull, as the bone will prevent the sound waves from penetrating the tissue. The probe will have to be placed over the neck, and a conductive gel used to achieve accurate results.

Final Concept

The final concept chosen is the electroencephalogram with inverse solution algorithm. It addresses the most of the acceptance criteria out of all other potential solutions by meeting the primary need of offering independent and continuous monitoring of the state of the patient's brain, while also meeting secondary needs.

A key issue with the duplex ultrasonography solution is that ultrasound machines require an operator to control, thus they cannot act independently from clinicians.

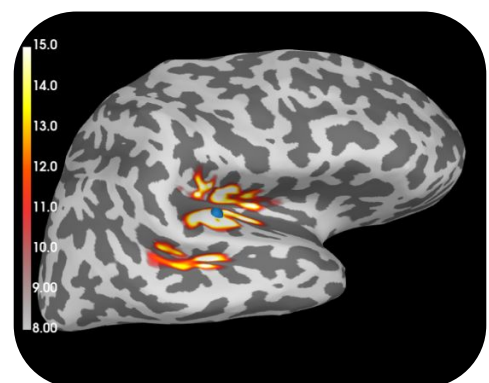
Out of the secondary needs, patient comfort was a key issue with the previous gold standard as the physical test would require the trained clinician to interrupt the patient's rest to do. Other potential solutions such as MRI and CT scans also did not meet this criteria as they required the patient to be in a small and cramped space while also being invasive, such as the CT scans' usage of radiation.

This solution is also relatively cheap when compared to other scanning devices as a single EEG monitoring device sells for a minimum of \$4000 AUD [18].

A few clinicians were interviewed about their thoughts on having this device in a hospital and two thirds claimed that it will greatly aid in lessening their workload while also providing greater care to stroke patients than before. It is important to note that the one third of clinicians who disagreed were senior neurologists who did not have to conduct the physical test of patients daily.

The innovative part of this solution will be the inverse solution software that is able to visualise the health of the brain over a long period of time, therefore this will be the main feature to be patented. As a software used for monitoring patients, it will be a class IIa device under TGA regulations [19]. Current proof of concepts of this software are created using open source APIs such as LORETA, Python MNE, and MATLAB fieldtrip, which are all unpatentable, thus the plan over the next year will be to create an in house inverse software that can be patented. As for the the EED medical device half of the solution, the plan will be to sell the software to medical device companies for them to package with their EEG devices.

Currently there are no EEG devices on the market that are programmed to monitor the physical health of a brain, including locations of brain cell death and deterioration over time of the physical structure of the brain. The competitive advantage of this solution is that the market is untapped, thus if this solution is able to enter the market soon, it will be in an uncontested monopoly for a period of time.



Inverse software proof of concept

Business Model

Reimbursement

The solution fits in with the existing Medicare code 11003, which covers diagnostic procedures involving EEG monitoring over a prolonged period of time [20]. It is anticipated that the existence of a current Medicare code will make the integration of the proposed software into the current system easier. Furthermore, it should act as an additional incentive for the end consumers (hospitals) to buy the medical devices equipped with the proposed solution software package, as they can expect up to 75% reimbursement on their purchase [20].

Category 2 - DIAGNOSTIC PROCEDURES AND INVESTIGATIONS

DN.1.1

Electroencephalography (EEG), Prolonged Recording - (item 11003)

Item 11003 covers an extended EEG recording of at least 3 hours duration, other than ambulatory or video recording.

Related Items: **11003**

[Next - Note DN.1.2 →](#)

Current hospital rates of mortality after a stroke are approximately 15%, and 143 million DALYs annually due to the consequences of experiencing a stroke [21, 22]. By most conservative measurements, it is anticipated that the proposed solution will decrease the DALY's associated with stroke by 5% (7.15 million DALYs). Depending on the country's human development index (HDI), the cost of DALY annually can range from \$1000 to \$70 000 USD [23]. Averaging this figure to estimate the global yearly losses, it is anticipated that the implementation of the proposed solution will save the global economy \$247 billion dollars (USD), if allowed to expand internationally.

Business Structure

The proposed business strategy will incorporate a B2B strategy, where we will sell the software directly to medical device producers. Amongst the proposed clients are MedTech giants such as Medtronic and Massimo. According to the research conducted by our clinician, the average cost of a software update by Medtronic is \$2000. We are planning to take a service fee of only \$400 per sold package, which should leave our clients with a profit of \$400 - \$1000.

In terms of competitors, it has been found that the niche we are trying to take is currently unfilled. However, companies like SeerAustralia, NextGenNeuro and Neurotech already produce various forms of continuous monitoring EEG technology [24, 25, 26]. None of the competitors directly produce visualisation software, but their services are more variable, so there is possibility of extension into the visualisation technology. Need for IP protection and barriers to entry reinforced.

Since we are smaller start-up company, the proposed market strategy will be focused on product differentiation, which will provide a unique visualisation experience, not currently offered on the market. Furthermore, taking advantage of partnering with well-known and trusted brands, such as Monash Health, MYMI and MIME should ensure that our product is trusted by the customers.

Exit Strategy

The proposed exit strategies for our company are the merger and acquisition (M&A deals) or the selling of stakes to partners and investors. The following scenarios would mean we have a variety of routes, which should lower the risk exiting the market.

Selling to potential customers and merging with the Medtech companies would be the preferred exit strategy, but merging with current market competitors or selling stakes to Monash Health can also be looked into.

Investment and De-risking Strategy

Projected ROI for investors into the company was modelled on CARG of neurology devices world-wide. According to various sources, this is estimated to be 6.1 to 8.1% annually, from 2019 to 2026 [27, 28].

There are some risks associated with the chosen strategy, which are summarised in the table below.

Risk	De-risking strategy
Industry risk (Problems with the market)	Quick entry into the untapped market to reduce risk of competition Protect IP early Create a brand name to secure a customer base Have competitive pricing
Execution risk (Company performance in the past in meeting its budgets and the strength of its management team)	Hire professional administrators.
Technology risk (Inefficient or outdated tools used in the business)	Acquire patient data and reviews to identify areas of improvement.
Supply chain risk (Problems with suppliers)	Make our software compatible with many different brands of EEGs. Keep up to date with modern hospital equipment.
Customer risk (Size of customer base that may find alternatives and affect demand)	Maintain continuous communication with existing customers. Use marketing and networking to expand the customer base.

Market Analysis

TAM

Global neuromodulation device market: 15.89 billion USD

Global stroke cases: 12.2 million annually

SAM

Medtronic global neuromodulation device market: 1.639 billion USD

Developed markets stroke cases: 2.3 million annually

87% of profit is from developed markets

SOM

Australian market of Medtronic neuromodulation devices: 25 million AUD

Australian stroke cases: 40,000 annually

Using the \$400 service fee model, the serviceable obtainable market from partnering up with Medtronic averages around \$1.6 million within the first year. This figure was calculated through Medtronic's financial reports [29], which indicates they are selling and maintaining over 4000 of their high end EEG systems. Medtronic will not need to make any new EEG device to accommodate our software; it should be possible to just install it into their existing EEG devices. For each of the 4000 units, our software installation will grant us \$400, which will result in a total potential profit of \$1.6 million. If the Australian market is successful for this business, the next area of expansion will be two fold: one will be to expand to other developed markets that can easily pay for a large sum of stroke monitoring systems, and the other area of expansion will be to partner up with other medical device companies, although this may be restricted due to contract terms.

Developed markets include: US, Canada, New Zealand, Japan, South Korea and Europe [29].

A key consideration for the future health of this venture is the growing neurological monitors market as it is expected to rise to USD 21.22 Billion and is expected to undergo a CAGR of 7.60% by 2029 [30].

Competitors

- Seer Australia - diagnostic monitoring using EEG at home
- NextGenNeuro - remote cEEG and EEG monitoring
- Neurotech - continuous EEG monitoring for hospitals

None of the competitors directly produce visualisation software, but their services are more variable, so there is possibility of extension into the visualisation technology. If we are to become competitive, we will need to get on market fast before these other companies pursue this gap, and to also get IP protection and reinforce barriers of entry to make it harder for these other companies to enter afterwards.

Proposed KPIs

Performance Indicators

The proposed solution is predicted to influence the following areas of hospital KPIs:

KPI	Particular area	Influence
Safety and effectiveness	In hospital mortality rates	Reducing the mortality rate of patients who were admitted to hospital due to an ischaemic stroke and are under clinical monitoring after their initial treatment.
	Hospital associated infection	A non-invasive method of monitoring patients, thus reducing the chances of infection.
	Postoperative VTE (Venous thromboembolism)	A monitoring system that checks for blood clots within the brain, reducing the damage caused by postoperative VTE in the brain.
	Harm	Providing a ground truth on the state of the brain of the patient, which should inform clinicians and surgeons on how to better treat the patient and to avoid causing harm.
Equity and access	Specialist care wait length	Taking over one of the menial tasks done frequently by neurologists, which is to check stroke patients for recurring strokes, thus freeing up their time and creating shorter specialist waiting times.
Efficacy/value for money	Cost	The cost over the entire length of stay for a patient using this solution is cheaper than current technologies such as the CT scan or MRI scan as the only hardware cost is an EEG, which is much cheaper to buy and maintain compared to the previously mentioned devices.
Patient centred/experience	Cost	A key issue of current monitoring methods where neurologists conduct physical tests is that it prevents the patient from resting which is an important need for the health and experience of recovering patients; solves these issues by using a wearable EEG cap.

Ask and Next Steps

The Team

The team working on the final concept comprises diverse skills in the engineering, science and medical fields. The 2 engineers with various specialisations, which will be working on optimising the existing algorithm and constructing the adjacent medical software. The clinical champion, Dr Thanh Phan, will be providing information about the current clinical landscape, to ensure that the proposed solution fits within the current needs of the existing system, and mentoring the team on ways to approach the Medtech market and the implementation process.

THE TEAM



Calvin Zheng
Bachelor of Engineering (Honours) & Bachelor of Computer Science



Dr Thanh Phan
Adjunct Clinical Professor



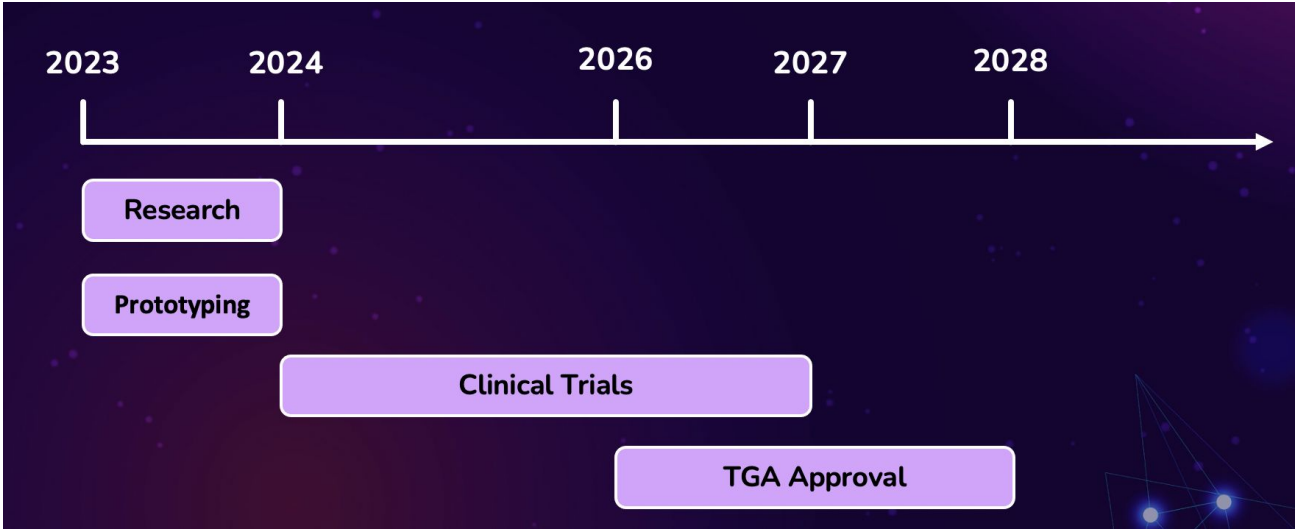
Diana Kovaleva
Bachelor of Engineering (Honours) & Bachelor of Biomedical Science

The Ask

To continue the development of the project for the next 5 years, the initial ask is as follows:

Costs	\$30 000 to cover: - Prototyping (\$8 000) - Clinical trials (\$20 000) - TGA (\$2 000)
Resources	Access to the MonARCH supercomputer for prototyping and optimisation Access to Monash Health database of patients for clinical trials
People	Clinical trial coordinators Additional 3-5 people on the development team to speed up prototyping

Timeline



The above figure details the approximate timeline from the end of the HISS program to the dispatch of the proposed solution on the market. It is predicted that the research and prototyping and optimisation of the product should take 8-12 months. Due to high medicolegal concerns, the clinical trials are anticipated to be extensive, and take 2 years. TGA approval will be sought 1 year before the end of the clinical trials, and can take up to 2 years to receive. The projected date for product implementation is early 2028.

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