ISCRR
Institute for Safety, Compensation and Recovery Research

HORIZON SCANNING

Issue 5 / July 2017

NEWSLETTER

Technologies to Prioritise

The Institute for Safety, Compensation and Recovery Research (ISCRR) Horizon Scanning program identifies new and emerging health technologies, treatments and services that have the potential to impact the lives of people affected by transport accidents or work-related illnesses and accidents. The program was established to identify and raise awareness of innovations entering the health care system to help decision makers consider their potential for impact. The health-related innovations presented are in the early stages of development, and research to determine their safety and effectiveness is ongoing. The technologies are estimated to emerge in the Australian market within one to three years.

The ten innovations presented in this newsletter have gone through a rigorous filtering and prioritisation process. They originated from a list of thirty-seven innovations that were identified through horizon scanning activities. Through consensus agreement amongst representatives from the Transport Accident Commission (TAC), WorkSafe Victoria (WorkSafe) and Monash University (ISCRR), the innovations were prioritised and selected as those with the greatest potential to influence both TAC and WorkSafe policy and investment decisions and potential client outcomes.

The clinical evidence and regulatory status of the innovations featured in the newsletter will be monitored on an ongoing basis.

For more information on ISCRR, The Horizon Scanning program or this newsletter, contact ***ISCRR.horizon.scanning@monash.edu***

TECHNOLOGIES INCLUDED IN THIS NEWSLETTER

A joint initiative of

WorkSafe VICTORIA · TAC Transport Accident Commission · MONASH University

GLITtER: A psychoeducational intervention for low back pain

Evidence-based management of non-specific low back pain includes reassurance about a favourable prognosis, advice to maintain daily activities and stay active and prescribing simple analgesic medications. However, there is limited high-quality data on how to reassure patients effectively.

It has been suggested that the way healthcare providers currently communicate spinal imaging reports with patients is not reassuring and may increase concern and heighten fear of re-injury and therefore reduce the likelihood of a good outcome. It is common to find abnormalities following spinal imaging and it is now believed that these changes are not abnormal and are also seen in pain-free individuals. It is also understood that spinal imaging findings are not well associated with pain or prognosis.

The Green Light Imaging Interpretation to Enhance Recovery (GLITtER) intervention involves a new and standardised method of communicating spinal imaging findings in a manner designed to reassure patients and promote patients' physical activity. The intervention can be integrated into current practice and be conducted face to face by clinicians. The model of care provides a framework for interpreting imaging findings and key messages to be communicated whilst reviewing a patient's imaging results. The key messages to be communicated are that scans do not necessarily indicate: 1) the patient's current pain, 2) the activity the patient is capable of, or 3) how likely the patient is to recover. The clinician will explain to the patient that after reviewing their imaging and assessing them, surgery and further scans are not required and they consider movement and activity to be safe. The patient is provided with a metaphorical 'green light' to increase their activity level and the message that this activity is important for their recovery. The green light message is re-iterated in take-home information which includes a four-week series of key messages displayed in poster style. The main themes of this information are:

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

Patients receive weekly SMS follow-ups with links to online education resources, a prompt to display and read the information sheet they were provided at their consultation, and a reminder to plan some activity/exercise for the coming week.

A feasibility study comparing the GLITtER intervention with standard care for patients with low back pain attending the Spinal Assessment Clinic at the Royal Adelaide Hospital is currently underway. The study will inform the feasibility of definitive testing of GLITtER to determine if this intervention integrated into routine practice in a spinal outpatient clinic setting is a cost-effective strategy to reduce lower back pain and disability. The feasibility study is due for completion in September 2017.

Developer:
University of South Australia

Australian approval status: Not applicable

Stage of development: Experimental

Setting for use: Secondary care

Intravenous immunoglobulin therapy for acute spinal cord injury

Spinal cord injury typically involves two stages: the primary and secondary injury. The primary injury is the mechanical injury or damage to the spinal cord immediately following trauma. The secondary injury occurs as a result of the cascade of events and the surge of chemicals released by the body in response to the trauma, which can cause inflammation, decreased spinal cord blood flow and cell death. New therapies that are being developed to treat spinal cord injury are typically directed at one or more steps in this cascade of events associated with secondary injury.

Intravenous immunoglobulin is a human blood-derived product that is already in clinical use in the treatment of autoimmune disorders because of its anti-inflammatory effects. Intravenous immunoglobulin is now under investigation to determine whether it can improve recovery following spinal cord injury by reducing the harmful aspects of inflammation.

In a clinical trial led by The University of Queensland and the Princess Alexandra Hospital, Privigen (liquid human immunoglobulin) will be administered to participants intravenously within 12 hours of traumatic cervical or thoracic spinal cord injury. Participants will receive a second dose the following day. Participants in the trial will be followed for up to a year after their injury to assess motor and sensory recovery, function and independence, and to monitor patient safety during and following treatment. The trial will run for three years (2017 to 2019) and aims to recruit 20 participants through the Princess Alexandra Hospital, which is Queensland's primary centre for spinal injury care.

Privigen is in clinical use as replacement therapy for immunodeficiency disorders and has a good safety profile. This has made it possible to quickly progress the treatment from animal studies to the first in-human studies.

Developer:
The University of Queensland and the Princess Alexandra Hospital

Australian approval status: Not approved

Stage of development: Experimental

Setting for use: Acute care

Ronopterin for the prevention of secondary injury following traumatic brain injury

Similar to spinal cord injury, traumatic brain injury (TBI) involves two stages: the primary and secondary injury. The primary injury is the mechanical injury or damage to the brain immediately following trauma. The secondary injury occurs as a result of the processes initiated by the trauma. This includes the release of chemicals that cause inflammation and swelling in the brain which may increase the pressure inside the skull, leading to further damage. There is an opportunity to improve outcomes following TBI by reducing the development of secondary injury.

A key molecule in secondary injury processes is nitric oxide, which is produced in excess during neuroinflammation. Ronopterin (VAS203) represents a novel pharmacological approach to the treatment of TBI that is hypothesised to reduce excess nitric oxide production and subsequent secondary injury.

Results of the NOSTRA (Nitric Oxide Synthase inhibition in TRAumatic brain injury) trial were published in 2014. The exploratory Phase IIa study assessed the safety, tolerability and pharmacodynamics (the biochemical and physiological effects of drugs and the mechanisms of their action) of Ronopterin in TBI. The study involved 32 patients who commenced Ronopterin therapy no later than 12 hours after injury and received one of three escalating doses by intravenous infusion over a three-day period. The study demonstrated a significant improvement in clinical outcomes suggesting Ronopterin-mediated neuroprotection after TBI. Outcome measures were assessed using the Therapeutic Intensity Scale (a measure of overall therapeutic effort directed at controlling intracranial pressure) and the extended Glasgow Outcome Score (a measure of recovery after TBI). Ronopterin was associated with a risk of acute kidney injury at the highest dose, which will reflect the upper limit and/or infusion rate in future studies. Further, the coadministration of other drugs known to impact kidney function and the potential impact of age-related changes in kidney function will need to be considered.

The NOSTRA-III trial seeks to confirm the results of the earlier trial and is a phase III, multicentre, randomised, placebo-controlled trial. The trial commenced in 2016 and is planning to enrol 220 patients with moderate and severe TBI, with results expected in 2019.

Developer:
Vasopharm GmbH
www.vasopharm.com

Australian approval status: Not approved

Stage of development: Investigational

Setting for use: Acute care

Emego for people with severe disabilities that use electronic assistive technologies

Assistive technology supports greater independence for individuals with severe disabilities by enabling them to perform tasks they are unable to, or have difficulty performing. Assistive technology may provide enhancements or change the way individuals interact with the technology required to achieve these tasks. Emego is a new device, intended for use by people with severe disabilities, that interfaces with existing assistive technology replacing or enhancing control methods, and in some cases, enabling control where currently no method exists.

Emego is a small, lightweight, body-worn switch that uses electrical signals from muscle activity to wirelessly control electronic assistive technology devices. It is designed to be used by people with severe disabilities to provide greater independence and control over their communication and environmental control devices. Emego can be attached to different muscle groups to detect small muscle movement including from the limbs, facial eye muscles or a jaw clench. The smallest muscle twitch can activate the patient sensor to transmit a wireless signal up to 10 metres to a small base unit that interfaces with existing electronic assistive technology devices.

The Centre for Assistive Technology and Connected Healthcare at the University of Sheffield is conducting two studies to develop and evaluate the performance of Emego. The first study involves a small number of individuals with severe physical disabilities who use electronic assistive technology as a communication aid. The users will trial the device and take part in an interview to provide feedback into the device design. A second trial will evaluate device performance, based on the detection of muscle activation and the ease of use by individuals with severe physical disability.

The Emego is being developed in the United Kingdom by GSPK Design Ltd. in collaboration with the Barnsley Hospital Assistive Technology team and the Devices for Dignity Healthcare Technology Co-operative. The developers anticipate receiving the CE mark approval and subsequently launching the product in the United Kingdom in September 2017 with the intention to launch in Europe soon after.

Emego was reviewed by the United Kingdom National Institute for Health Research, Horizon Scanning Research and Intelligence Centre in a December 2016 Technology Alert (www.euroscan.org/technologies/emego-for-people-using-electronic-assistive-technologies/).

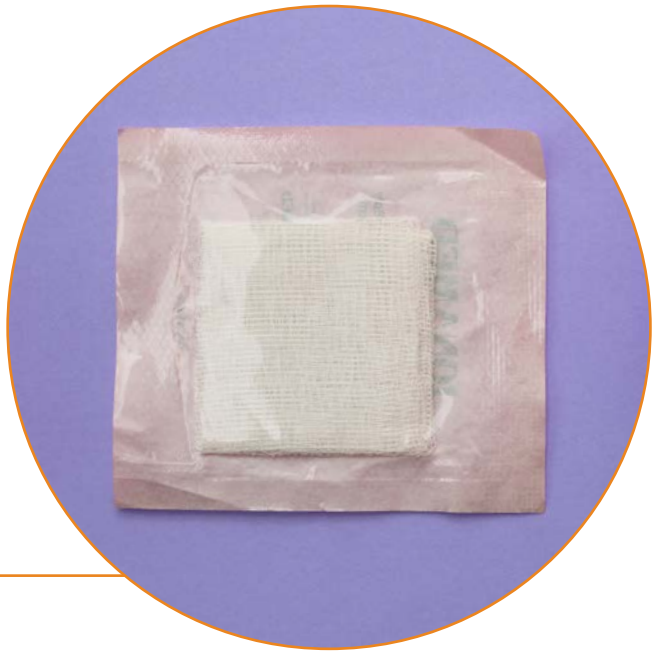
Developer:
GSPK Design Ltd.
emego.co.uk

Courtesy of GSPK Design Ltd.

Australian approval status: Not approved

Stage of development: Nearly established

Setting for use: Home care



Aurix chronic wound care system

Pressure ulcers present a significant health and economic concern. Pressure ulcers are common in individuals with reduced mobility or sensation, such as those who are bedridden or confined to wheelchairs, including individuals with spinal cord injury. Despite effective interventions for the prevention and management of pressure ulcers, many do not heal and become chronic wounds. Chronic wounds can have a significant impact on an individual's quality of life and can present a treatment challenge for healthcare providers. The Aurix System (previously known as AutoloGel) is claimed to be a breakthrough therapy for treating chronic, non-healing wounds.

The Aurix System, intended to be used at the point-of-care, isolates and activates platelet rich plasma from the patient's own blood. Platelet rich plasma is a source of chemicals involved in the natural wound healing process. The red blood cells are removed from the patient's blood sample, the platelets and plasma are then combined with other agents (ascorbic acid and calcified thrombin from bovine origin) to form a gel that can be applied to the wound within five minutes. The gel is applied topically and is covered with a clear dressing. Once applied, it stimulates the formation of new tissue to fill in wound defects and help reduce wound volume.

An observational case series of 285 non-healing wounds, including 142 pressure ulcers, showed that during an average of two weeks with 2.6 Aurix gel treatments, 88% of pressure ulcers responded with a 47% reduction in area (a two-dimensional measurement of wound size) and 90.8% responded with a reduction of 61% in volume (a three-dimensional measurement of wound size that also takes in account the depth of the wound). The average age of pressure ulcers prior to treatment was 58.7 weeks.

A phase four (post-market), open-label, randomised clinical trial is underway in the United States, to demonstrate the effectiveness of Aurix and standard care compared to usual and customary care in complete wound healing of pressure ulcers. The trial is due for completion in February 2017. Trials in diabetic foot ulcers and venous leg ulcers are also underway.

Aurix is approved by the United States Food and Drug Administration for use in treating chronic wounds.

Manufacturer:
Nuo Therapeutics Inc.
aurixsystem.com

Australian approval status: Not approved

Stage of development: Established

Setting for use: Acute care

Model of care for management of musculoskeletal pain and depression in general practice

Chronic pain and depression are common in primary care patients and frequently coexist in the same patient. When depression and pain coexist, the conditions can have a cumulative adverse effect on outcomes, including an increase in the severity of symptoms, poorer functioning and reduced response to treatment. It has been hypothesised that an integrated management approach targeting both pain and depression in the primary care setting is an opportunity to achieve better outcomes.

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 in a primary care setting improves clinical outcomes compared to usual care. The trial aims to determine, over a 12-month monitoring period, the effectiveness of the program on depression severity, pain severity and therapeutic response rates for pain and depression. The trial includes adults with moderate or severe musculoskeletal pain of at least three months duration, who despite having received oral analgesia meet the criteria for major depression. Patients with a workplace disability claim currently in progress are excluded. The trial is due for completion in December 2017, with publication of results anticipated by June 2018.

The model of care is based on a chronic care model and includes a structured program with integrated management of depression and pain with three main components:

1. Optimised Management of Depression: Depression will be managed using an electronic clinical support tool that incorporates algorithms and recommendations based on recent clinical practice guidelines.

2. Care Management: A psychologist care manager will support and collaborate with the treating physician in managing the patient. The care manager will ensure compliance with the care plan and will participate in monitoring the patient through periodic telephone follow-up. The structured telephone contact will occur monthly during the first two months of the study and then every two months after that.

3. Patient Education: A group-based psychoeducational program that promotes understanding and self-management of depression and pain. The program is designed to help patients take an active role in managing their conditions. The program is delivered face to face by the Care Manager in nine weekly interactive group sessions. A teaching manual and other support materials have been developed to facilitate these sessions.

Investigators:
Jordi Gol Institute for Research in Primary Care, Barcelona

Australian approval status: Not applicable

Stage of development: Investigational

Setting for use: Primary care

DermaTherapy for pressure ulcer prevention

Pressure ulcers are a preventable chronic wound common in individuals with reduced mobility, such as those bedridden or hospitalised due to an injury or an accident. Pressure ulcers present a significant health and economic concern, as they can lead to prolonged hospitalisation, pain and suffering, additional costs, and in some instances death. Strategies for preventing pressure ulcers include position changes, supportive devices, daily skin care, adequate nutrition and lifestyle changes. A new intervention to be considered as part of a comprehensive approach to pressure ulcer prevention is specialised healthcare bedding.

DermaTherapy bed linens help reduce the likelihood of patients developing pressure ulcers by reducing moisture, friction and shear on the patient's skin. Continuous filament yarns woven into the silk-like synthetic DermaTherapy fabric provide a smooth surface, free of broken or discontinuous fibres. The enhanced smoothness is reported to help minimise the potential for irritation and abrasion of sensitive skin. The DermaTherapy fabric also facilitates moisture wicking and rapid drying and incorporates an antimicrobial agent to inhibit the growth of bacteria on the bedding. DermaTherapy bed linens including pillow cases, top flat sheets, bottom fitted sheets, patient gowns and underpads are intended for use in the home or hospital setting.

DermaTherapy bed linens have been studied in hospital and long-term care facilities with users showing a reduction in the development of hospital- or facility-acquired pressure ulcers.

DermaTherapy bed linens have been approved by the United States Food and Drug Administration for use in the hospital setting for patients who are susceptible to pressure ulcers. DermaTherapy bed linens can be purchased online from the manufacturer.

Manufacturer:
Standard Textile Co.
dermatherapy.standardtextile.com
dermatherapy.com

Australian approval status: Not approved

Stage of development: Established

Setting for use: Acute care / Home care

UrgoStart dressing for chronic wounds

Chronic wounds are wounds that do not heal within the expected healing time of four to six weeks. Healing may be delayed due to patient, wound and/or environmental factors. The most frequent types of chronic wounds are diabetic foot ulcers, venous leg ulcers and pressure ulcers. Management of chronic wounds includes addressing the underlying causes delaying wound healing, administering appropriate wound dressings and maintenance of the healed wound. Many different wound dressings are available and the choice of dressing is influenced by the type of wound.

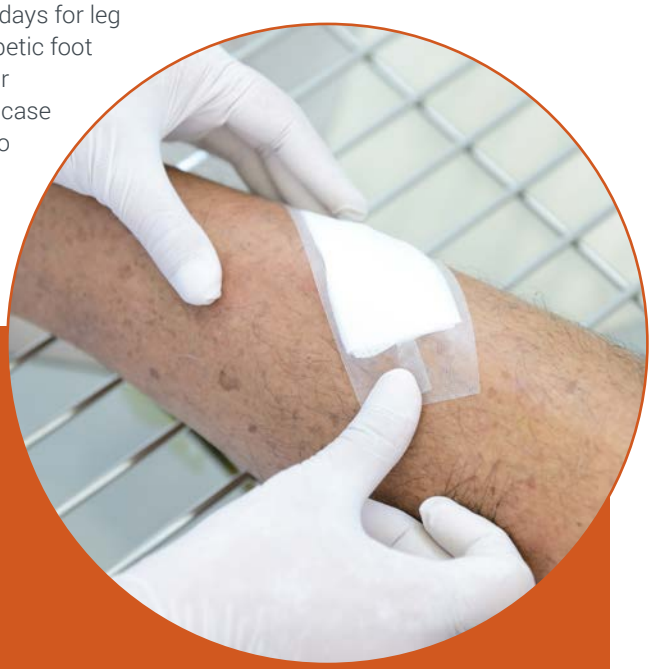
UrgoStart is a wound dressing that was developed to accelerate wound healing and is used to treat chronic wounds and non-healing acute wounds. UrgoStart is a soft, adherent foam dressing that includes a unique TLC-NOSF (Technology Lipido-Colloid with Nano-OligoSaccharide Factor) layer. The TLC-NOSF layer when in contact with the wound, forms a gel that creates a moist environment to support wound healing and also limits excess protease (an enzyme that breaks down protein) activity which can contribute to impaired wound healing.

Two randomised controlled trials assessing the use of UrgoStart in patients with venous leg ulcers have been conducted. The Challenge study compared UrgoStart with an identical dressing without the nano-oligosaccharide layer. The other trial compared UrgoStart with an alternative protease modulating dressing. In both studies there was a greater reduction in wound size in the UrgoStart treated group. A recent pooled analysis of observational studies included data from 10,220 patients treated with UrgoStart. The study demonstrated an overall 30.8% wound closure rate with an average time to closure of 112 days for leg ulcers, 98 days for diabetic foot ulcers and 119 days for pressure ulcers. In the case of leg ulcers the time to complete closure was reduced by 100 days compared to available data on wounds managed by standard care.

This class of dressing is approved for use by the Australian Therapeutic Goods Administration and UrgoStart dressings are available in Australia through Independence Australia, for approximately $10–$30.

Urgostart wound dressings were described in a National Institute for Health and Care Excellence (NICE), United Kingdom, Medtech innovation briefing in October 2016 (www.nice.org.uk/advice/mib82/chapter/Summary).

Manufacturer:
Urgo Medical
www.urgomedical.com



Australian approval status: Approved

Stage of development: Established

Setting for use: Acute care / Home care

Online exercise and pain-coping skills training for chronic knee pain

Post-traumatic arthritis, a form of osteoarthritis, is the wearing out of a joint that has had any kind of physical injury such as from a vehicle accident, a fall, or any other source of physical trauma. Such injuries can damage the cartilage and/or the bone, change the mechanics of the joint and make it wear out more quickly. Osteoarthritis is the leading cause of persistent knee pain and may cause loss of function, reduced quality of life and psychological disability. Effective treatments for chronic knee pain include home-based exercises and learning how to cope with symptoms. However, many people have problems accessing specialists who can prescribe and supervise these treatments due to cost, transport issues or geographical location.

An online treatment program combining home exercise and pain-coping skills training was developed by the Department of Physiology at the University of Melbourne. The program aims to improve pain and function in patients with chronic knee pain and improve access to effective treatments. The model of care includes three components delivered over a 13-week period:

1. Educational material about exercise and physical activity, pain management, emotions, healthy eating, complementary therapies and medications.

2. An eight-module interactive pain-coping skills training (PainCOACH) program.

3. A seven-session physiotherapy guided exercise program delivered online using Skype.

A randomised controlled trial to evaluate the effectiveness of the online model of care was conducted between 2014 and 2016. The study involved 148 community dwelling participants aged 50 years or older with chronic knee pain of more than three months duration. The study compared outcomes of administering all three components with a control group that only received the online educational materials. The study demonstrated that, compared to the control group, patients who had access to the online model of care reported significantly greater improvements in pain and physical functioning at three months and improvements were sustained at nine months. In addition, the intervention group showed greater improvements in knee pain and quality of life at three months and nine months. It was concluded that an online model of care may greatly improve access to these effective treatments.

In December 2016, the online model of care won the Research into Action category in the VicHealth annual health promotion awards.

Developer:
The University of Melbourne

Australian approval status: Not applicable

Stage of development: Investigational

Setting for use: Rehabilitation

Model of care incorporating collaborative care and active surveillance for subthreshold depression

Efforts to reduce the burden of illness and personal suffering associated with depression have mostly focused on those with severe depression. Less attention has been paid to those with mild or subthreshold depression. Subthreshold depression is the presence of some depressive symptoms but insufficient to meet the formal diagnostic criteria for major depression. Identifying effective treatments for subthreshold depression is important because many of these patients suffer persistent symptoms, experience significant impairments in their quality of life and level of functioning and many progress to major depression. There is currently no clear evidence-based guidance regarding treatment for those with mild or subthreshold depression.

A primary care model of service delivery that involves the provision of low-intensity psychosocial treatment by a case manager working in collaboration with the primary care team has recently been evaluated in older adults.

The CASPER (Collaborative Care in Screen-Positive Elders) trial was a randomised controlled trial of usual GP care compared with usual GP care with the addition of collaborative care for the treatment of mild depression in people aged 65 years or older. Collaborative care was delivered by a case manager with a background in mental health nursing or a graduate psychologist in eight weekly sessions. Collaborative care included telephone support, symptom monitoring and active surveillance, facilitated by computerised case management. The first session was delivered face to face and subsequent sessions by telephone. Participants also participated in a structured behavioural activation program designed to address the behavioural deficits of depression such as avoiding social interaction and the absence of rewarding activities.

Results of the CASPER trial demonstrated that collaborative care was effective and cost-effective for older adults with mild depression and reduced the proportion of people who went on to develop case-level depression at 12 months. Collaborative care produced a 12.1% reduction in the number of participants with a diagnosis of depression at 12 months. Symptoms of anxiety and health-related quality of life were also better in the collaborative care group at four and 12 months.

The study authors provided several recommendations for future research including whether the results of the trial can be replicated in a working-age population.

Developer:
University of York
www.york.ac.uk/healthsciences/research/mental-health/projects/casper

Australian approval status: Not applicable

Stage of development: Investigational

Setting for use: Primary care

Learn more about ISCRR: iscrr.com.au

Follow us on Twitter: @iscrr

Subscribe to our eNews: iscrr.com.au/subscribe

Contact us: ISCRR.Horizon.Scanning@monash.edu
(03) 9903 8610

Have you heard about a new health technology you think will have an impact on people injured on the roads or at work? Please let us know by contacting us at: iscrr.horizon.scanning@monash.edu