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Cost effectiveness of pain devices

Neuromodulation Society of Australia and New Zealand

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Deloitte Access Economics

Contents

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Glossary

AR-DRG	Australian refined diagnosis-related groups
CRPS	complex regional pain syndrome
CT	computed tomography
EQ-5D	EuroQol 5 dimensions
FBSS	failed back surgery syndrome
GP	general practitioner
ICER	incremental cost effectiveness ratio
MBS	Medicare Benefits Schedule
MRI	magnetic resonance imaging
NSANZ	Neuromodulation Society of Australia and New Zealand
PICO	population, intervention, comparator, outcome
PROCESS	Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation
QALY	quality adjusted life year
SCS	spinal cord stimulation
UC	usual care
VAS	visual analogue scale

Executive summary

Introduction

Access Economics (2007) estimated that chronic pain affected more than 3.2 million Australians and cost Australia $34.3 billion in 2007. There are a broad range of conditions that cause chronic pain, and there are numerous interventions that are often trialled before pain resolves. Many of these interventions have little or no clinical evidence and for many people the pain never completely goes away. Some pain conditions such as failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS) (typically type 1) and intractable cancer pain impose a significant burden upon the affected population, and upon the Australian health care system.

Spinal cord stimulation (SCS) is an effective treatment for FBSS and CRPS (and sometimes cancer pain), and intrathecal pumps can provide significant pain relief to patients with intractable cancer pain (and other pain conditions).[1] The scientific evidence for these devices is now well established.

Approximately 90% of all surgeries to insert a pain device are performed through the private health system in Australia. Given increasing cost constraints of the public system, this percentage is likely to grow, although at the same time, recent changes to private health insurance have restricted their coverage to gold level insurance policies.

Given the fragmented nature of minimum coverage levels prior to the private health insurance reforms, it is difficult to determine how many people the changes will affect. However, it is intuitive that not all people will take out gold level coverage to cover treatment for FBSS and CRPS. Similarly, patients that receive pain devices are much less likely to be employed, and therefore they may have reduced ability to afford high cost private health insurance policies. Furthermore, there are thousands of Australians who currently have neuromodulation systems implanted for their chronic pain conditions, many of whom will not qualify for gold level coverage under their existing private health insurance. These Australians may be vulnerable if they should require in-patient treatment related to their implanted device or when the time comes for their impulse generator ("battery") to be replaced.

This presents a significant challenge for patients who need pain devices or who currently have a device; as the comparators for neuromodulation treatment are covered by both silver and gold tier policies, more patients may choose to have a comparator treatment which is often less effective given their circumstances (section 2.3.8).

Methodology

The cost effectiveness of neuromodulation treatment was assessed from both a health care system and societal perspective, constructing a two-arm cost effectiveness model.[2] SCS and intrathecal devices were compared to reasonable alternative medical care, including a repeat spinal fusion for FBSS patients, and ketamine infusions for CRPS patients. For intractable cancer pain, the comparator arm includes opioid medications and local anaesthetics via infusion, sometimes in high doses, which can be delivered in a patient's home or in hospital.

To determine the effectiveness of SCS devices and intrathecal pumps, the model links the probability of a patient achieving optimal pain relief in either arm with the costs associated with delivering that treatment. For SCS, the costs include an initial trial phase, followed by implantation of the device and ongoing treatment costs. For usual care (UC), the costs included those associated with a repeat operation, or quarterly ketamine infusions, which is consistent with usual practice in Australia (noting that not all patients were modelled as receiving these treatments).

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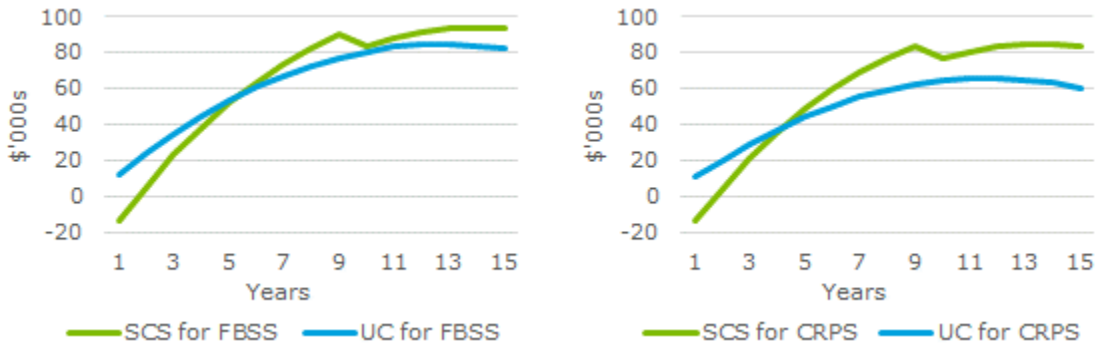
[1] Collectively, SCS and intrathecal pumps are referred to as pain devices in this report.
[2] The care pathways for this report are based on care pathways developed in consultation with the Neuromodulation Society of Australia and New Zealand, Painaustralia and the Faculty of Pain Medicine, Australia and New Zealand College of Anaesthetists. The care pathways are also consistent with international literature (e.g. Simpson et al, 2009).

Results

The net cost of SCS devices from the perspective of the health care system was estimated to be $958 per person per year for FBSS, and $188 for CRPS. The resultant incremental cost effectiveness ratios (ICERs) from a health system perspective were $15,070 per quality adjusted life year (QALY) gained for FBSS, and $2,321 per QALY for CRPS. From a societal perspective both FBSS and CRPS were cost saving (Figure i).

Intrathecal pumps are estimated to cost $792 per person per month. As the patient population have a prognosis typically measured in months, it was conservatively assumed that there are no benefits from a societal perspective. For intrathecal pumps, the ICER from the perspective of the health care system was $44,047 per QALY gained, which is still highly cost effective using World Health Organization benchmarks.

Figure i: Cost savings from SCS for FBSS (left) and CRPS (right), societal perspective



Source: Deloitte Access Economics modelling

Table i: Results of the cost effectiveness analysis

Intervention	Health system ($)	Productivity ($)	Utility (QALYs)	ICER HS ($/QALY)	ICER SC ($/QALY)
SCS for FBSS	958	-1,714	0.06	15,070	Dominant
SCS for CRPS	188	-1,716	0.08	2,321	Dominant
IT for cancer pain (per month)	792	-	0.02	44,047	-

Source: Deloitte Access Economics' calculations. Note: results derived based on the components in table may differ due to rounding. Dominant indicates that the intervention both saves money and improves wellbeing. IT refers to intrathecal pumps for cancer pain. HS = health system perspective. SC = societal perspective.

Conclusion

The chronic conditions of FBSS, CRPS and intractable cancer pain impose a substantial burden upon the affected population. SCS devices can provide significant pain relief to FBSS and CRPS patients who would otherwise be subject to conventional treatments with a lower probability of successful pain relief. With newer devices and stimulation techniques (e.g. high frequency or dorsal root ganglion devices) the cost effectiveness ratios of these devices are likely to improve beyond the estimations in this report. Moreover, the savings from these devices (for FBSS and CRPS) are likely to be magnified over time given the rising prevalence of chronic pain in Australia.

Under the proposed reforms to private health insurance, patients who have silver tier health insurance policies would likely elect to receive the comparator treatments as they would not be covered to receive a SCS device. Further research is warranted to ensure that patients have equitable access to the most effective treatments for their condition.

1 Background

1.1 Introduction

The Neuromodulation Society of Australia and New Zealand (NSANZ), Painaustralia and the Faculty of Pain Medicine, Australia and New Zealand College of Anaesthetists, engaged Deloitte Access Economics to estimate the cost effectiveness of neuromodulation treatment through spinal cord stimulation (SCS) and intrathecal pumps, which are collectively referred to as pain devices in this report.

Neuromodulation is defined as the alteration of nerve activity through the delivery of electrical stimulation or pharmaceutical agents to targeted sites of the body. The process involves the use of implantable and non-implantable devices to reversibly modify brain and nerve cell activity (International Neuromodulation Society, 2018). The process involves surgical placement of a device into a patient's body.

Neuromodulation is useful to provide pain relief for patients suffering from failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS) and intractable cancer pain. Although neuromodulation is not a treatment used in isolation to treat patients, it is key to facilitating an effective treatment pathway particularly where conventional treatment methods fail to provide effective pain relief.

Internationally, pain devices have been shown to be cost effective in the management of chronic pain for the aforementioned conditions (see for example Kumar and Rizvi, 2013, Taylor et al, 2010).

Despite this, the Australian Government has recently announced changes to private health insurance in Australia that would restrict access to neuromodulation treatment for patients. The new system (proposed to commence in April 2019) will classify insurance into four tiers – basic, bronze, silver and gold (Department of Health, 2018). As part of these classifications, SCS and intrathecal pumps are only included in gold tier insurance policies, while the usual comparators for neuromodulation treatment are included in silver (or silver and bronze) tier insurance policies. It is likely that more patients may elect to have the comparator treatment as a result, although it will only be possible to collect this evidence after the proposed reforms go ahead.

The justification of including pain devices in gold tier policies is the large upfront cost associated with the device. However, when appropriately used, it is known that pain devices can provide long term savings to the health system and broader society and in many instances significantly reduce pain compared to usual medical care.

Under the new reforms to private health insurance, one concern is that patients holding silver tier policies are covered to receive spinal fusion surgery, but are then not covered to receive SCS treatment in the case that the fusion surgery fails. This will likely lead to patients choosing a repeat operation in favour of SCS. Success rates of subsequent spinal fusion surgeries have been reported to drop significantly compared to the initial operation (Vleggeert-Lamkamp et al, 2013). Similarly, joint reconstructions can be a cause of CRPS and they are covered by bronze, silver and gold insurance policies (although joint replacements are only covered by gold insurance policies), while neuromodulation treatment will only be covered by gold tier insurance policies (Department of Health, 2018).

The primary objective of this report is to identify the benefits that pain devices can provide, and their associated cost effectiveness. Benefits are categorised into gains to the health system, to productivity and in terms of utility gain by the patients themselves.

1.2 Eligibility for neuromodulation treatment

There are a range of conditions that are effectively treated with SCS devices or intrathecal pumps. SCS devices can be used to manage spasticity deriving from stroke, cerebral palsy, multiple

sclerosis or brain injury (Elbasiouny et al 2009). SCS devices have also been used as treatment for chronic cancer pain, although their effectiveness in this area remains unclear (Peng et al, 2015).

SCS is most commonly used to treat chronic intractable neuropathic pain from many causes including pain after surgery (or multiple surgeries) and persistent neuropathic pain that has failed usual conservative treatment. The focus of this report considers the use of SCS for two conditions – FBSS and CRPS. In some cases, SCS can also be used as an alternative to spinal fusion.

Intrathecal pumps can be used to manage both chronic cancer and non-cancer pain (Hayek et al, 2011, Pope et al, 2016) and can also be used as a management option for spasticity (Deer et al, 2017). The current analysis considers only its use for chronic cancer pain.

1.2.1 Failed back surgery syndrome (FBSS)

Back pain is a highly prevalent condition within Australia and prevalence is anticipated to increase alongside an ageing population demographic (Baber and Erdek, 2016). Chronic pain can be highly debilitating and require interventional treatment to provide relief.

Spinal fusion surgery is one option to reduce the pain symptoms of leg and/or back pain. Spinal fusion involves the joining of two or more vertebrae, often performed where the origin of the pain is caused by an abnormal movement between the vertebrae. However, this surgery does not successfully alleviate the patient's pain symptoms in all circumstances, even where the surgery is deemed successful.

The International Association for the Study of Pain defines FBSS as "lumbar spinal pain of unknown origin either persisting despite surgical intervention for spinal pain originally in the same topographical location" (Classification of Chronic Pain IASP second edition, 1994). Patients with FBSS are characterised as having longstanding chronic back pain having had one or more unsuccessful surgical interventions to treat the pain.

1.2.2 Complex regional pain syndrome (CRPS)

CRPS is a condition most commonly affecting a patient's arm, hand, leg or foot causing significant pain in the region (Better Health Channel, 2015). According to the Better Health Channel, symptoms may include severe burning pain, tremors, spasms, stiffness or loss of motor control in the affected region. Treatment for CRPS focusses on restoring movement to the affected limb and reducing pain.

The condition often occurs after a patient experiences a traumatic injury to the affected area of the body. In some instances, people who have experienced spinal cord injury, stroke or heart attack will also develop CRPS (Better Health Channel, 2015). Trauma is a common cause (e.g. fractures of the hand, wrist or foot). Surgery is also a relatively common cause of CRPS notably orthopaedic surgeries like minor or major surgeries on bones and joints (e.g. knee arthroscopies and joint replacements).

As with FBSS, SCS can be used to reduce the level of pain that the patient experiences, allowing for the patient to engage in physical therapy as part of their rehabilitation process. CRPS may persist for years after the event and patients may experience varying severity levels of pain and the possibility for lost motor control in the affected area.

1.2.3 Intractable cancer pain

Intractable pain is defined as an excruciating, constant and incurable pain that is of such severity that it dominates almost every conscious moment of the patient. Patients with intractable pain are most commonly bed or house bound in the absence of opioid treatment.

Intractable cancer pain can arise from the cancer itself, from surgery in relation to the disease, from related medications or through a genetic predisposition to feeling greater levels of pain (Hughes, 2014). Intractable cancer pain can arise from all types of cancer and for many patients (around 10%) satisfactory relief is not achieved through the use of conventional first line approaches. Intractable pain is always associated with an underlying cause which is incurable, and as such treatment is focussed on limiting associated pain during the end stage of a patient's life.

2 Methods

2.1 PICO

The cost effectiveness of pain devices was estimated using a population, intervention, comparator and outcomes (PICO) approach. The PICO approach describes the eligible population for the intervention, the intervention and the comparator, and the specific health outcomes included in the analysis (e.g. change in resource utilisation, or a change in quality of life).

The cost effectiveness of SCS was considered for two populations: (1) people who have already had back surgery, which has failed, who are considering repeat back surgery to improve pain, and (2) people who have CRPS (type 1), who would otherwise be receiving pain relief through a combination of local anaesthetic and opioid infusions in hospital.

The other type of pain device considered in this report was intrathecal pumps. The pumps administer opioid and other drugs directly to the spinal region and can be much more potent than oral equivalents. These pumps are typically used for people who have intractable cancer pain, who would otherwise receive pain relief through a combination of local anaesthetic and opioid infusion in hospital on a regular (and potentially permanent) basis.

Most pain devices in Australia are spinal cord stimulators, and of that, most stimulators are inserted for FBSS, although 10%-15% of stimulators are used to treat CRPS. Approximately 3% of pain devices are intrathecal pumps which are used to treat cancer pain.

The pathways for FBSS and CRPS are similar, particularly for the intervention, although the comparator differs slightly. The comparator for FBSS includes a repeat operation and associated consultations, while the CRPS comparator can include a hospital admission to receive ketamine and opioid infusions every 3 months (noting this does not necessarily represent standard care for all patients).

For both the FBSS and CRPS model, the outcomes considered in the model are comparable, including changes in:

- health resource utilisation;
- ability to work;
- other costs such as informal care and deadweight losses; and
- wellbeing (measured using EQ-5D[3]).

For the intrathecal pump analysis, a more restricted set of outcomes was considered in the model as patients with intractable cancer pain are usually in the end stages of their life, and productivity and other costs are unlikely to materially differ. The intrathecal pump analysis, included changes in:

- health resource utilisation; and
- wellbeing (measured using EQ-5D).

The rest of this chapter describes the available interventions and comparators in more detail (section 2.2), and the modelling approach with a description of the model inputs (section 2.3).

2.2 Intervention and comparator

For this report, the cost effectiveness of SCS and intrathecal pumps was compared to UC for each eligible population.

2.2.1 Spinal cord stimulators

A spinal cord stimulator is an electrical device positioned near the spine delivering a pulsed current to the spinal cord (Australian Pain Management Association, 2014). The electrical current

[3] EuroQol 5 dimesions.

interrupts pain signals being sent to the brain delivering significant pain relief for the patient. A successful outcome is consistently defined within the literature as a patient achieving a pain reduction greater than or equal to 50% of the baseline level of pain (see for example Simpson et al, 2009; North et al, 2007; and Taylor et al, 2010).

The device itself is implanted under the skin of the patient, with the patient able to use a handheld control to alter the intensity of electrical impulse to achieve the desired pain reduction. Day surgery is required to implant the device, however, explantation is possible where stimulation proves unsuccessful (i.e. when the patient does not achieve a significant reduction in their pain).

There are a range of stimulators available on the market. The minimum benefit payable for rechargeable SCS devices ranges from $22,800.00 to $24,700.00 (Department of Health, 2018). The rechargeable devices are expected to last for 8-10 years.

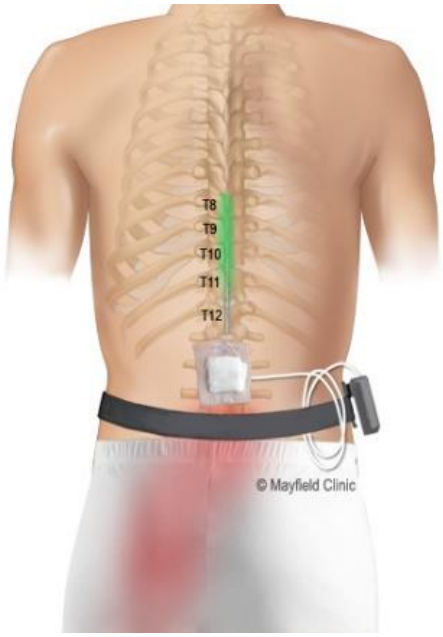
Patients with FBSS or CRPS are likely to try several alternative treatments before they trial SCS. Typical treatment pathways include physiotherapy in combination with opioid therapy (the doses of which may increase over time due to tolerance). Pathways can include other forms of allied health treatment like massage therapy, osteotherapy or chiropractic therapy. FBSS patients have also undergone at least one operation on their back which has been unsuccessful (failed to achieve pain relief). A significant group of these patients undergo further spinal surgeries.

If these interventions fail to bring adequate pain relief, SCS may be suggested to the patient. Once SCS is suggested to the patient, testing is used to determine if they are a suitable candidate to undergo SCS treatment. This will involve an evaluation of the patient's physical condition, medical regime, pain history and psychological state (Mayfield Brain and Spine, 2018). This evaluation is undertaken by a number of specialists, typically including a psychiatrist, social worker, pain specialist and neurologists (Simpson et al, 2009). In Australia this group would typically comprise a pain physician and/or neurosurgeon, a psychologists and likely a physiotherapist.

The patient will consult with their pain specialist or neurosurgeon to help determine if their condition is likely to be treated by SCS to receive SCS. This may involve investigations consisting of computed tomography (CT), magnetic resonance imaging (MRI) (Simpson et al, 2009). The patient will also undertake a psychological evaluation. This evaluation is necessary to determine if the patient is likely to have an adverse experience or outcome to SCS.

After this, the patient will undergo a trial phase stimulation. The trial stimulation is a 3-10 day screening trial allowing the patient to determine if the SCS is an appropriate treatment before the device is permanently implanted. The trial involves a surgery in which the patient is given anaesthetic sedation, before the pain specialist or neurosurgeon inserts small flexible wires, containing the stimulation electrodes, within the epidural space at the back of the spinal cord. The electrodes transmit electrical pulses to the back part of the spinal cord (dorsal columns), which, via many physiological mechanisms, alter pain signal processing and reduce pain. The electrodes are connected to an external SCS device as shown in Figure 2.1.

Figure 2.1: Illustrative spinal cord stimulation



Source: Mayfield Brain and Spine (2018).

After the surgery, the patient will typically be discharged from hospital on the following day (Manca et al, 2008). The patient then returns home and monitors their pain relief during the remainder of the trial period.

If the trial is successful (achieves adequate pain relief for the patient), they will undergo implantation of the stimulator device. This involves a second surgery. The leads used in the trial stimulation are replaced with permanent leads which are then connected to the implantable pulse generator. The pulse generator is implanted under the skin on the patient's abdomen, back or buttock. Surgery is typically performed by a pain specialist physician or neurosurgeon and the patient will typically remain in hospital overnight. The following day the patient is released from hospital.

The patient will then have regular check-ups with their pain specialist physician or neurosurgeon to ensure that the wounds from the surgery are healing and there are no complications. Patients monitored in Kumar et al (2002) made quarterly visits to their pain specialist or neurosurgeon to check up on their SCS progression. The patient then also visits their specialist bi-annually to monitor the continued operation of the device (Kumar et al, 2002). It is also necessary for the patient to visit a nurse 3 times a year for reprogramming adjustments to ensure the patient achieves the best results from their device (Kumar et al, 2002). In Australia this reprogramming is typically undertaken by representatives from the respective company producing the device.

The patient may also rely on supplementary treatments such as physiotherapy to support their pain reduction. These treatments are also used in UC, although it is anticipated the patient will require fewer sessions following SCS – for example, Manca et al (2008) observed that that only 7% of SCS patients use physical therapy (compared to 44% of UC patients) and 0% use massage therapy (14% UC).

In the UC pathway, a FBSS patient not selected for SCS will instead receive conventional treatment with the possibility of having a repeat operation. These patients will continue to receive therapies, including, but not limited to, strong opioid medications, physiotherapy, chiropractic therapy, massage or acupuncture. These patients are likely to use far more of these resources to support their treatment (see Kumar et al 2006, Simpson et al 2009). For those patients that are unable to obtain sufficient reductions in pain, their specialist spinal surgeon may recommend that they have another surgery to help reduce their pain. Consistent with Simpson et al (2009), it was

assumed that 5% of FBSS patients will undergo a repeat operation per annum. There is no limit on the number of repeat operations a patient can have.

For CRPS, the UC pathway is slightly different to the aforementioned pathway for FBSS. While overall resource utilisation is similar between CRPS and FBSS (Simpson et al, 2009), CRPS patients often receive ketamine infusions, rather than having an operation to relieve pain.

CRPS patients will typically be admitted to hospital to perform the procedure, where they receive a continuous infusion over 5-7 days. While ketamine infusions can effectively reduce or relieve pain, the effect can wear off and subsequent infusions are required to maintain an adequate level of pain relief. CRPS patients may receive ketamine infusions every 3-4 months. It was assumed that around 20% of CRPS patients receiving UC will have ketamine infusions, which was reduced to 5% for the SCS intervention (based on expert opinion).

2.2.2 Intrathecal pumps

An intrathecal pump forms part of what is known as an intrathecal drug delivery system, a possible treatment for intractable cancer pain and even some forms of chronic pain. The pump is connected to a small tube which is implanted in the spine and allows for drugs to be delivered directly into the spinal fluid.

As the drugs are delivered directly, they are much more potent, removing the need for high dose regimes of oral morphine or equivalents. As the patient is consuming less oral medication, the intrathecal pump can reduce the risk of side effects associated with high dose oral medications.

The SynchroMed II implantable pump is an example of an intrathecal pump sold within Australia. It is listed on the prostheses list at a price of $15,437.00 (Department of Health, 2018). The device is expected to last 5-7 years.

Many patients with incurable cancer experience varying degrees of pain which may compromise their quality of life. Health Quality Ontario (2016) reports that 10%-30% of patients receiving conventional pain therapies may continue to have persisting pain during the end stages of life. Conventional medical management may involve opioid rotation, parenteral infusions, neuraxial analgesia, nerve blocks or surgery. The requirement for constant management of pain often means that the patient spends a significant amount of time at hospital as an inpatient or may have to visit hospital daily to receive their pain management interventions. This process will remain in place until the patient is transferred into palliative care for the remainder of their life.

If a patient instead receives an intrathecal pump, they will first undergo surgery to have the pump inserted. The patient is admitted to hospital for the surgery but is able to return home thereafter. The pump is programmable and allows for the patient to self-administer a bolus of intrathecal medication using a hand held remote control device (Brogan et al, 2013). The intrathecal pump delivers pain medication directly to the spinal fluid (Health Quality Ontario, 2016). Thus the intrathecal drugs that the patient receives are more quickly absorbed, allowing for far smaller doses of medication to be used – for example, Brogan et al (2013) found that patients on high doses of opioids could reduce their drug costs from $172 per day to $16. As the drugs can be self-administered, the patient is admitted to hospital less frequently and can spend more of their time at home. Patients may also benefit from significantly lower levels of drug toxicity (Smith et al, 2005).

2.3 Modelling approach

An introduction to the model approach and specific model assumptions are described in detail in the following sections of the report.

2.3.1 Introduction to the modelling approach

A number of cost effectiveness studies have been conducted for SCS. Three recent studies considering both FBSS and CRPS population groups include Manca et al (2008), Kumar and Rizvi (2013) and Simpson et al (2009). The results of these studies are briefly summarised as follows.

- Manca et al (2008) studied 100 FBSS patients recruited across Europe, Australia, Canada and Israel. The patients were randomised into either SCS or UC. At the 6 month follow up period,

the study reports significantly higher health costs (£15,081 for SCS compared with £3573 for UC) associated with the intervention and significantly higher utility (mean gain of 0.22 units) for the intervention group. Manca et al (2008) indicated that the SCS intervention substantially reduced a patient's need for additional UC resources.

- Kumar and Rizvi (2013) implanted 184 FBSS and 42 CRPS patients with permanent SCS systems. These patients were compared with 72 patients receiving UC treatment. The trial compared mean EQ-5D measurements and total healthcare costs. The paper concluded that SCS is cost effective, finding that the ICERs were $9,293/QALY for FBSS and $11,216/QALY (measured in Canadian dollars) for CRPS.
- Simpson et al (2009) compared SCS to UC, including repeat operations (for FBSS, but not CRPS). Simpson et al (2009) found that the intervention is dominant for both FBSS and CRPS when the device longevity is 8 years or greater. Assuming devices lasted for 4 years on average, Simpson et al (2009) estimated the ICERs for FBSS and CRPS were £7,043/QALY and £25,095/QALY, respectively.

As with Simpson et al (2009), who conducted a health technology assessment for the United Kingdom, a large number of assumptions have been drawn from the Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation (PROCESS) trial. The PROCESS trial reports resource utilisation at 6 months, and follow up studies also report results for 24 months. As is fairly typical with cost effectiveness analyses – particularly for neuromodulation treatment – a simple Markov model was built to estimate the cost effectiveness of the devices (either SCS devices or intrathecal pumps). The model had a decision analytic structure for the first 6 months, followed by a Markov process for up to 15 years (as in Simpson et al, 2009), depending on patient characteristics. The cycle length of the model was one year.

- For FBSS patients, SCS was modelled relative to UC, including reoperation where indicated.
- For CRPS patients, SCS was modelled relative to UC, which includes inpatient hospital admissions to receive ketamine and opioid infusions.
- For intractable cancer pain, insertion of an intrathecal pump was modelled relative to UC, which includes inpatient hospital admissions to receive a local anaesthetic and opioid infusion.

Finally, it was necessary to define the health states that could be used in the modelling. The Visual Analogue Scale (VAS) is a psychometric instrument which documents the characteristics of disease related symptom severity in a statistically measurable and reproducible format (Klimek et al 2017).

In the context of chronic pain, the VAS scale measures the patient's subjective attitudes towards the pain that they are in. The test is conducted using a 100mm long horizontal line with word anchors at each end which express the extreme spectrums of what the patient can feel. The patient marks along the line the degree of pain (0 representing 'no pain' and 100 representing 'unbearable pain') that they are experiencing. The measure is a validated and widely used measure of pain intensity (Simpson et al, 2009).

For FBSS and CRPS patients, it is widely accepted that the SCS intervention is successful if the patient achieves a 50% or greater reduction in pain from their baseline VAS score (see for example Simpson et al, 2009; North et al, 2007; and Taylor et al, 2010).[4] It was assumed that this is also the case for cancer pain patients.

Consistent with Simpson et al (2009), the following health states were used in the modelling.

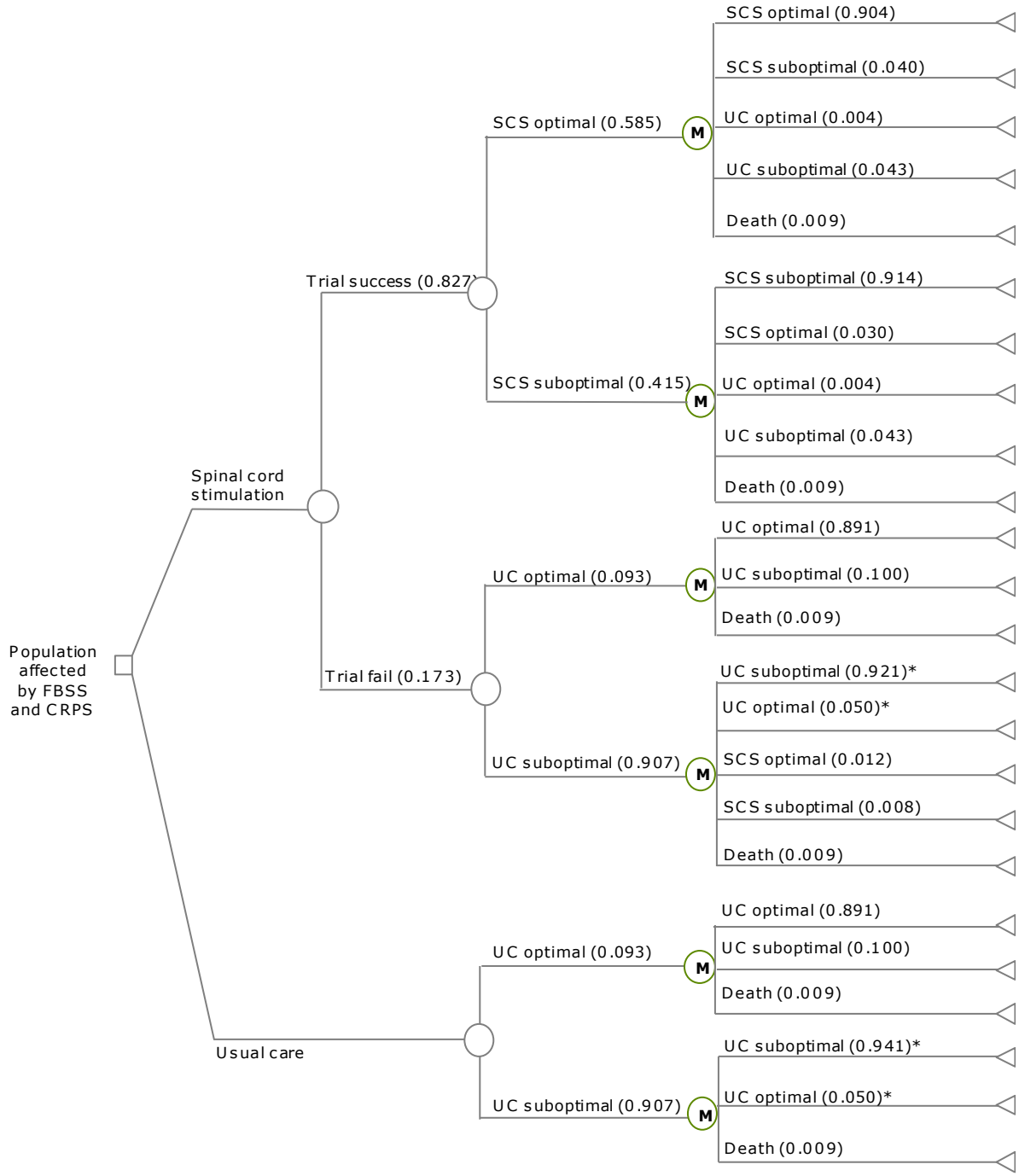
- Optimal health state: for patients who achieve a ≥50% reduction in pain from baseline VAS scores.
- Suboptimal health state: for patients who achieve ≤50% reduction in pain from baseline VAS scores.

[4] It is noted that the 50% or greater reduction in pain is an arbitrary definition of optimal pain reduction. NSANZ acknowledged that the VAS measurement is embedded within clinical practice and is considered the gold standard for interventional treatment; however, NSANZ also noted that 30% is the minimum pain reduction desired for patients.

Patients in both UC and SCS can achieve either health state, although the probabilities are different between the two arms of the model.

The model structure is shown diagrammatically in Figure 2.2, which shows the health states and probabilities of transitioning through the model. The "M" represents the start of the Markov process in the model. The model assumptions and structure are also summarised in Table 2.1.

Figure 2.2: Decision tree



Source: adapted from Simpson et al (2009). *The CRPS arm has a lower probability of transitioning from UC suboptimal to UC optimal. The transition from UC suboptimal to UC optimal is 4.0%, and the probability of transition from UC suboptimal to UC suboptimal is 5.0%.

Table 2.1: Assumptions incorporated into the model structure

Assumption	Paper
Perspective	Health system and societal
Intervention	SCS device for FBSS and CRPS. Intrathecal pump device for cancer pain.
Comparator	UC with reoperation (i.e. spinal fusion) for FBSS. UC including inpatient ketamine infusions for CRPS. UC including inpatient local anaesthetic and opioid infusion for cancer pain.
Time horizon	15 years for FBSS and CRPS. 15 months for cancer pain.
Model type	Decision tree with Markov with 1 year cycle length for FBSS and CRPS, and 1 month cycle length for cancer pain.
Health states	Optimal pain relief. Suboptimal pain relief. Death.
Discount rate	5% with sensitivity analysis.
Outcomes	Wellbeing. Health system resource utilisation. Workforce participation. Other financial costs, including need for informal care and aids and modifications.

Source: Deloitte Access Economics.

2.3.2 Probability of trial success

The probability of trial success determines whether a patient will have a follow up surgery to have the SCS device implanted. If the patient does not successfully complete the trial, they will continue to receive UC in the model (assumed to be equivalent to the comparator arm).

The probability of trial success varies between 66.7% (Kemler et al., 2000) to 88% (Kumar and Rizvi, 2013). A trial success probability of 82.7% was observed in the PROCESS trial (Kumar et al, 2005) and it was adopted in subsequent papers (see Simpson et al, 2009, Taylor et al, 2010). The probability of success was also assumed to be 82.7% in this analysis.

This is likely a conservative assumption as more recent studies (see Kapural et al, 2015 and Veizi et al, 2017) achieved a trial success rate closer to 90%. Similarly, Duarte et al (2018) commented that there is a need to evaluate the usefulness of the screening trial because trial success probabilities have increased substantially over the last two decades.[5]

2.3.3 Probability of complications

It is possible for SCS devices to malfunction, and for patients to experience adverse events due to their SCS treatment. Examples of hardware related malfunctions include electrode migration, lead fracture or loss of paraesthesia, while adverse events or biological complications generally refer to infection.

Kumar et al (2005) found that 27 out of 84 patients experienced a device related complication, with a total of 40 adverse events occurring. Similarly, Taylor et al (2005) observed that 43% of patients experienced complications in the first 6 months after receiving SCS treatment, of which 18% were related to the SCS device.

Consistent with recent studies (see for example Simpson et al, 2009; Taylor et al, 2010; and Kumar and Rizvi, 2013), it was assumed that device related complications occur at a rate of 18% per annum (after the initial 6 months). This assumption may be conservative as newer stimulation

[5] With continued improvement in this area, it is possible that the care pathways may change (to remove the need for a trial) leading to further savings in the future.

techniques, including dorsal root ganglion stimulation, offer increased lead stability (reducing the risk of lead migration). Similarly, the use of wireless neuromodulation systems could substantially reduce the rate of complications (Billet et al, 2017, Yearwood and Perryman 2015).

Complications are not modelled as a separate health state as patients are likely to spend a relatively short time in the health state (i.e. a surgery to correct any malfunction is likely to occur quickly).[6]

There may be a minor risk of infection with ketamine infusions, and it is also possible that there could be complications from repeat back surgeries. However, given that not all patients receive these alternative interventions, it was assumed that the cost of these complications in the UC pathway for FBSS, CRPS or for cancer pain would likely be small. The low rate of complications is also consistent with the findings of North et al (2005). However, it is noted that this simplifying assumption conservatively favours the comparator.

2.3.4 Utility values

Changes in utility are reported in EQ-5D measurements. EQ-5D is a standardised instrument used to measure a person's subjective health status. The EQ-5D values were based on the results in Kumar and Rizvi (2013), which are reproduced in Table 2.2. The utility values for cancer pain represent the average utility across all conditions in Kumar and Rizvi (2013). Further it was assumed that the utility for intrathecal pumps was comparable to the UC treatment, which is consistent with Health Quality Ontario (2016).

It is noted that the utility gained for patients receiving SCS is higher than in the UC arm in both optimal and suboptimal health states. For example, the utility in the UC arm for CRPS is lower as the treatment effectiveness of ketamine infusions is likely to wear off towards the end of each 3 month treatment cycle. That is, the SCS treatment is likely to have higher utility because it maintains pain relief, while the treatment effect of alternative therapies generally wear off over time.

There is no literature to accurately inform the utility values of cancer pain patients. The cancer pain utilities for optimal and suboptimal pain relief with an intrathecal pump (IT optimal and IT suboptimal, respectively) are informed by the average utility values of FBSS, CRPS, peripheral arterial disease and refractory angina pectoris as reported in Kumar & Rizvi (2013). The utility values for intrathecal pump care were assumed to be the same as for UC.[7] This is informed based on an assumption made by Health Quality Ontario (2016); in their study, the authors found no evidence that utility was higher with intrathecal pump treatment than it was for UC. Similarly, Smyth et al (2015) concluded that intrathecal pumps deliver no significant improvements in pain when compared to UC.

[6] This assumption diverges from the literature for modelling simplicity – for example, Simpson et al (2009) assumed different utility values and health system costs for patients with and without complications. In this model, the utility was held constant across the year, but the cost of complications was incorporated into the ongoing cost of SCS treatment.

[7] Although the utility values for health states in both arms are the same, utility is different over time because of the transition probabilities assigned to both arms. Different transition probabilities allow for differences in the number of people in each health state between the intervention and the comparator. See Table 2.9 detailing the differences in transition probabilities.

Table 2.2: Utility values

Health state	FBSS	CRPS	Cancer pain
SCS/IT optimal	0.62	0.59	0.53
SCS/IT suboptimal	0.41	0.42	0.26
UC optimal	0.54	0.52	0.53
UC suboptimal	0.32	0.27	0.26

Source: Kumar & Rizvi (2013). IT refers to intrathecal pumps for cancer pain.

2.3.5 Baseline employment and return to work

The average employment rate at baseline (pre-treatment) was set to 30% in the model for FBSS and CRPS patients, which was based on the simple average of the studies shown in Table 2.3.

Table 2.3: Baseline employment rates

Study	Employment rate (%)
Kumar et al (2008)	21.4
Kumar et al (2006)	4.6
North et al (1993)	37.4
Al-Kaisy (2017)	55.0
Gopal et al (2016)	79.0
North et al (1991)	20.0
Young et al (1978)	2.0

Source: Moens et al (2018).

It was assumed that there is no baseline employment for the cancer pain population as these patients generally have terminal phase cancer, with an average prognosis of 6 months (Brogan et al, 2013).

The probability of returning to work following treatment was informed based on Moens et al (2018) and expert opinion. In Moens et al (2018), the probability of returning to work for patients who achieve optimal pain relief through SCS was 15%. The probability of returning to work was only applied to the first year, assuming that patients who achieve optimal pain relief in the first year who have not yet returned to work are unlikely to return in subsequent years.

Based on consultation with NSANZ, it was also assumed that 3% of people who transition to SCS suboptimal or to UC optimal will return to work. The return to work percentages do not preclude a person from being employed prior to the trial and remaining employed throughout the trial, despite the patient not achieving any of the aforementioned health states.

Table 2.4: Probability of returning to work

Model input	SCS (FBSS)	SCS (CRPS)	UC
Probability of returning to work if optimal pain relief is achieved with SCS	15%	15%	-
Probability of returning to work if suboptimal pain relief is achieved with SCS	3%	3%	-
Probability of returning to work if optimal pain relief is achieved with UC	3%	3%	3%
Probability of returning to work if suboptimal pain relief is achieved with UC	0%	0%	0%

Source: Moens et al (2018) and consultation with NSANZ.

The average wage was calculated to inform the productivity benefits associated patients who are able to return to work. Annual wages were based on average weekly earnings from the Australian Bureau of Statistics (2018), where the average wage for a 50-54 year old male was $91,891 and $57,736 for a 50-54 year old female. It was assumed that the average patient is 50.4 years old and 51% of patients are male (Kumar et al, 2005). Thus, the average patient who returns to work following SCS was assumed to earn $75,155 per annum.

2.3.6 Health system costs for FBSS and CRPS

The cost of the intervention pathway for FBSS and CRPS incorporates the cost of trial stimulation, the implantation procedure and ongoing maintenance costs. The estimations for trial stimulation and implantation are based on publically-available data from the National Hospital Cost Data Collection (Independent Hospital Pricing Authority, 2018), and the Private Hospital Data Bureau annual report 2016-17 (Department of Health, 2018a), which respectively publish cost data for public and private hospitals by Australian refined diagnosis-related group (AR-DRG) code. The estimations for ongoing maintenance costs are informed by the Medicare Benefits Schedule (MBS) payable fees and resource utilisation are estimated with reliance upon the literature and expert opinion.

Table 2.5: Health system cost inputs, FBSS

Cost component	SCS ($)	UC ($)	Source/note
Trial stimulation	$7,476	-	Appendix Table A.1
Implantation	$31,630	-	Appendix Table A.2
Explantation	$2,155	-	Appendix Table A.8
Ongoing Costs	$5,709	$9,201 $11,797*	Appendix Table A.3

Source: as noted. * includes weighted cost of a repeat operation and additional imaging costs for people in the suboptimal care pathway.

Table 2.6: Health system cost inputs, CRPS

Cost component	SCS ($)	UC ($)	Source/note
Trial stimulation	$7,476	-	Appendix Table A.4
Implantation	$31,630	-	Appendix Table A.5
Explantation	$2,155	-	Appendix Table A.8
Ongoing annual maintenance costs (including ketamine infusions)	$6,046	$12,569 $13,482*	Appendix Table A.6

Source: as noted. *includes additional imaging costs for people in the suboptimal pathway.

Trial stimulation

The cost of a trial stimulation is $7,476 and this was assumed to be the same across both FBSS and CRPS. The trial stimulation cost comprises the cost of consultations, imaging, device costs and surgery costs.

The cost of consultations is $507 which comprises individual visits to a GP, pain specialist, neurosurgeon and psychologist. The unit cost of each of these is based on the MBS fees for these services (at 100% of the fee).

The cost of imaging assumes 1 CT scan, 1.5 MRI scans, 1 x-ray and 0.4 myelograms. The frequencies of imaging tests are based on expert opinion. The cost of each scan is based on the fees listed on the MBS, which multiplied by the number of images is $913.

Device costs include 2 temporary leads at $466 each, which was based on the average cost of trial leads on the prosthesis list (August 2018). It is assumed that there is no cost associated with the temporary external stimulator as the device could be reused.

Surgery costs for the trial were assumed to be $5,124, the same as the surgery costs in the implantation phase, which comprises costs of anaesthesia, the operating room and the average hospital stay.

- Anaesthesia costs are calculated as the cost of management of anaesthesia for extensive spinal cord procedures ($257.40 per MBS item 20670) combined with 1 hours of maintenance (4 units at a price of $19.45/unit). The total price of anaesthesia is $335.
- Operating room costs are calculated using the average cost of operating rooms in private and public hospitals for the insertion of a SCS device. This is based on the 2015-16 National Hospital Cost Data Collection and the 2016-17 Private Hospital Data Bureau. The total cost of operating rooms is $2,168.
- The remaining $2,621 is associated with the cost of the hospital stay, including ward costs, which was based on Independent Hospital Pricing Authority (2018).

It was assumed that patients unsuccessful in their trial will incur an additional cost as a result of the failed trial. The cost of explanting the device was estimated to be $2,155. The cost includes:

- the cost of anaesthesia (defined as initialisation per MBS code 20670) with 4 units of maintenance at $19.45/unit;
- the cost of surgical time to remove leads and device (MBS code 39136); and
- the cost of the operating room based on the average cost of other musculoskeletal procedures (minor complexity) (AR-DRG code I28C) across both private and public hospitals based on the National Hospital Cost Data Collection 2015-16 and the Private Hospital Data Bureau 2016-17 annual reports.

Permanent implantation

The cost of the SCS device implantation was assumed to be $31,630. This is assumed to be the same for FBSS and CRPS. The cost of implantation includes the cost of the device parts and the cost of surgery. The device parts include the cost of the permanent leads ($5,111) and the

implantable pulse generator ($21,395). These costs represent the average minimum benefit payable as listed on the Prostheses List (Department of Health, 2018). As for the trial, the surgery cost of implanting the device was estimated to be $5,124.[8] Similarly, if the device fails and needs to be explanted, the cost at the time of explant was assumed to be $2,155 as previously noted for the trial stimulation.

Ongoing maintenance cost

The ongoing maintenance cost is estimated at $9,201 (without reoperation) and $11,797 (with reoperation) for FBSS and $12,569 (without additional imaging) and $13,482 (with imaging) for CRPS. The maintenance cost includes medication and non-medication costs and the expected average cost associated with complications, the repeat operation (for 5% of FBSS patients in suboptimal UC) and ketamine infusions (for 2% of CRPS patients in the SCS arm and 20% of CRPS patients in the UC arm).

Non-drug costs comprise allied health treatments like physiotherapy, psychology, massage therapy, acupuncture and chiropractic treatment. Frequency of use for the UC population was derived from Kumar et al (2002) for the UC population, where they have:

- 57.6 physiotherapy sessions per year;
- 10.1 massage therapy sessions per year;
- 10.6 acupuncture sessions per year;
- 17.2 chiropractic sessions per year;
- 4 visits to a GP per year (assumed based on the care pathway); and
- 4 visits to a pain specialist per year (assumed based on the care pathway).

Manca et al (2008) also reported non-medication resource utilisation for SCS and UC. The percentage reduction in resource use from Manca was applied to the resource utilisation observed by Kumar et al (2002). Thus, the SCS population have:

- 7.4 physiotherapy sessions per year;
- 0 massage therapy sessions per year;
- 1 acupuncture sessions per year;
- 3.1 chiropractic sessions per year;
- 4 visits to a GP per year (assumed based on the care pathway);
- 4 visits to a pain specialist per year (assumed based on the care pathway);
- 2 visits to a neurosurgeon (assumed based on the care pathway); and
- 3 visits with a pain nurse (assumed based on the care pathway).

Using the MBS to price each service, the ongoing cost of non-medication treatment was $2,279 for SCS patients compared to $6,217 for UC patients.

Opioid medication reduction

In Australia there are over 3.2 million people using opioids, with more than 900 prescription opioid deaths in 2016-17 (Australian Institute of Health and Welfare, 2018). Patients who receive a neuromodulation device are typically high-dose opioid users, given that they are likely to have trialled opioids as treatment before receiving their SCS device (Sharan et al, 2018).

Opioids are chemical substances with morphine like attributes that are commonly used for pain relief, although they are also addictive and can cause associated problems of dependence including serious adverse events or death through overdose. There is also an increased risk when opioids are used to manage pain alongside other drugs including sedatives and alcohol. In Australia, there are currently more deaths associated with prescription opioids than with heroin, cocaine, or other illicit drugs (Australian Institute of Health and Welfare, 2018).

Opioids affect the brain in similar ways to heroin, attaching to opioid receptors throughout the brain and spinal cord triggering feelings of euphoria and wellbeing and reducing the patient's

[8] $31,708 is comparable with the average costs observed for the AR-DRG procedure code A12Z, *Insertion of neurostimulator device*. This method involves calculating the average daily cost across both private and public hospital which was approximately $29,823 in the 2016-17 financial year.

perception of pain (Tackett, 2018). However, the body can build tolerance to the effect of opioids over time, leading many patients to seek higher doses of the drug in order to achieve the same level of relief (Tackett, 2018). Dependence on higher doses of an opioid may lead to opioid addiction, creating a higher risk of overdose.

The average cost of an opioid prescription was assumed to be $5 a day, which is consistent with research from the US (see Han et al, 2017). To estimate the average daily cost of opioid therapy, a weighted average was derived from the most commonly prescribed items in Australia, which were then converted to morphine equivalent doses.[9] At a cost of 11 cents for 1mg of morphine (or equivalent), and assuming that the average patient has 47mgs of opioids (or equivalent) per day (Blanchard et al, 2017), the cost of opioid therapy is approximately $5 per day. For the UC group, the cost of opioid therapy was therefore likely to be $1,662.50 per year[10]. In the PROCESS trial, other medication costs made up about 44.3% of the total medication bill (Manca et al, 2008). Thus, the total costs of medication in the UC group were estimated to be $2,984.75.

SCS can successfully relieve pain and enable some patients to cease using opioids, which can lead to a reduced risk of opioid dependence and misuse, which has the potential to save additional lives (although these benefits have not been quantified in this report).

Conservatively, it was assumed that opioid-related medication costs are reduced by 25%, reflecting the reduction observed by Sharan et al (2018).

- Sharan et al (2018) estimated a 25% reduction in morphine equivalent dose after one year of SCS (both FBSS and CRPS patients).
- Sanders et al (2016) estimated a 45% reduction in morphine equivalent dose for FBSS patients and a 53% reduction for CRPS patients after one year.
- Kumar et al (2002) estimated that total drug costs reduced by 68% after one year.
- Zucco et al (2014) estimated a 73% reduction in total drug costs after one year.
- Calvillo et al (1998) estimated a 50% reduction in morphine equivalent dose 3 years after SCS for CRPS patients.

It was further assumed that the 25% reduction in opioid usage observed in SCS patients (Sharan et al, 2018) is reflective of the total reduction in medication costs. Thus, a 25% total reduction was applied, giving medication costs of $2,239 for SCS patients.

The ongoing maintenance cost also comprises the cost of complications. As noted, complications were only modelled for the SCS population, which is a conservative assumption that favours UC. As complications can vary from minor adjustments of the device to a complete explant and reimplant of the SCS device, there is a large variation in costs.

The average expected cost of a complication was assumed to be $1,191 (18% of $6,619), which was based on Simpson et al (2009) where the average annual expected cost of a complication was £393 in 2007.[11]

As noted earlier, 5% of FBSS patients in suboptimal UC will have a repeat operation annually (Simpson et al, 2009). The cost of the repeat operation was assumed to be $33,653, which was based on the average weighted cost of I09A (major complexity), I09B (medium complexity), and I09C (minor complexity) AR-DRG procedure codes for spinal fusion surgeries in the National

[9] Typically, utilisation of opioids is reported relative to morphine, where 1mg of codeine = 0.13mg of morphine, 1mg of tramadol = 0.2mg of morphine, 1mg of oxycodone = 1.5mg of morphine, and 1mcg of buprenorphine = 2mg of morphine. These conversion units were used to derive the average cost of 1mg of morphine (or equivalent) for each opioid, which were 18 cents, 7 cents, 11 cents, 1 cent and 7 cents, respectively. Weighted by script volume, the average cost of 1mg of morphine (or equivalent) was estimated to be 11 cents.
[10] Patients had medication therapy covering 332.5 days of the year on average.
[11] The annual expected cost was converted to current Australian dollars using purchasing power parity for the health sector, which was then adjusted to 2018 dollars by applying Australia's rate of health inflation. This was then divided by the complication rate (18%) to find the expected cost of a complication ($6,619). Weighting by the expected probability of a complication (18% again) yields an annual expected cost of complications of $1,191.

Hospital Cost Data Collection 2015-16 annual report (Independent Hospital Pricing Authority, 2018).[12] Thus, the expected cost of a repeat operation was assumed to be $1,683 per year.

Finally, the cost of a ketamine infusion was assumed to be $4,209, which was modelled by assuming that patients receive the infusion as an inpatient of a hospital, delivered over 5 days. In the SCS arm, 2% of CRPS patients receive ketamine infusions every 3 months compared to 20% in the UC arm.

- A patient typically receives 20-30mg of ketamine per hour, for 24 hours of the day (Sigtermans et al, 2009). By assuming that patients receive 22mg of ketamine per hour (as in Sigtermans et al, 2009), 2.64g of ketamine is required for their stay in hospital. Based on prices listed by Chemist Warehouse in December 2018, 1mg of ketamine costs $0.20 ($200 for 1000mg), so the total cost of ketamine is approximately $528.
- As well as the cost of ketamine, a patient will also have an opioid infusion, which based on Casamayor et al (2018) and Palmer et al (2017) costs $297.64.[13]
- The cost of the infusion also includes the cost of staying in hospital for 5 nights, which was estimated to be $677 per day based on the average cost of an infusion for musculoskeletal disorders from Independent Hospital Pricing Authority (2018) and the Department of Health (2018a), noting that this excludes pharmacy-related costs.

It was assumed that the ketamine cost is additional to other ongoing costs of maintenance therapy for CRPS patients.

In summary, the ongoing cost for:

- **FBSS SCS patients was assumed to be $5,709** comprising $2,279 in non-medication costs, $2,239 in medication costs, $1,191 in complication costs;
- **FBSS UC patients with optimal pain relief was assumed to be $9,201**, comprising $6,217 in non-medication costs and $2,985 in medication costs;
- **FBSS UC patients with suboptimal pain relief was assumed to be $11,797**, comprising $6,217 in non-medication costs, $2,985 in medication costs, $1,683 in repeat operations, and $913 in imaging costs;
- **CRPS SCS patients was assumed to be $6,046** comprising $2,279 in non-medication costs, $2,239 in medication costs, $1,191 in complication costs, and $337 in ketamine infusion costs;
- **CRPS UC patients with optimal pain relief was assumed to be $12,569**, comprising $6,217 in non-medication costs, $2,985 in medication costs, and $3,367 in ketamine infusion costs; and
- **CRPS UC patients with suboptimal pain relief was assumed to be $13,482** comprising $6,217 in non-medication costs, $2,985 in medication costs, and $3,367 in ketamine infusion costs, and $913 in imaging costs.

2.3.7 Health system costs for cancer pain

The health system costs for intrathecal pumps include the cost of implantation, ongoing maintenance and device explantation.

[12] NSANZ indicated the surgery can cost up to $60,000 to $70,000, which is comparable to the average cost of a major complexity spinal fusion (AR-DRG I09A) (Independent Hospital Pricing Authority, 2018).
[13] Country estimates, including drugs, materials, workforce, adverse events and intravenous therapy complications, were converted to Australian dollars using purchasing power parity in 2014, and then updated for health inflation.

Table 2.7: Health system cost inputs, cancer pain

Cost component	Intrathecal pumps ($)	UC ($)	Source/note
Implantation	30,913	-	Appendix Table A.7
Ongoing monthly maintenance costs	2,698	5,730	Appendix Table A.7
Explantation	2,155	-	Appendix Table A.8

Source: as noted.

The cost of an intrathecal pump was assumed to be captured by AR-DRG codes A11A and A11B, which cover the insertion of implantable spinal infusion devices (major and minor complexity) (Independent Hospital Pricing Authority, 2018; Department of Health, 2018a). The average cost of implanting an intrathecal pump was estimated at $30,913, which is the weighted average cost of the procedure across both public and private hospitals. Of this total, the average cost of prostheses represented $14,962, which is comparable with the cost of an intrathecal pump outlined in section 2.2.2.

It was assumed that the cost of explanting the pump was assumed to be same as explanting a SCS device, or $2,155.

Ongoing monthly costs were assumed to be $2,698 for the intrathecal pump patients and $5,730 for the comparator group. This is based on the monthly maintenance costs observed in Health Quality Ontario (2016), converted to current Australian dollars using purchasing power parity for the health sector and health inflation in Australia.

The monthly costs included additional inpatient hospitalisations, outpatient hospital visits, physician visits, home care and inpatient rehabilitation costs (Health Quality Ontario, 2016).

It is noted that the costs of treating intractable cancer pain in hospital can be substantially higher on a monthly basis. For example, the average daily cost of a hospital bed is approximately $1,342 (Independent Hospital Pricing Authority, 2018; Department of Health, 2018a).[14] For some patients, the only option will be to manage their pain in hospital. However, for conservatism, the modelling uses the data from Health Quality Ontario (2016).

2.3.8 Baseline and annual transition probabilities

Baseline and annual transition probabilities for FBSS and CRPS

The probability of a patient achieving an optimal health state after undergoing SCS implantation is 59%, which was based on Kumar et al (2007). The remaining 41% achieve a suboptimal health state at baseline.

This assumption may be conservative as more recent studies (see Russo et al, 2017) show that newer SCS systems can achieve an initial optimal health state for upwards of 90% of patients with back pain. Similarly, Kapural et al (2015) found that patients receiving high frequency neurostimulation devices were significantly more likely to achieve optimal pain relief (76.5%) compared to patients with low frequency neurostimulation devices (49.3%). Burst stimulation and 3D neural targeting SCS devices also offer superior pain relief compared to traditional SCS devices (Veizi et al, 2017).

Furthermore, developments in the use of dorsal root ganglion stimulation are also likely to improve a patient's likelihood of achieving optimal pain relief through neurostimulation. Deer et al (2017) found that 81% of dorsal root ganglion patients achieved optimal pain relief compared to 55% of

[14] The average daily cost was calculated as the weighted average of AR-DRG codes for the treatment of malignant or musculoskeletal neoplasms, adjusted to remove costs of medical interventions and pharmacy costs that are not related to ward nursing.

patients with traditional SCS devices.[15] The sensitivity analysis presents results showing the likely effect of these newer technologies on the cost effectiveness results.

The annual transition probabilities for FBSS patients were based on Simpson et al (2009) and updated in consultation with NSANZ. The probabilities are presented in Table 2.7.

A patient may transition out of their respective SCS health state if their device fails to provide any pain relief in a given period or if they experience a complication which requires explantation. The rate of withdrawal from SCS is set to 4.7% for all patients with SCS devices, which was based on annual complication rates requiring explantation reported by Hayek et al (2015), van Buyten (2003), Han et al (2017), and van Buyten et al (2017). Of those transitioning out of SCS approximately 91% will transition into UC suboptimal with the remainder transitioning into UC optimal (Simpson et al, 2009). The estimated explant rate may be conservative as explant rates are lower with newer SCS technologies (see for example Veizi et al, 2017).

Patients in the UC optimal arm will remain in UC optimal or transition to UC suboptimal. It is estimated that 10% of patients will transition to the suboptimal health state (informed based on consultation with NSANZ). It was assumed that 5% of patients will transition from UC suboptimal to UC optimal and that a further 2% of patients will successfully transition to SCS.

It was also assumed that 1% of patients may transition from UC suboptimal to UC optimal, which is the weighted probability of a successful repeat operation based on Simpson et al (2009). It was assumed that a further 4% of patients may transition from UC suboptimal to UC optimal through alternative therapies based on consultation with NSANZ.

A mortality rate of 0.9% was applied to patients within the model (Simpson et al, 2009). The mortality rate is independent of the health state of the individual and thus remains constant regardless of the person's current and previous health states – that is, the interventions do not affect the mortality rate.

Table 2.7: Baseline probabilities and annual transition probabilities, FBSS

Probability	SCS optimal	SCS suboptimal	UC optimal	UC suboptimal
Baseline probabilities				
Intervention	58.5	41.5	0.0	0.0
Comparator	0.0	0.0	9.3	90.7
Annual transition probability				
SCS optimal	90.4	3.0	0.0	1.17
SCS suboptimal	4.0	91.4	0.0	0.83
UC optimal	0.4	0.4	89.1	5.0
UC suboptimal	4.3	4.3	10.0	92.1
Death	0.9	0.9	0.9	0.9

Source: based on Kumar et al (2008) and expert opinion.

The annual transition probabilities for CRPS were assumed to be comparable, with the exception that repeat operations do not occur, and thus, only 4% of patients in UC suboptimal transition to UC optimal.

[15] With an estimated 30%-40% of patients now receiving high frequency variants of SCS (based on expert opinion) it is likely that the estimated probability of achieving optimal pain relief is understated.

Table 2.8: Baseline probabilities and annual transition probabilities, CRPS

Probability	SCS optimal	SCS suboptimal	UC optimal	UC suboptimal
Baseline probabilities				
Intervention	58.5	41.5	0.0	0.0
Comparator	0.0	0.0	9.3	90.7
Annual transition probability				
SCS optimal	90.4	3.0	0.0	1.17
SCS suboptimal	4.0	91.4	0.0	0.83
UC optimal	0.4	0.4	89.1	4.0
UC suboptimal	4.3	4.3	10.0	93.1
Death	0.9	0.9	0.9	0.9

Source: based on Kumar et al (2008) and expert opinion.

Baseline and annual transition probabilities for cancer pain

It is assumed that there is a 40% probability that a patient implanted with an intrathecal pump will achieve an optimal pain reduction. This assumption is informed by Rauck et al (2003) where 37%-43% of patients achieved optimal pain reduction across the first four months of the trial. The remaining 60% of patients were assumed to achieve a suboptimal pain reduction.

For simplicity, it was assumed that no intrathecal pumps are explanted; however, it is noted that there remains a possibility of complications (such as infection) requiring explant, which may increase the costs of the intervention. That said, there are also risks of infection from catheters, which would be used in the UC group to give patients a local anaesthetic and opioid infusion

As there are no explants, there is a 0% transition probability of changing to UC. However, it is assumed that 5% of patients transfer to suboptimal pain relief in each period (based on consultation with NSANZ).

UC can also effectively manage cancer pain. It was conservatively assumed that 40% of patients will achieve optimal pain relief at baseline (i.e. comparable with intrathecal pumps). However, there is likely to be a significant decline in the effectiveness of UC treatment beyond that observed for intrathecal pumps; the probability of transitioning to suboptimal pain relief in each month was set at 20% (based on consultation with NSANZ).

The mortality rate was set higher than for FBSS and CRPS as the patients have terminal phase cancer. A monthly mortality rate of 11.6% was applied in the model based on Brogan et al (2013). The population in Brogan et al (2013) survived for 5.6 months on average.[16]

[16] S = 1 – (1-M)^(1/K). *M* is set to 0.5 and represents the proportion of people still alive at a given point in time. The point in time is given by *K* and is set to 5.6 (months). Solving this equation for *S* yields *S*=0.116 which is now the proportion of people alive at one month. Thus the monthly probability of death is derived to be 11.6%.

Table 2.9: Baseline probabilities and monthly transition probabilities, cancer pain

Probability	IT optimal	IT suboptimal	UC optimal	UC suboptimal
Baseline probabilities				
Intervention	40.0	60.0	0.0	0.0
Comparator	0.0	0.0	40.0	60.0
Monthly transition probability				
IT optimal	83.4	0.0	0.0	0.0
IT suboptimal	5.0	88.4	0.0	0.0
UC optimal	0.0	0.0	68.4	0.0
UC suboptimal	0.0	0.0	20.0	88.4
Death	11.6	11.6	11.6	11.6

Source: Deloitte Access Economics based on expert opinion and Rauck et al (2003). IT refers to intrathecal pumps for cancer pain.

2.3.9 Other benefits not quantified

Absenteeism refers to short-term absences from work due to either FBSS or CRPS associated pain. This includes days off of work to visit health professionals, as a result of hospital admissions or remaining at home because of the associated pain. As a conservative assumption, the current analysis does not capture the benefits to absenteeism from the intervention. It is expected that the SCS intervention would reduce absenteeism amongst both FBSS and CRPS patient groups because they may have less pain than their respective UC cohorts. This benefit would occur in the 30% of the population initially employed and in those patients who return to work after the intervention.

Presenteeism relates to reduced productivity while at work due to the patient's condition. Conservatively, costs related to presenteeism are also not captured in the current model. It is noted that the SCS intervention is expected to improve presenteeism as patients may be able to work more effectively if they have less pain while at work. In a similar way, this benefit would occur in the 30% of the population initially employed and in those patients who return to work after the intervention.

As discussed in section 2.3.6, SCS is also likely to reduce the number of patients who rely on long-term opioid therapy to achieve pain relief. For example, Sharan et al (2018) reported that 44% of patients with SCS were able to reduce their opioid usage by 10% or more. A further 26% of patients stabilised their opioid use, which had been increasing over time. There are significant risks associated with greater reliance on opioid therapy, including risk of dependence and subsequent serious adverse events or death through overdose. SCS can lower the risk of these outcomes, although it was not possible to include these benefits in the modelling due to a lack of available data.

3 Model results

3.1 SCS for FBSS

SCS is cost effective for FBSS under the base assumptions in the model. For FBSS, the intervention costs the health system $958 per person per year, with expected productivity benefits of $1,714 per person per year compared to UC.

Furthermore, each patient will gain 0.06 QALYs per year compared to UC. This yields an ICER from the health system perspective of $15,070/QALY, which is considered to be highly cost effective based on World Health Organization benchmarks.

Including the productivity benefits, SCS dominates UC – meaning that the intervention saves society money, and improves wellbeing at the same time.

Table 3.1: Cost effectiveness of SCS for FBSS patients

Intervention	Health system ($)	Productivity ($)	Utility (QALYs)	ICER HS ($/QALY)	ICER SC ($/QALY)
SCS for FBSS	958	-1,714	0.06	15,070	-11,902

Source: Deloitte Access Economics' calculations. HS = health system perspective. SC = societal perspective.

The results of the sensitivity analysis are shown in Table 3.2. The results of the analysis are most sensitive to the time horizon, discount rate, ongoing costs of SCS/UC treatment, and device longevity. As the time horizon shortens and the discount rate increases, health system costs increase, reflecting the high upfront costs of the intervention with benefits over a longer time period.

Increasing the cost of ongoing maintenance for SCS also has a significant effect on health system costs. Increasing the cost of UC maintenance by 20% results in the SCS intervention becoming the dominant treatment. The ICERs from a health system perspective range from $7,335/QALY to $45,017/QALY with the only exception being the 2 year time horizon (97,986/QALY).

Higher return to work rates and a higher probability of initial placement in an SCS optimal health state lead to significant productivity gains, while shorter time horizons do not encapsulate the future benefits associated with patients returning to work. The ICER from a societal perspective ranges from being dominant to $18,045/QALY when the time horizon of 2 years ($69,322/QALY) is excluded.

Table 3.2: Sensitivity analysis for FBSS

Model modification	Health system ($)	Productivity ($)	Utility (QALYs)	ICER HS ($/QALY)	ICER SC ($/QALY)
Base case	**958**	**-1,714**	**0.06**	**15,070**	**-11,902**
Return to work = 10%	958	-1,000	0.06	15,070	-664
Return to work = 20%	958	-2,429	0.06	15,070	-23,141
Return to work = 30%	958	-3,857	0.06	15,070	-45,617
Initial probability of achieving SCS optimal = 50%	958	-1,532	0.06	16,308	-9,784
Initial probability of achieving SCS optimal = 75%	958	-2,065	0.07	13,146	-15,194
Trial success probability = 70%	946	-1,483	0.06	17,077	-9,700
Trial success probability = 90%	965	-1,847	0.07	14,134	-12,929
Time horizon = 2 years	1,727	-505	0.02	97,986	69,322
Time horizon = 5 years	1,127	-1,043	0.04	31,402	2,336
Time horizon = 10 years	1,333	-1,536	0.05	24,812	-3,782
Discount rate = 3%	893	-1,862	0.07	12,801	-13,891
Discount rate = 7%	1,014	-1,588	0.06	17,376	-9,844
UC utility = SCS utility	958	-1,714	0.03	37,025	-29,244
UC utility = 90% of SCS utility	958	-1,714	0.08	12,023	-9,496
SCS ongoing costs = 120%	1,449	-1,714	0.06	22,804	-4,168
SCS ongoing costs = 80%	466	-1,714	0.06	7,335	-19,637
UC ongoing costs = 120%	958	-1,714	0.06	15,070	-11,902
UC ongoing costs = 80%	958	-1,714	0.06	15,070	-11,902
Device lifespan = 5 years	2,861	-1,714	0.06	45,017	18,045
Device lifespan = 7 years	1,823	-1,714	0.06	28,682	1,710

Source: Deloitte Access Economics modelling. HS = health system perspective. SC = societal perspective.

3.2 SCS for CRPS

SCS is cost effective for CRPS under the base assumptions in the model. For CRPS, the intervention costs the health system $188 dollars per person per year, with expected productivity benefits of $1,716 per person per year compared to UC.

Furthermore, each patient will gain 0.08 QALYs per year compared to UC. This yields an ICER from the health system perspective of $2,321/QALY, which is considered to be highly cost effective based on World Health Organization benchmarks. From a societal perspective, SCS dominates UC – meaning that the intervention saves society money, and improves wellbeing at the same time.

Table 3.3: Cost effectiveness of SCS for CRPS patients

Intervention	Health system ($)	Productivity ($)	Utility (QALYs)	ICER HS ($/QALY)	ICER SC ($/QALY)
SCS for CRPS	188	-1,716	0.08	2,321	-18,868

Source: Deloitte Access Economics' calculations. HS = health system perspective. SC = societal perspective.

The results of the sensitivity analysis are shown in Table 3.3. The factors affecting both the health system and productivity remain the same as those presented above for FBSS. If the time horizon

of two years is excluded, the range of ICERs for the health system are $-4,115/QALY to $25,869/QALY.

Thus the intervention remains highly cost effective so long as a time horizon for the model is at least 5 years. From a societal perspective the ICERs range from being dominant to $4,680/QALY when the time horizon of two years is excluded.

Table 3.4: Sensitivity analysis for CRPS

Model modification	Health system ($)	Productivity ($)	Utility (QALYs)	ICER HS ($/QALY)	ICER SC ($/QALY)
Base case	**188**	**-1,716**	**0.08**	**2,321**	**-18,868**
Return to work = 10%	188	-1,001	0.08	2,321	-10,039
Return to work = 20%	188	-2,431	0.08	2,321	-27,698
Return to work = 30%	188	-3,861	0.08	2,321	-45,356
Initial probability of achieving SCS optimal = 50%	188	-1,534	0.08	2,439	-17,465
Initial probability of achieving SCS optimal = 75%	188	-2,066	0.09	2,124	-21,223
Trial success probability = 70%	281	-1,485	0.07	3,977	-17,072
Trial success probability = 90%	135	-1,849	0.09	1,549	-19,706
Time horizon = 2 years	1,567	-505	0.02	73,833	50,034
Time horizon = 5 years	765	-1,043	0.04	17,367	-6,311
Time horizon = 10 years	726	-1,537	0.07	10,761	-12,019
Discount rate = 3%	34	-1,864	0.09	376	-20,518
Discount rate = 7%	319	-1,590	0.07	4,300	-17,158
UC utility = SCS utility	188	-1,716	0.02	7,973	-64,809
UC utility = 90% of SCS utility	188	-1,716	0.09	1,981	-16,103
SCS ongoing costs = 120%	709	-1,716	0.08	8,758	-12,432
SCS ongoing costs = 80%	-333	-1,716	0.08	-4,115	-25,305
UC ongoing costs = 120%	188	-1,716	0.08	2,321	-18,868
UC ongoing costs = 80%	188	-1,716	0.08	2,321	-18,868
Device lifespan = 5 years	2,095	-1,716	0.08	25,869	4,680
Device lifespan = 7 years	1,055	-1,716	0.08	13,029	-8,161

Source: Deloitte Access Economics analysis. HS = health system perspective. SC = societal perspective.

3.3 Intrathecal pump for cancer pain

Using intrathecal pumps for cancer patients is also expected to be cost effective given the base assumptions. The intervention is expected to cost the health system $792 per person per month compared to UC, with an associated gain of 0.02 QALYs per person per month.[17] From a health system perspective, the ICER was estimated to be $44,047/QALY.

The small utility gain, large upfront cost and the high mortality rate associated with the relevant population are all significant drivers of the results.

[17] The QALY gain occurs despite assuming both pathways have equal utility for the optimal and suboptimal health states as it was assumed that patients with an intrathecal pump maintain an optimal reduction in their pain for a longer period of time (5% of patients transition monthly, compared to 20% for UC).

The results of the sensitivity analysis are shown in Table 3.6. The cost effectiveness of intrathecal pumps for cancer pain is highly sensitive to the mortality rates in the model, and the monthly costs of care. For example, intrathecal pumps are highly cost effective (ICER of $4,887/QALY) if 50% of patient survive for 12 months, and cost saving if 50% of patients survive for 18 months.

Table 3.5: Average results for cancer pain

Intervention	Health system ($)	Utility (QALYs)	ICER HS ($/QALY)
IT for cancer pain	792	0.02	44,047

Source: Deloitte Access Economics analysis. HS = health system perspective. IT refers to intrathecal pumps for cancer pain.

Similarly, if the costs of UC increase to $8,000 per month, intrathecal pumps would save the health system money. However, if the ongoing costs of UC decrease to $4,000 per month, intrathecal pumps are unlikely to be cost effective (ICER of $84,347/QALY).

Table 3.6: Sensitivity analysis for cancer pain

Model modification	Health system ($)	Utility (QALYs)	ICER HS ($/QALY)
Base case	**792**	**0.02**	**44,047**
Median survival = 3 months	1,318	0.01	131,025
Median survival = 12 months	138	0.03	4,887
Median survival = 18 months	-141	0.03	-4,322
UC monthly costs = $4,000	1,516	0.02	84,347
UC monthly costs = $8,000	-159	0.02	-8,850
IT monthly costs = $2,000	499	0.02	27,777
IT monthly costs = $3,500	1,127	0.02	62,725

Source: Deloitte Access Economics analysis. HS = health system perspective.

Two other studies have also concluded that intrathecal pumps do not break even compared to UC within a 15-month period. Brogan et al (2013) found that for the majority of patients, time to cost equivalence is greater than 24 months. It is noted that the analysis in Brogan et al (2013) is based on a small sample size and highly sensitive to the results for a small number of patients. Excluding these cases, the percentage reduction in ongoing costs is similar to that observed by Health Quality Ontario (2016). Mueller-Schwefe et al (2002) similarly found that intrathecal pumps do not reach cost equivalence before 18 months.

In the base case, 50% of patients survive for 5.6 months. Removing the implications of mortality, the sensitivity analysis revealed that intrathecal pumps would save the health system money for each patient after 8 to 13 months (depending on the monthly costs for intrathecal pumps and UC, respectively).

3.4 Scenario analysis

Three scenarios were considered that outline the potential pathways of a select group of patients who would be clinically indicated to receive SCS treatment. In each pathway, the health system costs are compared to the most relevant comparator (NSANZ provided scenarios for the modelling that reflect real world uses for neuromodulation treatment) available to the patient.

Under the proposed changes to private health insurance, neuromodulation treatments are covered in the gold tier health insurance policies, while the comparator treatments are covered by silver tier health insurance policies (Department of Health, 2018). The scenarios focus on the expected interactions with the health system for a patient who holds a silver tier health insurance policy.

Given the relative simplicity of the new tiered health insurance system, it is possible that patients may choose to upgrade their level of coverage to gold tier policies where they can afford to do so. Similarly, it is possible that patients may be able to afford neuromodulation treatment out of pocket, although the up-front costs can be prohibitively high. Importantly, the interactions of patients who would be eligible for neuromodulation treatment have not been modelled in this report.

With that in mind, for each scenario, it has been assumed that the patient's level of private health insurance cover will determine if the patient receives neuromodulation treatment or the comparator treatment. So, for each scenario, the patient is unable to switch from the silver tier policy to an alternate policy. Thus, the scenarios demonstrate the potential gains for the health system (and for individuals) if neuromodulation treatments were included in silver tier health insurance policies.

The scenarios are representative of a typical care pathway that is modelled earlier in chapters 2 and 3, although the following modifications have been made.

- For FBSS, the patient undergoes a repeat operation (which is successful) at baseline. The model assumes that 5% of patients undergo a repeat operation each year with a 20% success rate.
- For CRPS, the patient commences a course of ketamine treatment. The model assumes that 20% of patients will follow this pathway, and 2% of patients with SCS may still require treatment with ketamine.
- For cancer pain, the patient will be admitted to hospital as an inpatient. They will receive full time care in hospital. The model bases ongoing maintenance costs on Health Quality Ontario (2016), where the ongoing cost does not reflect the cost of a patient spending their time as an inpatient in hospital.

The scenarios assume that both the intervention and comparators are successful, and benefits associated with the patient's return to work, increased tax revenue and reduced deadweight loss are assumed to be comparable across both pathways (i.e. both treatments are successful). Thus, the focus is on potential reductions in healthcare expenditure and any associated utility gain (informed by the assumptions in chapter 2).

3.4.1 Scenario 1: Access to SCS for a patient with FBSS

Brian is a 45 year old chartered accountant with three children. One day while undertaking some home renovations, Brian has a fall and injures himself – he sustains disc injuries at L4/5 and L5/S1 and develops severe sciatica and lower back pain. He can't cope at work because of his pain and decides to take sick leave.

On the advice of his local GP, Brian decides to try some analgesics and physiotherapy. After a month, however, Brian's symptoms have not improved and he returns to his GP who refers him to an orthopaedic spinal surgeon.

Based on Brian's imaging results, his surgeon recommends that Brian have a L5/S1 microdiscectomy. He advises that this will have a good chance of helping Brian's leg pain and that continued physiotherapy and prescription analgesics should control the back pain. Brian undergoes the surgery but his pain persists.

Brian returns to see the surgeon who arranges another MRI and then advises that there is still a significant disc at L5/S1. He recommends a laminectomy to "free up the nerve roots". Brian sees no other choice and proceeds with the surgery.

Three months later, his leg pain has improved somewhat but his back pain remains. He is entirely compliant with his prescribed physiotherapy and the management advice from his GP, but he is still struggling.

Brian returns to see his surgeon and also gets an opinion from a specialist pain physician. At this point he is offered 2 pathways:

1. a two-level (L4-L5 and L5-S1) anterior lumbar interbody fusion with posterior decompression and pedicle screw to stabilise the back
2. a trial of neuromodulation.

With neuromodulation available under his silver tier private health insurance policy, Brian chooses to undergo the trial phase, where he is told he has an 80% chance of noticing a considerable reduction in his level of pain. Brian is admitted to hospital where he undergoes monitoring with an external stimulator. Brian completes the trial successfully and has a neuromodulation device implanted to use as a long term treatment option. The cost of the neuromodulation device trial and implant comes to approximately $39,000 (see Table 2.5).

Over the following months, Brian continues to see his GP and physiotherapist for continued pain management, although his level of pain is greatly reduced. Over time, Brian is able to reduce his reliance on prescription opioid medications and the opioid risks reduce substantially. Brian's device continues to provide pain relief and he has an additional operation after 10 years to have the device battery replaced. The costs associated with Brian's continued treatment and maintenance of pain under the SCS care pathway (see Table 2.5) total approximately $120,000 over 15 years.

If neuromodulation is not covered by Brian's silver tier insurance policy, he chooses to undergo the anterior lumbar interbody fusion operation. The cost of the operation is conservatively estimated at $33,000[18] (section 2.3.6), which is covered by Brian's health insurance policy. The operation is a success, but Brian is more reliant upon his physiotherapy and on medication to maintain his pain relief. As a result his yearly maintenance costs are significantly higher than if he had chosen the neuromodulation pathway ($9,201 as shown in Table 2.5). The associated health system costs over a 15 year period total $132,000.

If neuromodulation is categorised as a silver tier level policy, Brian's health system expenditure could be reduced by $12,000. He also has a personal gain of 1.2 QALYs – a result of the higher utility achieved in the neuromodulation pathway (discussed in section 2.3.4).

3.4.2 Scenario 2: Access to SCS for a patient with CRPS type 1

Susan is a 50 year old woman who is in otherwise good health, she works part time as a secretary at a retirement village. One Saturday when she is gardening with her family, Susan has a fall and suffers a rotator cuff strain that goes on to become a frozen shoulder.

Within three weeks, the pain has worsened and Susan returns to her GP to learn that she has developed the 'shoulder hand' variant of complex regional pain syndrome (CRPS) type 1. The specialist pain physician advises Susan to keep undertaking her physiotherapy and chiropractic sessions.

After three weeks, Susan's pain has continued to deteriorate – it is now 10 out of 10 on the pain scale and it is making normal everyday activities unbearable. On return to the specialist pain physician, Susan is advised of two options for the ongoing treatment of her pain:

1. receive regular ketamine infusions; or
2. a trial of neuromodulation.

With neuromodulation available under Susan's silver tier insurance policy, Susan elects to undergo trial stimulation. After a period of two weeks, she has noticed a considerable reduction in her level of pain and is able to use her hand with minimal impairment. Her specialist pain physician and GP agree that the trial has been a success and assign her a permanent machine complete with a device and associated leads. Susan's health insurance covers most of the cost of this treatment, with Susan left with minimal out of pocket expenses.

Over the following months, Susan continues to see her GP and physiotherapist and she notices a sustained improvement in her level of pain. Susan is able to reduce her reliance on prescription

[18] NSANZ indicated the surgery can cost up to $60,000 to $70,000, which is comparable to the average cost of a major complexity spinal fusion (AR-DRG I09A) (Independent Hospital Pricing Authority, 2018).

opioid medications and the opioid risks reduce substantially. Her ongoing costs are representative of the average CRPS patient (Table 2.6).

If instead neuromodulation is not covered under Susan's silver tier insurance policy, Susan would need to receive regular ketamine infusions to achieve relief from her pain. To receive her treatment, she is admitted to hospital and an anaesthetist applies the ketamine infusion.

Over the week following her treatment, Susan sees her specialist pain physician each day to monitor her progress and stability. Her pain has improved substantially, and she is more able to undertake her standard daily activities and she even has more use of her hand. After six weeks, however, Susan notices that her pain starts to flare back up – she settles into a long term pattern of regular ketamine infusions four times per year, alongside other conventional management treatments. Susan's ongoing costs total $27,000 (this is significantly higher than the average ongoing costs presented in Table 2.6 as only 20% of patients are expected to receive ketamine infusions). This presents a significantly higher annual cost to the health system than under neuromodulation treatment.

Overall, if the neuromodulation pathway was chosen, Susan's total health expenditure would have been $55,000 lower. Susan also benefits from improved quality of life – an additional gain of 0.4 QALYs – as the pain relief from SCS does not wear off as it does for ketamine treatments (discussed in section 2.3.4).

3.4.3 Scenario 3: Access to intrathecal pumps for intractable cancer pain

Meg is a retiree and has recently quit smoking. On a recent holiday to Asia with her husband and three dependent children, Meg experienced a continued cough and wheezing. After six weeks, Meg has not recovered from her condition and is experiencing severe pain across her chest, shoulder and arm.

Meg attends her local GP who recommends that she undergo a CT scan and an MRI. Based on her presentation and the diagnostic scans, the GP explains that she has advanced stage primary lung cancer. The tumour is invading the brachial plexus causing severe neuropathic pain. Her GP prescribes medication to control her pain, including opioids and oral antineuropathic pain agents.

After a month, however, Meg's symptoms have not improved and she returns to her GP who refers her to a surgical radiologist. Over the subsequent months, Meg undergoes radiotherapy for her tumour. Meg's condition continues to deteriorate and she becomes increasingly frail. Meg is told that she is unlikely to live beyond the next six months and she is given two options for her pain management:

1. brachial plexus catheter insertion; or
2. placement of an intrathecal pump.

If the intrathecal pump is available under Meg's silver tier insurance policy, Meg may choose to select this option. Meg presents to hospital for the placement of the intrathecal pump and she is then able to return home. She visits the pain clinic for a refill every three weeks. Meg is looked after by her family in her own home, affording her dignity and privacy. After six months of receiving this care, Meg is transferred to the hospice where she lives the remainder of her life. The cost of this treatment pathway is approximately $47,000 (see Table 2.7).

If intrathecal pumps are not covered under Meg's insurance policy, Meg will choose the brachial plexus catheter insertion. Meg is admitted to a private hospital for catheter insertion and receives a continuous local anaesthetic plus opioid infusion. She is placed in a high dependency bed and a nurse is assigned to monitor the severity of her pain and to check on her vital signs every hour, around the clock. Meg receives this treatment for six months until she is transferred to the hospice where she lives her remaining life. Over the six months, the total cost comes to around $245,000, assuming an average daily cost of $1,342 (see section 2.3.7).

If Meg is able to choose the intrathecal pump, there is an associated $198,000 saving to the health system. While this is a substantial saving, it should be noted it does not appear that all patients with intractable cancer pain receive care exclusively in hospital (discussed in section 2.3.7), as the average monthly cost totals $5,730 for UC (see Table 2.7).

Conclusions

The chronic conditions of FBSS, CRPS and intractable cancer pain pose a substantial burden upon the affected population. Cost effective interventions are essential to provide effective pain relief to those patients and to reduce the burden upon the health system and society more broadly.

SCS devices can provide significant pain relief to FBSS and CRPS patients who would otherwise be subject to conventional management with a lower possibility of achieving optimal pain relief. There is demonstrable evidence that SCS devices can halve the amount of pain a patient is in for more than 50% of the relevant population. With continual advances in technology in this area it is possible that upwards of 90% of patients can achieve this pain reduction.

SCS devices were estimated to be cost effective from the perspective of the health care system. Using SCS devices for FBSS cost $15,070 per QALY gained and $2,321 per QALY gained for CRPS. From a productivity perspective, SCS devices are dominant for both FBSS and CRPS patients. This is driven by the significant proportion of people who are able to return to work.

Intrathecal pumps are estimated to provide optimal pain relief to 60% of patients with intractable cancer pain. There are immeasurable benefits from affording dignity, privacy and comfort to patients who are able to remain at home instead of spending the majority of their remaining life in a hospital bed. Intrathecal pumps were estimated to cost the health system $44,047 per QALY gained.

The results in this report suggest that SCS devices in particular are highly cost effective, and in certain circumstances, can be cost saving. As such, SCS devices should be made available to as much of the applicable patient population as possible. Under the proposed reforms to private health insurance (to take effect in April 2019) this may not be possible. For example, patients who have silver tier health insurance policies may elect to receive the comparator treatments (repeat operations, or a local anaesthetic with opioid infusion in hospital), which would be covered by their policy. More research is warranted to ensure that patients have equitable access to the most effective treatments for their condition.

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Appendix A Detailed model inputs

A.1. Detailed health system cost tables

Table A.1: Trial stimulation cost inputs, FBSS

Cost component	SCS ($)	UC ($)	Source/note
Consultation costs	*507*	-	Assuming 1 visit with each of GP, neurosurgeon, pain specialist and psychologist. Unit costs based on the MBS fee. $51.60 for GP visit, 291.2 for neurosurgeon, 101.84 pain specialist, $62.3 for psychologist.
Imaging costs	*913*	-	Assuming 1.0 CT scans, 1.5 MRI scans, 1.0 X-rays and 0.4 myelograms on average. Unit costs based on the MBS fee. $240.85 per CT scan, $368.7 per MRI scan and $85.3 for x-ray or myelogram.
Device costs	*932*	-	Two temporary leads, based on the minimum benefit payable on the prostheses list. $466.0 per lead
Surgery costs	*5,124*	-	Anaesthetist costs based on the MBS, and surgery and operating fees based on Independent Hospital Pricing Authority (2018). $335.2 for anaesthetic, $2,621 for hospital fees and $2,168 for operating fees.
Trial stimulation	**7,476**	-	

Source: as noted.

Table A.2: Implantation cost inputs, FBSS

Cost component	SCS ($)	UC ($)	Source/note
Permanent Leads	5,111	-	Prostheses costs are based on the average minimum benefits payable for products listed on the Prostheses List as at August 2018.
Pulse Generator	21,395	-	As above
Surgery	5,124	-	Anaesthetist costs based on the MBS, and surgery and operating fees based on Independent Hospital Pricing Authority (2018). $335.2 for anaesthetic, $2,621 for hospital fees and $2,168 for operating fees.
Implantation	**31,630**	**-**	

Source: as noted.

Table A.3: Ongoing maintenance cost inputs, FBSS

Cost component	SCS ($)	UC ($)	Source/note
Medications	*2,239*	*2,985*	Assuming 332 days utilisation of prescription opioids for UC. Assumed $5 cost per day. Assumed SCS total medication expenditure 25% lower. Opioid expenditure sums to 44.3% of total SCS medication and 44.3% of UC medication.
Non-medication (GP visits, physiotherapy, nerve blocks etc.)	*2,279*	*6,217 for optimal relief* *Additional surgery costs of 1,683 for suboptimal relief (weighted expected value)* *Additional imaging costs of 913 for suboptimal relief*	Resource utilisation is based on results from the PROCESS trial as reported in Manca et al (2008), or Kumar et al (2002). For SCS, assumes 4 GP visits per year, 2 neurosurgeon consultations, 3 nurse consultations, 4 pain specialist visits, and 7.4 physiotherapy sessions, 4 psychotherapy sessions, 0 massage therapy, 1 acupuncture visit, 0 nerve blocks and 3.1 chiropractic treatments. For UC, assumes 4 GP visits per year, 4 pain specialist visits, 57.6 physiotherapy sessions, 10.1 massage therapy, 10.6 acupuncture sessions, and 17.2 chiropractic treatments. It was assumed that patients with suboptimal pain relief also receive 1.0 CT scans, 1.5 MRI scans, 1.0 X-rays and 0.4 myelograms on average. Unit costs based on the MBS fee. $240.85 per CT scan, $368.7 per MRI scan and $85.3 for x-ray or myelogram. Unit costs based on the MBS fee. $101.8 for pain specialist, $51.60 for GP consultation, $127.8 for nurse consultation, $62.3 for physiotherapy and chiropractic treatment, $45.7 for massage therapy and acupuncture. 5% of patients have a subsequent spinal fusion each year, at a weighted cost of $33,653.
Ongoing cost of complications per year	1,191	-	Expected value based on Simpson et al (2009). The annual probability of a complication was assumed to be 18%.
Ongoing cost of maintenance per year	**5,709**	**9,201 for optimal relief.** **11,797 for suboptimal relief.**	

Source: as noted.

Table A.4: Trial stimulation cost inputs, CRPS

Cost component	SCS ($)	UC ($)	Source/note
Consultation costs	*507*	-	Assuming 1 visit with each of GP, neurosurgeon, pain specialist and psychologist. Unit costs based on the MBS fee.
Imaging costs	*913*	-	Assuming 1.0 CT scans, 1.5 MRI scans, 1.0 X-rays and 0.4 myelograms on average. Unit costs based on the MBS fee. $240.85 per CT scan, $368.7 per MRI scan and $85.3 for x-ray or myelogram.
Device costs	*932*	-	Two temporary leads, based on the minimum benefit payable on the prostheses list. $466.0 per lead.
Surgery costs	*5,124*	-	Anaesthetist costs based on the MBS, and surgery and operating fees based on Independent Hospital Pricing Authority (2018). $413.00 for anaesthetic, $2,621 for hospital fees and $2,168 for operating fees.
Trial stimulation	**7,476**	-	

Source: as noted.

Table A.5: Implantation cost inputs, CRPS

Cost component	SCS ($)	UC ($)	Source/note
Permanent Leads	5,111	-	Prostheses costs are based on the average minimum benefits payable for products listed on the Prostheses List as at August 2018.
Pulse Generator	21,395	-	As above
Surgery	5,202	-	Anaesthetist costs based on the MBS, and surgery and operating fees based on Independent Hospital Pricing Authority (2018). $335.2 for anaesthetic, $2,621 for hospital fees and $2,168 for operating fees.
Implantation	**31,630**	**-**	

Source: as noted.

Table A.6: Ongoing maintenance cost inputs, CRPS

Cost component	SCS ($)	UC ($)	Source/note
Medications	*2,239*	*2,985*	Assuming 320 days utilisation of prescription opioids for SCS and 332.5 for UC. Assumed $5 cost per day. Opioid expenditure sums to 30.7% of total SCS medication and 44.3% of UC medication.
Non-medication (GP visits, physiotherapy, nerve blocks etc.)	*2,279*	*6,217* *Additional imaging costs of 913 for suboptimal relief*	Resource utilisation is based on results from the PROCESS trial as reported in Manca et al (2008), or Kumar et al (2002). For SCS, assumes 4 GP visits per year, 2 neurosurgeon consultations, 3 nurse consultations, 4 pain specialist visits, and 7.4 physiotherapy sessions, 4 psychotherapy sessions, 0 massage therapy, 1 acupuncture visit and 3.1 chiropractic treatments. For UC, assumes 4 GP visits per year, 4 pain specialist visits, 57.6 physiotherapy sessions, 10.1 massage therapy, 10.6 acupuncture sessions, and 17.2 chiropractic treatments. It was assumed that patients with suboptimal pain relief also receive 1.0 CT scans, 1.5 MRI scans, 1.0 X-rays and 0.4 myelograms on average. Unit costs based on the MBS fee. $240.85 per CT scan, $368.7 per MRI scan and $85.3 for x-ray or myelogram. Unit costs based on the MBS fee. $291.2 for neurosurgeon, $101.8 for pain specialist, $51.60 for GP consultation, $127.8 for nurse consultation, $62.3 for physiotherapy and chiropractic treatment, $45.7 for massage therapy and acupuncture.
Ketamine infusions	*337*	*3,367*	For SCS, it was assumed that 2% of patients would still require a ketamine infusion each year. For UC, it was assumed that 20% of patients would receive a ketamine infusion, at an average cost of $4,209 (ketamine and hospital costs).
Ongoing cost of complications per year	1,191	-	Expected value based on Simpson et al (2009) – the annual probability of a complication was assumed to be 18%.
Ongoing cost of maintenance per year	**6,046**	**12,569 for optimal relief.** **13,482 for suboptimal relief.**	

Source: as noted.

Table A.7: Health system cost inputs, cancer pain

Cost component	Intrathecal pumps ($)	UC ($)	Source/note
Implantation	30,913	-	Captured by AR-DRG codes A11A and A11B, the insertion of implantable spinal infusion device (major and minor complexity) (Independent Hospital Pricing Authority, 2018; Department of Health, 2018a).
Ongoing cost of maintenance per month	2,698	5,730	Based on the reduction observed by Health Quality Ontario (2016) in cancer patients with intrathecal pumps

Source: as noted.

Table A.8: Cost of device explant, 2018

Cost component	Cost ($)
Anaesthesia	335
Surgical time	159
Operating room	1,661
Total cost	**2,155**

Source: Independent Hospital Pricing Authority (2018), MBS (2018), Department of Health, 2018a.

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