

ROADMAP FOR SPINAL CORD INJURY RESEARCH

Proposal for Funding

submitted to

The Hon. Greg Hunt
Minister for Health

The Hon. Stuart Robert
Minister for Disability

Prepared by:
The Australian Spinal Cord Injury Research Collaborative

THE OPPORTUNITY: ACCELERATE NEW TREATMENTS AND CURES FOR SPINAL CORD INJURY

“Unlike those suffering from many other conditions, people with a spinal cord injury can’t rely on surgery, a pill or a lifestyle change to cure us. Investing in research is our only hope.”

Joanna Knott, co-founder and Chair, SpinalCure Australia

Spinal cord injury is one of the most significant 'wicked' problems for the modern world to solve. Some progress has been made to tackle the critical issue of getting people to reclaim function and ultimately to walk again. What is needed, is a *'game changer'*.

Australian of the Year, Professor Alan Mackay-Sim, said in 2017, Australia should prioritise research and health spending not only to care for the disabled and diseased in the community but for radical treatments to reduce health costs, including the seven clinical trials under way in Australia testing new treatments for spinal cord injury.

A cure for spinal cord injury is within reach.

It is not a pipedream. The science has progressed some way to improve outcomes, but it is time to invest to define a pathway to better results, sooner.

Current Australian and international spinal cord injury research is getting results.

- Early intervention can reduce inflammation and have profound effects on long term mobility and function

- Neurostimulation can produce improvements even after many years living with spinal cord injury
- Sophisticated nuclear imaging can pinpoint injury sites and better understand impacts to function

The ultimate goal is to help people regain their ability to walk and regain full control over their bodily functions that are significantly affected by spinal cord injury. However, 'cure' is a journey and there are a spectrum of impacts, from regaining some or all of the control over key body functions, all the way through to full independence again.

The top priorities of people with spinal cord injury are better bowel, bladder, sexual function, and pain relief.

Many people with spinal cord injury will see the ability to walk again as important, but they value functionality in their hands, and their ability to manage bowel and bladder function more, along with reducing the pain they experience every day.

The imperative is to invest in science that enables function to be restored on the path to full mobility and normal quality of life, including returning to work.

And while the obvious priority is to manage and treat new injury effectively, the focus must be on both new (acute) injuries and long-standing (chronic) injury because treatments for acute spinal cord injury may not always be useful for chronic spinal cord injury. With almost 400 new injuries a year and over 20,000 people living with spinal cord injury in Australia, there must be a comprehensive approach and scope to research.

A national research agenda to achieve better outcomes.

The Australian Spinal Cord Injury Research Collaborative has a vision for a national research agenda that drives focused quality research to achieve better outcomes for people with spinal cord injury and the Australian community. Australia can:

- Capitalise on its strong historic base of outcome driven research
- Get a better return on investment in spinal cord injury research to date by strengthening our understanding of what has been achieved nationally
- Be a strong international partner contributing significant expertise and experience

Attract international attention to our world-class talent, lure international research stars to Australia.

Australia already punches above its weight internationally:

- **Professor Ruth Marshall** is an Adelaide-based clinical researcher, and Head of Rehabilitation at the Central Adelaide LHN, is the President of the International Spinal Cord Society (ISCoS).
- **Professor James Middleton** is a Consultant in Rehabilitation Medicine with over 25 years clinical and research experience in the field of SCI medicine and rehabilitation. He is the Chair of the ISCoS External Relations Committee.
- **Professor Lisa Harvey** is Editor-in-Chief of *Spinal Cord*: the official journal of ISCoS. She teaches widely both nationally and internationally and has been the recipient of numerous grants and scholarships.
- **Professor David Berlowitz** is an internationally recognised multi-centre triallist with a track record in successfully running large clinical trials. David leads an international team of clinician researchers, students and staff who examine the causes and treatments of sleep and breathing disorders in neuromuscular disease, especially in Spinal Cord Injury and Motor Neurone Disease.

- **Professor Simon Gandevia** has worked at international institutes such as Yale University, McMaster University, California Institute of Technology, the Department of Neurology at the Institute of Psychiatry, and the Institute of Neurology, London. He founded the Motor Impairment Program at Neuroscience Research Australia; an initiative designed to research and treat a range of motor impairments.
- **Associate Professor Marc Ruitenberg** is a Brisbane-based spinal cord injury researcher who's work spans the continuum of both basic and applied clinical research. He is internationally recognised for his work on inflammation following spinal cord and brain injuries, serves on the Editorial Board of *Spinal Cord*, and is directing the world's first clinical trial on intravenous immunoglobulin (IVIG) to treat acute spinal cord injury.

Building international partnerships and collaboration in spinal cord injury research opens the door to exchanges between research organisations, and faster outcomes. There is also the goal of attracting world-leading researchers to Australia, bringing their profiles, their teams, and international funds.

Importantly, Australia could have a significant regional impact. There is opportunity to improve outcomes in developing countries, with high injury rates and limited resources, to apply Australian expertise to research and treatments. Neighbours with good facilities and excellent research, such as Singapore, may collaborate more strongly once a national research agenda and resources are available.

A high tech and sophisticated research workforce, delivering jobs growth, improved health, and economic outcomes.

Medical research from 1990 to 2004 has delivered net present gains of \$78 billion; \$52 billion in health gains and a further \$26 billion in wider economic gains.

A KPMG report found that for every dollar invested in medical research, there is \$3.90 in benefits to the population.[1]

Medical research creates high value, knowledge-based jobs that contribute substantially to the economy. Over 110,000 people are employed in medical research and the medical technologies and pharmaceuticals (MTP) sector.

The economic benefits for investment in spinal cord research include reduced demands for care.

Applying the most advanced technologies through research, across the continuum, will improve outcomes for all people with spinal cord injury.

- **Neuroprotection:** Early intervention therapies that prevent cell death and limit damage to the spine. Ongoing trials include use of Minocycline, IVIG, Riluzole, Hyperdynamic therapy, and others.
- **Neuromodulation:** Epidural or transcutaneous electrical stimulation of the spinal cord. Ongoing clinical trials are delivering positive results using biphasic stimulators.
- **Neuroregeneration:** Therapies focused on regrowth of damaged neurons, especially in long-term chronic injuries. Clinical trials using a variety of cell types are currently underway.
- **Biomaterials:** Biomaterials such as neuro-spinal scaffolds, QL6, and others provide structural support or delivery channels for therapies that promote axonal growth.[2]

[1] <https://aamri.org.au/resources/reports/kpmg-medical-research-delivers-roi/> KPMG, Economic Impact of Medical Research in Australia, released 16 October 2018.

[2] AlphaBeta Australia, 2020, Spinal Cord Injury in Australia Commissioned by Spinal Cure Australia and Insurance and Care NSW (iCare), Sydney, Australia (in press),

Economic benefits will flow directly to government and the community, while the physical, social, and economic benefits will be extraordinary for individuals and their families/carers:

1. Reversing paralysis in just ~10% of spinal cord injury cases can deliver \$3.5B in cost savings to the Australian economy
2. Treatments targeting specific functional recovery such as chronic pain relief, bladder & bowel control or hand function can conservatively achieve up to \$2.8B in savings.
3. New spinal cord stimulation treatment, requiring \$20M in investment, can potentially achieve a cost saving of \$1.3B, resulting in a benefit cost ratio of 1.96
4. Critical mass - coordination and collaboration
5. Close the gap for a cure quicker
6. Accelerating the diagnostic, treatment, and rehabilitation processes
7. Get people walking again, regain functionality, improve quality of life, get people back to work and contributing to economy and tax base[3]

[3] ibid

WHY WE NEED TO PRIORITISE SPINAL CORD INJURY RESEARCH

Approximately 20,800 Australians are living with a spinal cord injury. These injuries are mostly the result of traumatic causes and are incurred by people under the age of 65. One third of Australians with a spinal cord injury have a severe injury, defined as resulting in no movement in the affected parts of their body.

This is a men's health issue – 80% of people with spinal cord injury are male.

This is a mental health issue – 40% of people with spinal cord injury will develop post-traumatic stress and 30% will develop depression.

Importantly this is an economic issue – the overall lifetime costs of the 20,800 people living with spinal cord injury is \$75B – for care, lost productivity, and wellbeing. That is approximately \$3.7B per year.

Spinal cord injury incurs exceedingly high costs to the individual, to government and insurance companies over long periods – this high cost is unique to spinal cord injury, compared to other injuries and conditions.

There are high lifetime costs to the government, individuals and their families, and losses in broader economic productivity. People with severe injury generate an average lifetime cost of \$8.5M. People with less severe injury still incur \$2.3M in lifetime costs.

There will be approximately 380 new cases of spinal cord injury in Australia each year. Those people will have seven times the risk of dying earlier than other Australians. And they have ten times the rate of unemployment.[4]

[4] Alpha Beta Australia 2020.

THE SOLUTION: A NATIONAL SPINAL CORD INJURY RESEARCH ROADMAP AND INVESTMENT IN GROUND- BREAKING RESEARCH FOR THE NEXT DECADE

A Roadmap is essential for:

- Identifying paths to a cure
- Identifying IP and commercialisation targets
- Defining governance and accountability
- Ensuring the best return on investment for government
- The best possible use of resources for the community and people with spinal cord injury
- Advising on the structure and management of funds dedicated for spinal cord injury research

Capabilities, strengths, gaps, opportunities

A key activity within the Roadmap development will be to map the current and emerging capabilities of spinal cord injury researchers carefully and comprehensively in Australia.

This process will involve engagement with current and past researchers; and take into consideration complementary fields of expertise such as data analytics, digital health monitoring and bio engineering. Analysis will be conducted to highlight major strengths, significant gaps and where the key opportunities lay for the future research skills gap development.

Past research investments in spinal cord injury could also be mapped to understand what research could and should be continued, and specifically, how the previous research outputs could be incorporated into new areas of impact.

This insight on capability and the required workforce will also be mapped, to understand the potential for growth and development of Australian STEM sector. Research teams require multiple levels of experience, expertise, and focus. Of critical importance, will be the need to understand how the workforce can become sustainable, with a strong cohort of emerging researchers, a pipeline of students in higher degree research programs and mid-career researchers who can be developed to take on the senior roles in research, when leaders retire.

Once the spinal cord injury research capabilities have been mapped, the Roadmap will present a recommendation for the opportunities for scaling these up nationally or internationally. Areas of strength will be identified, while skills-gap closure plans will be recommended. These strengths can then be leveraged globally. The existing national partnerships and networks will be mapped. New collaborations will be identified that have the potential for strengthening spinal cord injury research by bringing the necessary expertise, technologies, and workforce capacity to bear.

There may be potential for sharing data and technological capability across research teams. Replicating expensive infrastructure would be avoided.

A National Roadmap within an international context

Australia has a strong spinal cord injury research profile internationally, with collaborations in place. However, this profile could be strengthened and more sustainable. There are significant efforts in ground-breaking research for restorative and curative spinal cord research in North America, Europe, and Asia. This work, along with other leading global spinal cord injury foci would be drawn on to inform the Australian Spinal Cord Injury Research Roadmap.

Opportunities for collaboration and partnership with international research teams would be identified. Complementary efforts would be mapped, to ensure the Australian research helps to build the international evidence base and contributes to progression of major research programs.

Opportunities for Australia to lead major research efforts with international collaborators will be foremost in the development of the Roadmap.

Identify investment – current and future

A current unknown is the levels of investment to date in spinal cord injury research in Australia. There are multiple funding sources at the national and jurisdictional level. Understanding the current investment and what has been created is critical to understanding the need for investment for the future. The goal will be to:

- Build on past investments
- Bolster current investments and activities
- Imagine and define future needs

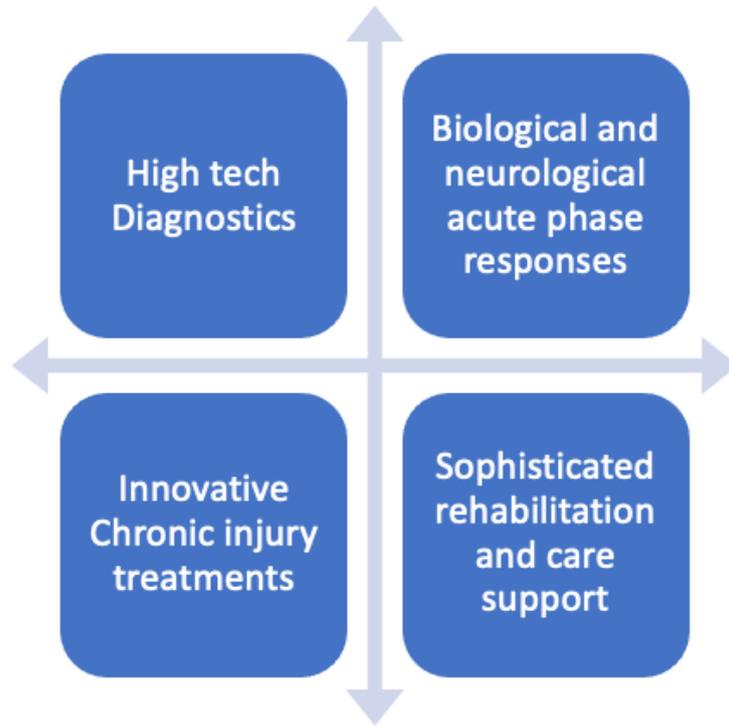
As has been identified recently with the COVID research and manufacturing capacity in Australia, sovereign capability is fundamental for Australia to not only contribute to the local efforts with 'wicked' world problems, but to have the expertise and discoveries and capabilities to deliver in Australia.

Identify Infrastructure and technology

This is about determining what infrastructure exists to drive innovation in research to find the solutions based on sophisticated science:

- High-tech diagnostics – accurate, effective diagnoses for targeted treatments
- High-tech treatments – immediate responses, short-term and long-term
- Novel technologies that work on central nervous system plasticity
- High-tech rehabilitation – to achieve maximum function
- High-tech supports and care – smart houses, transport, mobility aids, and equipment

High-tech science for a cure



THE PLATFORM: BUILDING ON STRENGTHS AND NETWORKS

Partnership with government and researchers

The proposed Australian Spinal Cord Injury Research Roadmap would be built via input from the Australian Government, researchers, jurisdictional authorities, people with spinal cord injury and their representative bodies. This informal partnership is necessary to ensure all perspectives are considered and that there is 'ownership' of the Roadmap and its recommendations for priority research and investment. An Advisory Committee could be appointed by the Minister to ensure broad representation.

A central role of people with spinal cord injury

The lived experience of spinal cord injury must drive priorities for research. There is outstanding leadership in research and advocacy for a cure, amongst people with spinal cord injury. Their voices will be critical to ensure an alignment with the priorities of people living with spinal cord injury, their carers and family. The Advisory Committee overseeing the Roadmap would be Chaired by a person with spinal cord injury. The Advisory Committee will have significant representation by people with spinal cord injury.

THE AUSTRALIAN SPINAL CORD INJURY RESEARCH COLLABORATIVE MEMBERS

Perry Cross Spinal Research Foundation

Mr Perry Cross AM, President and Founder

The Perry Cross Spinal Research Foundation has one main aim, to find a cure for paralysis.

SpinalCure Australia

Mr Duncan Wallace, Executive Director and CEO

SpinalCure is committed to making a cure for spinal cord injury not only achievable but available.

Spinal Research Institute

Professor David Berlowitz, Board Member

The Spinal Research Institute provides the means for spinal cord injury researchers to build collaborations and translate research into solutions for people living with spinal cord injury.

Spinal Cord Repair Laboratory

Associate Professor Stuart Hodgetts, Director

The Spinal Cord Repair Laboratory focuses on new therapies for repairing the spinal cord after traumatic injury. It is allied with the Perron Institute for Neurological and Translational Science and the University of Western Australia.

Spinal Life Australia

Mr Mark Townend, CEO

Spinal Life Australia's (SLA) purpose is to support a life journey approach to assist people with spinal cord damage. SLA aim to support people with spinal cord damage to live an accessible, equitable and empowered life.

Neil Sachse Centre

Ms Sarah Boucaut, Director

The Neil Sachse Centre's (NSC) vision and mission is to find a cure for spinal cord injury and to connect the dots with spinal cord injury, enabling clinical research that would otherwise go unfunded. The NSC sits within the South Australian Health and Medical Research Institute (SAHMRI).

STRENGTHS - LIVED EXPERIENCE

Perry Cross AM – Just two years after his accident, Perry Cross became Australia’s first motivational speaker on life support and was runner-up in the prestigious International Communicator of the Year Awards. He’s been awarded Suncorp Young Queenslander of the Year, finalist in the Young Australian of the Year Awards, was the first quadriplegic to complete a Communications and Business degree at Bond University, published numerous books, was named “Cure Warrior Advocate of the Year” at the International Working 2 Walk Symposium and in 2018 was chosen as a Gold Coast Commonwealth Games baton bearer. Perry has strong international connections and has been extraordinarily successful in raising funds for research.

Duncan Wallace – With a strong career in communications, technology, business development and management, and training in agriculture, Duncan Wallace has spent the past 10 years working with SpinalCure Australia to progress the discovery of treatments and cures for people with spinal cord injury. Duncan has been active in advocacy, lobbying and fundraising for spinal cord injury research for many years.

STRENGTHS - RESEARCH EXPERTISE

Professor David Berlowitz – is an internationally renowned triallist in neurological recovery, breathing and sleep disorders. He holds the University of Melbourne Chair in Physiotherapy at Austin Health. David has a strong track record in running large international multi-centre clinical trials. He is a Founding Board member of the Spinal Research Institute and the immediate past-CEO of the Institute for Breathing and Sleep in Melbourne.

Associate Professor Stuart Hodgetts – directs a laboratory researching clinically relevant strategies for the treatment of spinal cord injury. He has worked extensively in the field of cell based-transplantation therapies since 1998, with experience internationally (Oklahoma Medical Research Foundation). Stuart focuses his expertise on spinal cord repair using adult mesenchymal precursor and induced pluripotent stem cells, as well as gene therapy and non-invasive therapies. He continues to work with colleagues in the USA and Australia in these important areas of research.

STRENGTHS - MANAGEMENT, FUNDRAISING, ADVOCACY

Sarah Boucaut – has a track record in international relations, research management, strategic planning and fundraising for research. As Director of the Neil Sachse Research Centre, she has steered the organisation through a period of transition after the passing of Founder Neil Sachse.

Mark Townend – has a strong record of senior management and governance. He recently joined Spinal Life Australia as CEO after a successful career as CEO of the RSPCA in Queensland for almost 20 years. He oversees and large organisation delivery services and advocacy for people with spinal cord injury.

THE PROPOSAL:

Researching and Developing the Roadmap - \$600K over 1 year

Development of the Australian Spinal Cord Injury Research Roadmap requires an intensive period of data gathering, analysis, consultation and drafting of recommendations. Ideally the work would be conducted by a team with a sophisticated set of skills and expertise in this type of work.

It is anticipated that once funds were available, and a Consultancy Team appointed, the work would be conducted over a 12-month period.

The budget would include:

Consultancy fees.....	\$500,000	(Minimum 250 consulting days)
Travel.....	\$ 50,000	(Team travel to each State/Territory x 4 visits)
Advisory Committee...	\$ 50,000	(Travel, accommodation, sitting fees)

Commit to create pool of funds for 10-year horizon

An Australian Spinal Cord Injury Research Roadmap once completed and accepted by governments, the research community, and people with spinal cord injury and their advocates, would require resourcing for the conduct of the priority research.

Quarantined funds would be needed, to be determined in scale, partly by the Roadmap, and partly by the Australian Government and jurisdictional partners. A central pool of dedicated funds would likely need to be in the order of \$500M over a 10-year period.

Australian Spinal Cord Injury Research Collaborative - \$550K over 5 years

Critical to the effective development of the Australian Spinal Cord Injury Research Roadmap would be the sustained operation of the Australian Spinal Cord Injury Research Collaborative. This unique group has come together in the past year to address common concerns about the future of Australian spinal cord injury research. The importance of this group cannot be overstated. It is essential to have a national body, as a partnership between researchers and people with lived experience of spinal cord injury to drive the research within Australia. The competitive nature of research internationally makes these types of collaborations challenging, however, there is a significant common set of goals amongst this group. There is representation of the major spinal cord injury research groups in Australia.

The members have supported the efforts of the collaboration with their own resources to date, with significant input from the Neil Sachse Centre for Spinal Cord Injury Research based at SAHMRI in Adelaide, playing a coordination and support role. Assistance to maintain the effort during the development of the Roadmap and beyond is requested. The annual budget proposed is:

Salary – ASCIRC Executive Officer	\$90,000 per annum
Travel EO to each jurisdiction 1/yr	\$10,000 per annum
Communications and sundries	\$10,000 per annum

AUSTRALIAN SPINAL CORD INJURY RESEARCH COLLABORATIVE

