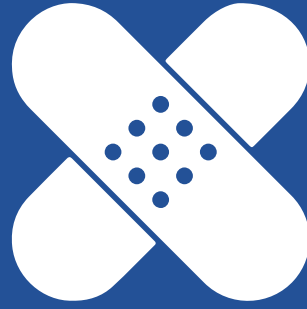




Research
Priority Areas
July 2015



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About the Wound Management Innovation CRC

The Wound Management Innovation Cooperative Research Centre (WMI CRC) has been a catalyst for change in the wound industry since its inception in 2010.

The WMI CRC is an industry led, cooperative organisation whose activities are transforming wound outcomes by addressing the key issues affecting wound healing and prevention. The WMI CRC brings together the best of industry, academia and end user organisations.

Vision

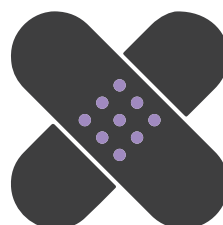
Transforming Wound Outcomes.

Mission

We will improve wound healing and quality of life for people with wounds and implement cost effective wound care that lessens the burden on the Australian Health System.

Goals and Objectives

- Translate research for the benefit of patients
- Develop next generation wound management products
- Address near term, high impact research questions
- Education of researchers, healthcare providers and patients
- Deliver clinical resources of national importance
- Empower healthcare providers and wound sufferers



Executive Summary

The WMI CRC Research Priority Areas has been drafted to articulate the research priorities of the WMI CRC. The document identifies the areas the WMI CRC will invest in to achieve the highest impact in healing and preventing wounds in Australia and in satisfying the agreed commitments to the Commonwealth Government and Participants.

The WMI CRC Research Priority Areas will also act as a guide to support and add value to current WMI CRC Core and Development activities. This document will be updated periodically to reflect changes in the clinical need, technological advances and capabilities of the WMI CRC and partners.

Research projects will be selected that have the potential for a significant impact on patient wound healing and prevention and deliver on the WMI CRCs goals and objectives as specified in the research priorities below. Note that the WMI CRC will not consider resubmissions of projects that have been rejected in previous rounds.

1. Projects that support the WMI CRC Core and Development activities
2. Industry guided development of promising wound technologies
3. Projects that have a demonstrated need/impact on wound healing or prevention
4. Projects which value add to projects previously funded by the WMI CRC

Following the release of the WMI CRC Research Priority Areas, management will assess a range of project proposals. The selection of projects to be undertaken in the WMI CRC requires careful consideration and balancing of a range of

factors, the most important of which are the clinical need, quality of science, requirement to deliver on all contracted outputs and alignment with the WMI CRC's Core and Development activities and transition plan.

Decisions to support research projects will ultimately be made by the Board, based on recommendations from the CEO, who draws advice from the Research Advisory Committee (RAC) and Development Advisory Committee (DAC).

Research, Core and Development Activities

The WMI CRC research projects are structured into three inter-disciplinary programs; Enabling Technologies (Research Program 1), Tools and Therapies (Research Program 2) and Clinical Application (Research Program 3).

- Research Program 1 is focused on improved understanding of the wound microenvironment and the application of this knowledge to identify new diagnostics, prognostics and therapeutics, including preclinical models.
- Research Program 2 is focused on the development of new wound management products including bioactives, diagnostics and dressings.
- Research Program 3 is focused on delivery of best practice wound care, including conducting clinical studies, developing risk assessment tools and translating evidence-based care into practice, including education of health care practitioners.

While these research programs provided the foundation for research priorities initially, as the WMI CRC has entered its translation phase the organization’s activities have evolved into four operational areas: research, education, development and clinical translation (See Figure 1).

This strategic shift towards clinical research and its translation has become a key focus of the WMI CRC and is highlighted by the commencement of several core research activities. These core research activities leverage the unique position of the WMI CRC in enabling the collaboration of a large and diverse set of participants to create impact on a national scale.

As part of our transition planning, the WMI CRC will significantly expand our efforts in this area during the remainder of the current funding term. The WMI CRC Core and Development activities are described on the following pages.

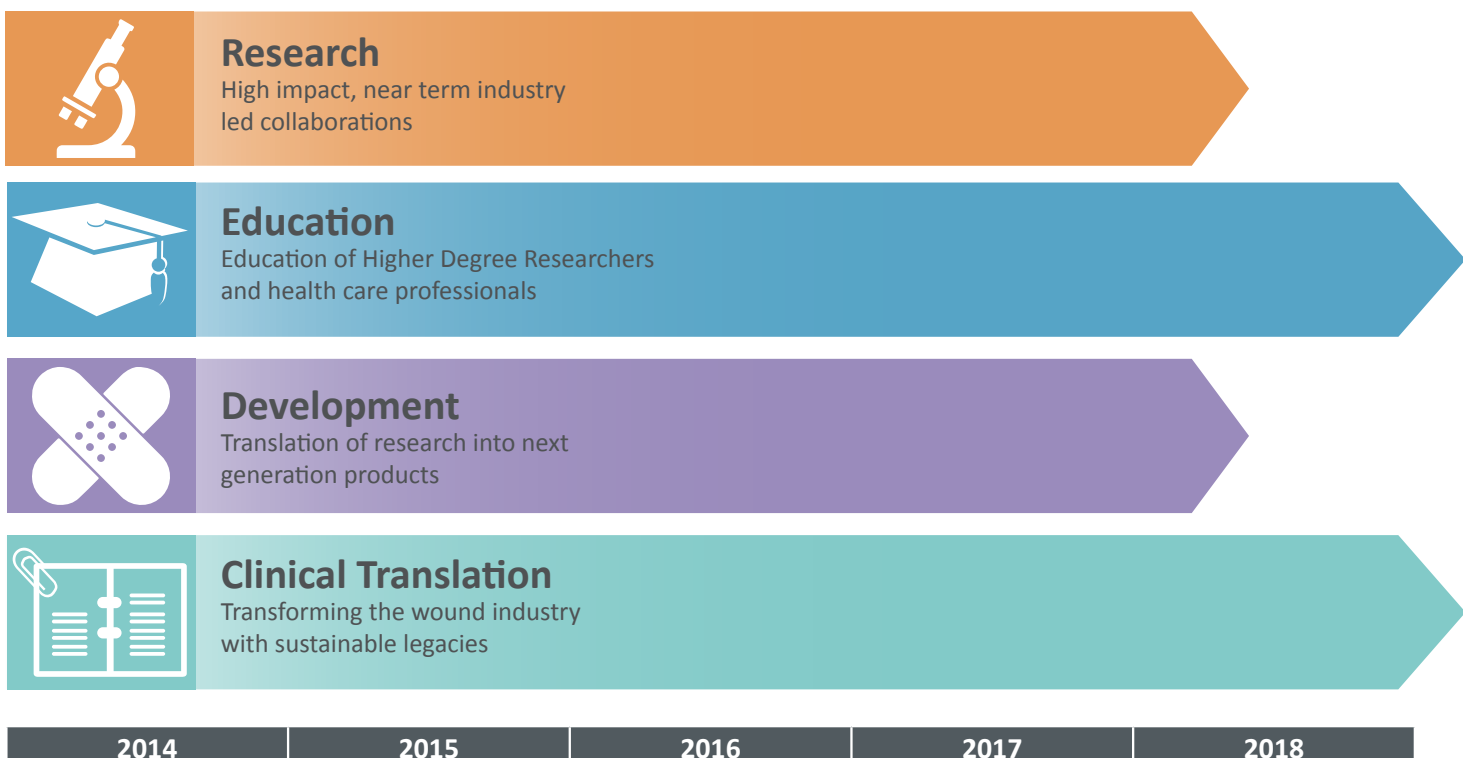


Figure 1. WMI CRC has four operational areas: research, education, development and clinical translation.

Research, Core and Development Activities

Wound Healing Institute Australia

The Wound Healing Institute Australia (WHIA) is a new not-for-profit organisation formed as a spin-out from the WMI CRC and Participants WA Health, Curtin University and SilverChain. This exciting new venture expands on the recently wound-up WoundsWest Program (an initiative of WA Health, Curtin and SilverChain) and enables these services to continue into a nationwide, sustainable operation. WHIA offers high quality wound prevention and wound management education, training, advice and research. WHIA's services will be offered nationally with a primary focus on education, practice and research.

Australian Wound Registry

Currently the costs of wound management in Australia are not well understood. There is limited data, it is not consistently collected, and there is uncertainty that the data sets are connected. Without this information health care policy makers, care providers, industry and patients are not able to make informed choices. To address this issue, the WMI CRC is building the Australian Wound Registry (AWR). The AWR will provide rich data to promote evidence-based practice in the management and prevention of wounds, inform healthcare policy and reimbursement, and generate a valuable industry database for product and marketing information. Building on this initiative, the AWR, Welsh Wound Innovation Initiative and the Canadian Association of Wound Care will form the International Wounds Registry.

Diabetic Foot Australia

The Diabetic Foot Australia (DFA) initiative will create a National body that will partner with related organisations and networks to empower patients, clinicians and researchers, and form a conduit for outcomes from the WMI CRC. A key output from the DFA Initiative will be the establishment of a national minimum dataset for DFU within Australia (which will also form part of the Australian Wound Registry). The database will capture existing data in a consistent format across Australia and will form the basis of a National DFU Dashboard that will publish national key performance indicators on DFU's, their occurrence, healing times, amputations, treatments, trends etc. This registry will also link with other registries across Australia (e.g. Queensland State-wide High Risk Foot Database).

Aged Care Wound Services

The CRC is developing a business model that will provide wound services into aged care. In collaboration with WHIA, the services offer a number of activities including online wound education programs, face to face training, educational resources and publications, wound prevalence surveys and a wound advisory service (telehealth). This service will improve outcomes for residents with wounds and promote organisational, clinical and educational

strategies for the prevention of wounds in residential aged care. Tailored packages of services will be negotiated with aged care facilities based on their specific needs.

Australian Wound Clinical Services

The WMI CRC is developing specialty clinical services which will deliver outcomes of local, national and international significance. The model of clinical service will be the cornerstone of the WMI CRC clinical translation activities and will be the nation's first dedicated facility for the provision of expert wound care, clinical research and face-to-face training. These activities complement other key translation initiatives of the WMI CRC, including the Wound Healing Institute of Australia, Diabetic Foot Australia, the Aged Care Wound Service and the Australian Wound Registry.

Health economics and healthcare reform

The estimated cost of chronic wounds is huge - around \$2.85 billion each year, representing around 2% of the health care budget. Using data from our WMI CRC participants and health economic modelling this initiative will:

- Evaluate the current cost of wounds to the Australian economy and quantify the costs and benefits of adopting evidence-based practice
- Influence health policy to provide incentives for low cost wound care in Australia
- Conduct economic and sustainability analyses for new models of wound care services (eg. Australian Wound Clinic and Aged Care Wound Services)

Development activities

- Insoles for diabetic patients: This project will develop an insole for diabetic ulcer management. The technology utilises a patented biosensor material and wireless technology to map the pressure distribution and alert the wearer if "hotspots" are detected.
- Hyperspectral imaging of cutaneous wounds: This study aims to demonstrate the efficacy of using hyperspectral imaging for a cost effective and easy to use device for point of care wound monitoring and diagnostics.
- Smart Material for Negative Pressure Wound Therapy: This project will develop new materials to improve open abdomen wound closure following surgery. The new materials will maintain their height but contract laterally under negative pressure to close the wound without using invasive mechanical devices.
- Smart compression: This project will develop medical compression devices. The technology utilises a patented biosensor material integrated with a wireless detection technology.

Research Priority Areas

The WMI CRC Research Priority Areas outlines the areas the WMI CRC will invest in to achieve the highest impact in healing and preventing wounds in Australia and in satisfying the agreed commitments to the Commonwealth Government and Participants.

The WMI CRC Research Priority Areas will also act as a guide to support and add value to current WMI CRC Core and Development activities. Research projects will be selected that have the potential for a significant impact on patient wound healing and prevention and deliver on the WMI CRCs goals and objectives as specified in the research priorities below.

- 1. Projects that support the WMI CRC Core and Development activities** e.g. projects promoting the expansion and use of the Australian Wound Registry.
- 2. Industry guided development of promising wound technologies** e.g. new technologies, products or services which are well advanced in the product development pathway and have a clear IP position and regulatory pathway.
- 3. Projects that have a demonstrated need/impact on wound healing or prevention** e.g. projects addressing key research questions for specific wound types (see Table 1 for more detail).
- 4. Projects which value add to projects previously funded by the WMI CRC** e.g. projects which successfully delivered on their outcomes and will yield considerable clinical or commercial impact with additional funding.

Note that WMI CRC will not consider resubmissions of projects that have been rejected in previous rounds. Within these research priorities the WMI CRC will also give consideration to proposals that align with the Wound targeted research questions on page 9 (Table 1).

Project areas which will not be considered include early stage drug development such as bioactive discovery or therapeutic target identification which have timelines to impact that are not compatible with the remaining WMI CRC funding term. Traditional medicine technologies would only be considered if there is a clear regulatory and development path to commercialisation and a well-defined intellectual property position.

The CRC has funded a number of clinical studies in the area of skin tears and is now focused on translation of these into practice and as such will not fund further clinical studies in this area. We recommend potential applicants visit our website www.woundcrc.com to view the project portfolio to avoid submitting applications for research previously conducted.

Research Priority 1

Projects that support the WMI CRC Core and Development activities

Research Priority 2

Industry guided development of promising wound technologies

Research Priority 3

Projects that have a demonstrated need/impact on wound healing or prevention

Research Priority 4

Projects which value add to projects previously funded by the WMI CRC

Research Priority Areas

Wound Type	Key Research Questions
Acute/Surgical wounds	Strategies to ameliorate complications with acute/surgical wounds and surgical site infections with a focus on risk assessment, monitoring and translation of best practice into hospitals and community health care. Dressings and devices for surgical scar reduction, wound dehiscence and infection prevention. Dressings, therapies and devices will need to be well advanced in the development pipeline with data demonstrating some level of efficacy and safety and have a strong intellectual property position.
Burns	Prevention and healing of burns, strategies for the translation of best practice into primary care. Public awareness (adults and/or children) to reduce the incidence of burn trauma and improve burn outcomes including the use of eHealth technologies. Dressings and therapies for management and scar reduction. Dressings, therapies and devices will need to be well advanced in the development pipeline with data demonstrating some level of efficacy and safety and have a strong intellectual property position
Diabetic foot complications	Prevention of diabetic foot complications including a reduction in amputations, improved healing of diabetic foot ulcers, translation of best practice into aged care, hospitals and the community. Linkages to high risk groups such as aboriginal (rural and remote) or migrant communities will be well regarded. Education and training for health practitioners, carers, patients including eHealth. Public and government awareness including policy development, health economics and reimbursement. Therapies, dressings and devices for foot injury prevention and offloading with particular reference to technologies for self-monitoring and management. Dressings, therapies and devices will need to be well advanced in the development pipeline with data demonstrating some level of efficacy and safety and have a strong intellectual property position.
Leg ulcers	Implementation of healing and prevention strategies, translation of best practice into aged care, hospitals and the community. Education and training for health practitioners, carers and patients including eHealth. Public and government awareness including policy development, health economics and reimbursement. Therapies, dressings and devices for compression therapy, debridement or infection control. Dressings, therapies and devices will need to be well advanced in the development pipeline with data demonstrating some level of efficacy and safety and have a strong intellectual property position.
Pressure Injury	<p>The following list represents the ranked priority for pressure injury research in Australia, as identified by 16 Australian pressure injury experts:</p> <ol style="list-style-type: none"> 1. Strategies to assess the skin and tissues. 2. Consensus on appropriate outcome measures for indicators of pressure injury healing and recurrence. 3. Studies exploring heel pressure off-loading and shear reduction strategies. 4. The economic cost of pressure injuries and strategies for their prevention and treatment. 5. Effectiveness of skin moisturisers and barrier products in preventing pressure injuries. 6. Effectiveness of early mobilisation interventions in preventing and treating pressure injuries. 7. Strategies to prevent and treat medical device related pressure injuries. 8. Frequency and content of consumer education for sustained knowledge and best practice in pressure injury prevention and treatment. 9. Comparison of high specification reactive surfaces with active surfaces (e.g. low-air- loss, alternating pressure) for preventing pressure injuries. 10. Effectiveness of different strategies for positioning and offloading the heels in the operating room. 11. Efficacy of polyurethane foam dressing compared with other prophylactic dressings. 12. Comparison of high specification reactive surfaces with active surfaces (e.g. low-air- loss, alternating pressure) for treating pressure injuries. 13. Strategies to relieve pressure in seated individuals. 14. Efficacy and cost-effectiveness of using prophylactic dressing in populations and clinical settings other than critical care (e.g. aged care, paediatrics, spinal cord injury). 15. Prevention of pressure injuries in the acute phase of spinal cord injury.
Skin tears	No new proposals sought at this time. Research from previously funded projects will continue to translate findings into practice.

Table 1 - 2014 Research Priority Areas

Project application and selection process

The review process will be commenced by a call for expressions of interest bi-annually, but may also be initiated by targeted project requests or projects directly commissioned by the WMI CRC. The expression of interest template can be downloaded from the WMI CRC website at www.woundcrc.com. Research Projects will be funded in the July 2015 round for up to 2.5 years (although shorter projects delivering near term impacts are encouraged) for commencement on Jan 1st 2016. Future rounds will be funded for shorter periods (e.g. if the WMI CRC has a round in Feb 2016 funding will only be available for 2 years starting from 1st July 2016).

There is no set budget for individual research projects, as projects are funded on a “as needs” basis. Previously funded projects have varied in budget from \$20,000 to around \$500,000. Projects with substantial in kind and cash contributions from partners are highly regarded. Please note that all funded applications must involve a WMI CRC Participant.

The current WMI CRC participants are:

- Curtin University of Technology
- Queensland University of Technology
- Smith & Nephew Pty Limited
- University of South Australia
- Royal Melbourne Institute of Technology
- Australian Wound Management Association Inc.
- Blue Care
- Department of Health South Australia
- Department of Health Victoria
- Ego Pharmaceuticals
- Metropolitan Health Service/Wounds West
- Queensland Health
- Royal District Nursing Service Limited
- Royal District Nursing Service South Australia
- Silver Chain Group
- Southern Cross University
- The University of Queensland
- University of Western Australia

The Research Advisory Committee (RAC) will review proposals and recommend projects for final approval by the Governing Board. The RAC will consider the quality of the science, clinical relevance and need, alignment with WMI CRC Core and Development Activities and transition plan,

timeline for delivery of impact, end-user support, intellectual property, team track record and financial commitment required to progress the research into the Development or Clinical programs. Proposals may be submitted for up to 2.5 years of funding (July 2015 round, with shorter periods for future rounds). Projects which include a phased approach in which funding is released based on reaching key deliverables will be viewed favourably.

A response to expressions of interest will be returned as soon as practically possible, but 15 working days from the closing date will be indicative. Well drafted proposals that are strategically aligned with the WMI CRC Research Priority Areas and WMI CRC Commonwealth Milestones will be considered further. The RAC will categorise expressions of interest into one of two categories: Reject or Accept and will provide feedback in both cases.

Applications categorised as Reject will be sent notification by email, including feedback from the RAC. No further correspondence will be entered into.

Applications categorised as Accept will be sent notification by email and asked to submit a full proposal by downloading the full proposal template from the WMI CRC website. These applicants may be asked to provide a presentation to the RAC to clarify details of their project proposal. It is the responsibility of the applicant to produce a high quality full proposal aligned to the WMI CRC Research Priority Areas. When the full proposal has been approved by the RAC, the project will then be presented to the WMI CRC board at its next meeting.

Approved research projects will undergo review each time the Research Advisory Committee meets with payment of project invoices subject to performance against agreed milestones and approval by the CEO. With this in mind the quarterly milestones will be written into new proposals such that they can be aligned to the reporting and invoicing period.

If the Research Advisory Committee determines that the project, for whatever reason, is no longer something that the WMI CRC should pursue then their recommendation shall be moved to the WMI CRC governing board for ratification.

Student Projects

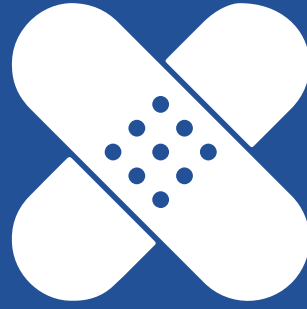
The WMI CRC postgraduate program aims to deliver industry ready graduates and increased clinical capacity for Australia's healthcare industry. The WMI CRC is dedicated to enhancing the educational experience of higher degree research students to better prepare them for professional careers in research or clinical practice.

Students undertaking a research project in association with the WMI CRC are likely to benefit from working in collaboration with industry and clinical partners, developing commercial and project management skills alongside advanced research and technical skills.

The WMI CRC has performed ahead of expectations in the recruitment and training of higher degree research students and the continuation of this success is critical for establishing the next generation of wound researchers. Applications for Honours and Masters students are open and can be submitted at any time using the student project expression of interest template which can be downloaded at www.woundcrc.com.

Student projects should be aligned with the Research Priority Areas but may contain a broader academic focus to provide a greater understanding of wound biology such as fundamental tissue biology. Higher education projects may be considered for follow on funding if IP opportunities or compelling utilisation pathways are demonstrated. Student projects would be expected to be completed by the end of the CRCs existing round of funding in June 2018.

Student projects may be approved by the CEO, following recommendations from the Program Leaders. Funding for Honours (1 year) and Masters (2 years) candidates is provided in the form of a part-scholarship of \$5,000 p.a. and \$7,500 p.a. in operating costs.





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