



HORIZON SCANNING

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BRIEF

Emerging technologies for pain management

Background

“Chronic pain is the leading cause of long-term disability in Australia and the major cause of forced workplace retirements leading to lost productivity, reduced taxation revenue and the need for welfare payments.”¹

Most Australians, at some time in their lives, will experience some form of pain: most often acute pain, which passes, enabling return to normal daily activities; and occasionally persistent pain, which is ongoing and lasts for more than three months. Most pain is managed through the primary health care system; with current evidence demonstrating that more than 25% of Australians who visited their General Practitioner (GP) in 2015 were diagnosed with chronic pain.² Over 90% of those experiencing severe pain

Medications (see table 1)

- Off-label use of cosmetic cross-linked hyaluronic acid for neuropathic pain
- CNTX-4975 for chronic pain associated with knee osteoarthritis

Nerve stimulation techniques and surgery (see table 2)

- SPRINT peripheral nerve stimulation system for acute and chronic pain
- StimQ peripheral nerve stimulation system for the relief of severe, difficult to manage chronic pain
- DenerveX™ system to treat back pain associated with spinal osteoarthritis

Models of care for pain management

- Multicomponent program for the integrated management of chronic pain and depression
- On-line exercise and pain-coping skills training for chronic knee pain
- GLITtER - A new psychoeducational intervention for low back pain
- A vocational rehabilitation program for individuals with persistent pain

reported that it interfered with their normal daily activities, including work. In 2007, the total cost of chronic pain in

Australia was estimated at \$34.3 billion (approximately \$11,000 per person with chronic pain).³

A joint initiative of

In addition, approximately 31% of adults with persistent pain experienced high levels of psychological distress; and 20% additionally suffered from depression or other mood disorders. Despite the growing social and economic burden of persistent pain in Australia, pain management is “one of the most neglected aspects of health care”.⁴ This brief provides an overview of recent developments in interventions

that aim to improve outcomes for people with persistent pain.

There are four main approaches to managing persistent pain:

1. medications,
2. physical therapy,
3. nerve stimulation or surgical procedures,
4. pain management programs.

These are often implemented in a step-wise manner, depending on the extent to which pain relief is achieved, or an integrated manner depending on the healthcare and funding environment the individual with chronic pain exists within.

Models of Care

Management of persistent pain is often complicated by medical and

Table 1. Update on medications

Technology	Brief description of study results (as of October 2017)	Current status
Cross-linked hyaluronic acid for neuropathic pain	<p>In its natural form, hyaluronic acid is a liquid that is broken down in the body within a day. Cross linking chemically binds the components of the acid which extends the life of the acid from being broken down within 1 day to 6-12 months.</p> <p>A 2015 study is reported as the first to assess the safety and efficacy of cross-linked hyaluronic acid in the treatment of neuropathic pain.⁵ The case series enrolled 15 patients with 22 different pain syndromes who had experienced neuropathic pain for an average duration of 5.5 years. Following targeted injection of cross-linked hyaluronic acid into the painful area (including face, spine, shoulder, elbow, wrist, thigh and feet) all patients achieved pain relief. Visual analogue pain scores (self-reported measure of pain intensity) decreased from an average of 7.5/10 before treatment to 1.5/10 after treatment. The average time to achieve pain relief was 24 hours and the average duration of pain relief was 7.7 months.</p>	<p>Status: Available in Australia as:</p> <p>Juvederm (Allergan)</p> <p>Restylane (Galderma)</p> <p>Not for this indication.</p> <p>A patent for the novel indication and technique for use was granted in November 2015.</p> <p>An additional 75 patients with similar pain profiles (e.g., post-herpetic neuralgia, carpal tunnel and tarsal tunnel syndrome, Bell's Palsy tinnitus and head pain) have been treated successfully.</p> <p>No further studies or trials have been identified.</p>
<p>CNTX-4975 for chronic pain associated with knee osteoarthritis</p> <p>Developer: Centrexion Therapeutics centrexion.com</p>	<p>CNTX-4975, which is a synthetic form of capsaicin, is injected directly into the site of pain to provide rapid onset and long-lasting pain relief. CNTX-4975 targets the capsaicin receptor to inactivate local pain fibres that transmit signals to the brain. This novel mechanism of action provides pain relief that can last for months until the ends of the local pain fibres regenerate. The rest of the nerve fibres function as usual, enabling normal sensation, such as touch, pressure and position.</p> <p>The developer has announced results from the TRIUMPH study, a randomized, double-blind, placebo-controlled, multicentre Phase 2b clinical trial in patients with chronic moderate to severe pain due to knee osteoarthritis (NCT02558439).^{6,7} A pilot study demonstrated that following a single injection of CNTX-4975 into the knee after local anaesthesia, there was a rapid and significant reduction in pain with walking that occurred within days and lasted at least six months. Twenty percent of patients achieved a 90% or greater reduction in pain and 67% achieved a 50% or greater reduction in pain. Improvements in knee stiffness and physical function were also reported. CNTX-4975 was well tolerated.</p>	<p>Status: in development (FDA approval has not yet been obtained)</p> <p>Research Trial Updates: New 6 month data show statistically significant pain relief for up to 24 weeks following a single 1 mg injection of CNTX-4975.⁸ Compared with placebo, patients with moderate to severe knee osteoarthritic pain also reported significant improvement in knee function after injection.</p> <p>The developers state they plan to commence a Phase 3 trial for the treatment of chronic pain in moderate to severe knee osteoarthritis in late 2017.</p>

mental health comorbidities. The stepwise approach described above may be incompletely implemented. Patients may seek pain relief from multiple health care providers resulting in fragmented care. Growing evidence supports a more integrated holistic approach to pain management. This involves the combination of evidence-based interventions which are tailored to the patient’s needs.

Recent developments have occurred in many approaches to pain management. This brief provides an

update on the status of two drugs, two nerve stimulation techniques, one surgical procedure and a summary of four models of care that were identified through ISCRH’s Horizon Scanning program (2016-2017). The identified technologies are in different stages of development and implementation, thereby impacting on the level of evidence available for review. These interventions have been identified as technologies which show promise, however, research is ongoing and evidence of their effectiveness may not be available at this time.

Medications

The updated details of medications identified through the Horizon Scanning program which aim to improve chronic pain are presented in table 1.

Nerve Stimulation Techniques and Surgical Procedures

The updated details of technologies identified through the Horizon Scanning Program which target nerve stimulation or surgical intervention to improve persistent pain are presented in tables 2a and 2b.

Table 2a. Update on nerve stimulation techniques and surgical procedures

Technology	Brief description
<p>SPRINT peripheral nerve stimulation system</p> <p>Manufacturer: SPR Therapeutics</p>	<p>The SPRINT system (also known as the Smartpatch system) was developed to relieve persistent pain as well as post-surgical and post-traumatic pain.</p> <p>A thread-like lead is inserted through the skin with a fine needle, and a matchbox-sized stimulator activates the peripheral nerves to achieve pain relief. Unlike other peripheral nerve stimulation systems, SPRINT does not require permanent implantation and is designed to be withdrawn without surgery at the end of the 30 day treatment period.</p> <p>Early case studies report pain relief up to 12 months following the 30 day treatment period.</p>
<p>StimQ Peripheral nerve stimulator system</p> <p>Manufacturer: Stimwave</p>	<p>The StimQ Peripheral Nerve Stimulator System is used for peripheral nerve stimulation to provide therapeutic relief of persistent pain of peripheral nerve origin.</p> <p>The system comprises a small implantable stimulator that is less than 5% of the size of other standard implanted options and an externally worn wireless transmitter to power the device. Stimwave claims it is the world’s first wireless, fully programmable Peripheral Nerve Stimulator device. In contrast to other similar products that require general anaesthesia and a large surgical incision to implant batteries, this device is implanted through a standard needle-size insert or small incision next to peripheral nerves at the origin of pain. Patients trial the device for 3-7 days to test its effectiveness before permanent implantation.</p>
<p>DenerveX™ system</p> <p>Developer: Medovex medovex.com</p>	<p>Facet joints are cartilage and synovial fluid joints located between the vertebrae in the spine. Nerves branch from the spinal cord and exit next to facet joints.</p> <p>Spinal osteoarthritis affects the facet joints, and is associated with thinning cartilage, narrowed joints and bony overgrowth at the edge of joints. The cause is unknown, but the prevalence increases with age. It can be associated with trauma to the joint. It is postulated that some spinal pain is caused by osteoarthritis, although many people with these changes do not have pain. Sometimes bony growths can irritate the nerves nearby.</p> <p>The DenerveX® System is a new minimally-invasive device that aims to provide long-lasting pain relief from pain caused by spinal osteoarthritis. The DenerveX® System is a small hand-held device with a specially designed power generator. The device uses Rotacapsulation™, a system that combines the shaving of joint capsule tissue with high heat ablation. The rotational action removes joint material, and heat ablation deactivates nerves.</p> <p>The procedure is completed with a local or general anaesthetic. A small incision of 10-15 mm is made at each treatment location through which a 1 cm diameter tube is inserted into the facet joint. The DenerveX® device is placed through the portal tube into the joint and activated. Patients may have treatment at one or several facet joints in one session; and they are dismissed within a few hours after surgery. Some soreness may occur at the treatment site for 2-4 days and full recovery is expected within 1-2 weeks.</p> <p>The company has reported that 14 patients with spinal osteoarthritis have been treated successfully with the DenerveX® System in England, Germany and Italy. A video of the procedure can be viewed here: medovex.com/denervex-providers/.</p>

Table 2b. Update on nerve stimulation techniques and surgical procedures

Technology	Current status
SPRINT peripheral nerve stimulation system Manufacturer: SPR Therapeutics	Status: Available in Australia: The SPRINT® Peripheral Nerve Stimulation (PNS) System has FDA approval, European CE mark and Australian Therapeutic Goods Administration approval in 2013 to treat chronic shoulder pain. Research Trial Updates: Small case studies have demonstrated significant reduction in pain intensity in approximately 70% of patients with shoulder or lower back pain, as well as post-amputation, or post-operative pain. Pain relief was ongoing for 78% of participants at 12 months post-treatment. No infections or serious adverse events have been reported. ⁹ In June 2017, participants were recruited for a clinical trial to treat post-amputation pain. ¹⁰ Two case studies reported sustained pain relief for low back pain. ¹¹ In September 2017, SPR Therapeutics announced \$25 million investment to commercialise the SPRINT® System; and undertake further research to evaluate its use in multiple indications including post-surgical acute pain and chronic low back pain. ¹²
StimQ Peripheral nerve stimulator system Manufacturer: Stimwave	Status: The StimQ system received US FDA approval in March 2016 and CE mark of approval in May 2017. It is estimated that the product will be available in Australia in 2018. No further studies or trials to evaluate the effectiveness of the StimQ system were identified.
DenerveX™ system Developer: Medovex medovex.com	Status: Available in Australia. Regulatory approval was received from Australia's Therapeutic Goods Association (August 2017). No further studies or trials were identified.

Models of care for pain management: Technology overview

Biopsychosocial models of care, which incorporate physical, psychological and social factors that contribute to the causes and consequences of pain, are considered the most effective approach to managing the complexities of chronic pain.¹⁴ Typically, this involves a continuum of care delivered by a multidisciplinary team of health care professionals working collaboratively. Evidence suggests that patients who are actively engaged in managing their pain suffer less disability than those passively receiving treatment from their doctor.¹⁴

The four models of care described below aim to prevent the onset of persistent pain or help people with persistent pain to return to their

normal daily activities, including work. Although their approaches differ, they all incorporate an element of active patient engagement by encouraging self-management and/or providing patient education about managing and coping with pain.

Table 3 provides a summary of the clinical application and costs for the four models of care and table 4 summarises the clinical trials associated with these models.

Clinical effectiveness of models of care for pain management

GLITtER – a new psychoeducational intervention for low back pain

Clinical Indication: It has been hypothesised that the current approach to the communication of spinal imaging results to patients may influence their recovery outcomes. Specifically, negative communication

that highlights abnormalities shown in spinal imaging reports from X-rays, CT (computerised tomography) or MRI (magnetic resonance imaging) scans may increase patients' fear of re-injury, reduce their sense of wellbeing and lead to poorer outcomes. Although abnormalities are often detailed in reports of scans, it is common to find similar abnormalities in individuals who do not experience pain. Therefore, the presence of abnormalities is not necessarily related to pain or a poor prognosis.

Model of Care: The Green Light Imaging Interpretation to Enhance Recovery (GLITtER) intervention involves a new and standardised method of communicating imaging reports from X-Ray, CT or MRI scans in a way that promotes reassurance of the individual, and encourages physical activity to promote recovery.¹⁹

Table 3. Summary of clinical application and cost

Intervention	Objective	Indication	Setting for use	Cost
Green Light Imaging Interpretation to Enhance Recovery (GLITtER) ¹⁹	To determine the feasibility of a trial to evaluate the effectiveness of the GLITtER intervention to reduce persistent low back pain and to integrate it into existing practice	Low back pain	Secondary care – spinal outpatient clinic	No cost information available
Internet-delivered education, exercise and pain-coping skills training ¹⁸	To evaluate the effectiveness of an online exercise education intervention to reduce pain and improve function	Persistent knee pain	Community/ Rehabilitation	No cost information for this intervention is available. However, one component of the program, the PainCOACH app is freely available to download.
Integrated approach to chronic musculoskeletal pain and depression ¹⁶	To determine whether an integrated approach to persistent musculoskeletal pain and depression leads to better outcomes than usual care	Musculoskeletal pain and depression	Primary care	No cost information available
A vocational rehabilitation program for individuals with persistent pain ²²	To determine the feasibility of an Individual Placement and Support (IPS) program to assist people with persistent pain to get back to work	Persistent pain	Vocational Rehabilitation	Information on costs and cost-effectiveness of IPS programs are highly variable in the available literature. In particular, there was little information on cost-analyses in an Australian setting

This intervention provides a framework that can be incorporated into existing practice. Health care providers explain scan results in a way that clearly informs patients that abnormalities are not necessarily related to the patient’s pain, the activity they are capable of, or their likelihood of recovery. Moreover, the clinician will explain that surgery is not needed, further scans are not required and movement and activity are not only safe, but also important for recovery. In this way, patients are given a metaphorical ‘green light’ to increase their activity level. This message is highlighted in take-home information that consists of a 4-week series of key messages displayed in poster style. The main themes of this information are:

1. Scan findings should not cause worry; it is safe to be active.
2. Pain is complex and lots of things contribute to the experience of pain.
3. Activity and exercise are important for recovery and have many benefits.

Patients also receive weekly SMS follow up for four weeks with links to online education resources and reminding them to plan some activity or exercise for the coming week.

Clinical Effectiveness and Safety:

A feasibility study of GLITtER is currently underway at Royal Adelaide Hospital. The study is the first step in definitive testing of GLITtER and aims to determine if this intervention in a spinal outpatient clinic setting

is cost-effective strategy to reduce lower back pain and disability. The trial is due for completion in September 2017. Results of this study are not yet available.

Use in Australia: The GLITtER intervention is in a testing phase and not currently in widespread use in Australia.

Multicomponent program for the integrated management of chronic pain and depression in general practice

Clinical Indication: Chronic musculoskeletal pain and depression commonly present together in primary care patients. This comorbidity has additive adverse effects on health, increasing the complexity of treatment

Table 4. Summary of clinical trials

Intervention	Location	Participants	Trial ID	Stage of development
Green Light Imaging Interpretation to Enhance Recovery	South Australia	40 participants aged 18–75 years*	ACTRN12617000317392	Anticipated completion Sep 2017 Cost effectiveness trial planned
Internet-delivered education, exercise and pain-coping skills training	Australia	148 participants aged 50 years or older	ACTRN12614000243617	Evaluation complete, No results published to date
Integrated approach to chronic musculoskeletal pain and depression	Spain	330 participants aged 18–80 years*	NCT02605278	Trial ongoing Anticipated publication of results Jan–Jun 2018
Vocational rehabilitation program for individuals with persistent pain	Norway	100 participants aged 18-65 years*	NCT02697656	Trial ongoing Due for completion December 2018

*No. of participants anticipated

and management of both conditions; and resulting in a poorer prognosis for patients. Evidence suggests that individuals experiencing comorbid depression and musculoskeletal pain may benefit from an integrated management program at the primary care level.

Model Overview: The Multicomponent Program for the Integrated Management of Chronic Pain and Depression in Primary Care (DROP) trial is currently underway in Spain to evaluate whether implementing an integrated model of care for chronic musculoskeletal pain and depression improves clinical outcomes compared to usual care in a primary setting. The trial is due for completion in December 2017.^{15,16}

The model of care is based on a chronic care model¹⁷ and includes three main components:

1. Care management by a psychologist, who collaborates with the patient's physician and monitors treatment, ensuring compliance with treatment, referrals, psychoeducation and visits occur. The care manager

follows up with periodic telephone contact to monitor progress.

2. Optimised management of depression, using electronic clinical support tools, and based on recent clinical practice guidelines.
3. Patient education. The care manager delivers a group-based psychoeducational program that promotes understanding and self-management of depression and pain as well as the related difficulties. This program aims to provide participants with adaptive strategies for managing their conditions on a daily basis and provide incentives for them to play an active role in managing their illness. A teaching manual and supporting materials have been developed

Clinical Effectiveness and Safety:

Results from this study are not yet available.

Use in Australia: Currently not in use in Australia. However, a similar approach that combines pain management and pain education in an integrated, shared care model has been described in a South Australian government report on managing chronic pain.¹

On-line exercise and pain-coping skills training

Clinical Indication: Post-traumatic arthritis, a form of osteoarthritis, describes long term changes in a joint that has experienced physical injury such as from a vehicle accident or a fall. Osteoarthritis may cause loss of function, reduced quality of life, and psychological disability. Many people have problems accessing specialists who can prescribe and supervise treatments due to cost, transport issues or geographical locations.

Model Overview: A pain management program delivered via the internet aims to improve patient access to effective treatments by combining home exercise and pain-coping skills training. Developed by the Department of Physiotherapy at the University of Melbourne, the model involves three online interventions delivered over a 3 month period:

1. Educational material about exercise and physical activity, pain management, emotions, healthy eating, complementary therapies and medications
2. Eight modules providing interactive pain-coping skills

3. Seven Skype sessions with a physiotherapist to learn home exercises.

Clinical Effectiveness and Safety:

In a randomized controlled trial to evaluate the effectiveness of this program, patients with access to the online educational materials reported clinically significant improvements in pain, physical functioning and quality of life that were sustained at three and nine months compared to a control group.¹⁸ There are currently no data available assessing the efficacy of the interactive pain-coping modules or the Skype-delivered physiotherapy sessions.

Use in Australia: The online exercise and pain-coping skills program is still being evaluated and the developers anticipate it will be publically available in mid to late 2018.

A vocational rehabilitation program for individuals with persistent pain

Clinical Indication: Persistent pain is characterised by pain that continues beyond normal tissue healing time (3 months) and is of sufficient duration and intensity to negatively impact an individual's daily activities, relationships, mood, sleep, overall health and wellbeing, and employment. Long-term work absence also impacts negatively on mental and physical health, high social and economic costs, and can result in permanent work disability.

Model of Care: Individual Placement and Support (IPS) is an internationally recognised evidence-based vocational

rehabilitation model for individuals with severe mental illness to obtain and maintain employment.^{20,21} The model is now being explored for people experiencing persistent pain. The program is delivered by an employment specialist and follows eight principles:

1. Every person who wants to work, can work if the person is provided with appropriate work and a supportive environment,
2. The goal is employment in regular, competitive employment,
3. IPS is integrated with treatment,
4. Job search is personalised and is based on the individual's preference and competence,
5. Work incentives planning is provided which includes counselling about how work can influence social security and other public benefits,
6. The job support is not time-limited,
7. IPS does not involve pre-vocational training, often referred to as "train then place"; and
8. IPS job search begins as soon as the individual expresses an interest in employment and follows the principle of "place, then train".

Effectiveness: A study to assess the effectiveness of IPS for persistent pain patients (IPSinPain study) is currently underway and is due for completion in February 2018 (NCT02697656).²² The trial will compare the effect of individual job support as part of multidisciplinary management of patients with persistent pain in an outpatient pain clinic in Oslo, Norway. In addition, two feasibility studies are

underway in the United Kingdom to inform larger more definitive trials of IPS for patients with persistent pain. The Return to Work with Individualised Supported Employment (RISE) study is being conducted by the Warwick Medical School and will employ trained Case Managers to provide IPS to place unemployed people with persistent pain to work with selected large employers. The Case Manager will support the individual and their employer.²³ The second study is being conducted by the University of Southampton to test the feasibility of a randomised controlled trial (ISRCTN30094062).²⁴ These studies are expected to be completed in 2018–19.

Settings for technology use

The interventions described here may be implemented in primary health care and community care settings, including the patient's home.

Potential for impact

These programs for managing persistent pain have potential for application in the primary health care and community care settings. While cost analyses are currently unavailable, implementation of the interventions may be incorporated within existing processes with relative ease. These interventions address the three key aspects of pain management - physical, psychological and social; and each intervention highlights the importance of patients' active engagement with the intervention, which has been demonstrated to increase the likelihood of positive outcomes.

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