Business Plan for 2013 – 2018

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Contact Information

Rick Hansen Institute
Blusson Spinal Cord Centre
6th Floor, 818 West 10th Avenue
Vancouver, BC V5Z 1M9
Telephone: (604) 707-2100
Website: www.rickhanseninstitute.org

Rick Hansen Foundation
300 - 3820 Cessna Drive,
Richmond BC V7B 0A2
Telephone: (604) 295-8149
Website: www.rickhansen.com
EXECUTIVE SUMMARY

Imagine a not too distant future where....

In 2018, a newly injured individual with a traumatic spinal cord injury (SCI) in Canada will have greater chances of some neurological recovery than today and certainly far greater than when Rick Hansen suffered his SCI in 1973.

They will be triaged at a Rick Hansen Institute (RHI) SCI network site which adheres to national SCI standards of care and they will have access to leading edge SCI research. Their treatment will consist of best practices agreed upon by International experts to ensure they have access to early surgery, guidelines are in place to minimize pain and programs are available to maximize physical function such as reaching, grasping and walking. They will also be encouraged to enrol in International clinical trials that can promote neurological recovery within their lifetime. And throughout the continuum of care they will be an active participant in their treatments and will receive the information in a personal and timely manner to ensure they can actively manage their injury and achieve full participation when they return to the community.

Data on the clinical practice will be collected in the Rick Hansen SCI Registry (RHSCIR) using internationally agreed upon data standards and this data will be aggregated with other Canadian and International sites. This state of the art information technology platform will also collect imaging and biomarkers, paving the way for an era of personalized medicine.

Decision-makers in government and health authorities, meanwhile, will be able to evaluate improvements in patient care, outcomes and cost savings, which can be viewed as a model for other health conditions.

It is within our reach...

Every year, care and treatment for Canadians with traumatic SCI costs our health care system approximately $2.7 billion. As the population ages, the number of injured, and the related care costs, will grow.

Thanks to the support of our federal government, RHI remains focused on galvanizing the world’s best researchers, scientists, surgeons, and rehabilitation practitioners to collaborate on accelerating the translation of the most promising research into practical solutions for individuals with SCI.

With continued government support, the glimpse of the near term future offered above can be achieved and is only a few years away.

This Business Plan for the period 2013-2018 outlines the steps – the broad strategies and specific tactics and projects – required to reach the next milestone in achieving a world without paralysis after SCI.
Over the next few pages, this document will outline how we will:

- Bridge short term activities with its long term Vision
- Outline specific areas of focus, projects and core activities
- Show how and where we will use Government of Canada resources
- Deliver on specific outcomes
- And, submit a budget for 2013-2018

**BACKGROUND**

SCI is one of the greatest survivable catastrophes experienced by a human being. Regardless of cause or age at injury, SCI has a devastating impact on an injured person’s health and well-being, and far reaching consequences for individuals, their families and the health care system.

Required care is highly specialized and complex – including costs for acute, rehabilitative, emergency, primary, mental health, home and long term care and adaptive equipment – resulting in substantial financial costs for governments. In Canada, the cost of care for people with traumatic SCI is now estimated at approximately $2.7 billion a year.

The provision of SCI care across the country is not standardized. As a result, not all newly injured Canadians benefit from any emerging treatment advances as they become available. Therefore, there is a critical need to ensure that standards and best practices are implemented nationally. Availability of standardized care across Canada will not only ensure equitable care for individuals with SCI but also result in efficiencies and cost savings. Furthermore, recovery of the newly injured is complex and often fraught with secondary complications such as pressure ulcers, pain and bladder infections. The prevention and care of these secondary complications through the standardization of care for the newly injured is equally important and necessary when considering a path towards the cure.

Although there is still much that remains to be done for both the newly and chronically injured, we recognize that ultimate success will be limited if care and mechanisms across the country are not standardized to disseminate and apply life-saving and cost-saving new knowledge.

**Before 2007 – A Disconnected Patchwork**

Despite the commitment of well-trained and educated scientists, researchers, surgeons and clinicians, SCI research and care had changed relatively little since World War II.

Hampered by isolation, different standards of clinical care, a lack of clear best practices and an uncoordinated health care system, it was impossible until very recently to track injuries, interventions and outcomes across provincial jurisdictions, to recruit enough subjects for clinical trials and to conduct multi-centre SCI clinical trials.

Prior to 2007, the limited funds available for SCI research in Canada were directed primarily to basic science rather than to the translational research needed to address priority needs for people with SCI. Scientists and researchers worked in pockets, with no integrated national strategy or mechanism to collect and share data, to set priorities and manage funds efficiently; nor to standardize care across the country.
When Health Canada committed to a five-year funding agreement with the Rick Hansen Foundation in 2007, it demonstrated a progressive and insightful approach to tackle the staggering costs of SCI to our health care system, and to the quality of life of affected Canadian individuals and communities. The funding enabled the Foundation to launch the RHI, its most significant program, to begin to address the needs of Canadians with spinal cord injuries. This commitment also established Canada as a thought-leader in SCI research.

NOTE: Before 2007, GoC (through WD) provided $15M over seven years to begin the first work to bring disconnected SCI stakeholders and consumers together for the first time. The work led to a submission to Health Canada promoting the concept of a national network, which has ultimately become the RHI today.

**Progress to Date**

Despite having faced challenges typically encountered by any new organization, RHI has matured into one that works effectively and efficiently with a strong focus on collaboration, outcomes and accountability.

While the name of the organization has changed over the years, collaboration remains the key to its success, as does its vision: *a world without paralysis after SCI*.

In five short years, progress has been made to improve treatment and ultimately outcomes for people with SCI. RHI’s focus has tightened on maximizing impact in areas of strategic importance to individuals with SCI, continuing the advancement of our Rick Hansen SCI Registry (RHSCIR) and Global Research Platform (GRP), and accelerating progress with new partnerships and greater international collaboration.

In 2007, RHI, after extensive consultation with SCI stakeholders, developed a national strategy for cooperation in research and standardization of care for people with SCI. Since then, it has undertaken 67 projects in translational research and best practice implementation in the treatment and care of people with SCI. It has developed a pan-Canadian registry of SCI patients, and provided support to improving the lives and community participation of individuals across Canada.

To date, and in a modest timeframe, it has achieved progress in its program areas and created infrastructure that is leading to unprecedented collaboration in the field of SCI research and care.

**Barriers to Further Progress**

**The Missing Link: A Global Strategy to Cure SCI**

Although an impressive amount of work has been done and continues to be done to generate scientific and clinical evidence towards the cures for SCI (including the use of stem cells in neuro-regeneration of damaged tissue after SCI), **there is no Global Strategy or roadmap in place guiding these efforts.** To date there is no consensus on what clinical studies should be done or what preclinical (animal) studies need to be undertaken to inform these studies.
Instead institutions are working in silos without a single overall vision. There are frequent published reports of animal and human studies that provide promise to individuals with SCI about restoring function but almost all of these studies are too preliminary for assessment due to the limited size of the studies or the lack of demonstrated repeatability. These potentially risky trials may further jeopardize the health and safety of Canadians living with SCI participating in these trials. Part of the Global Strategy to Cure SCI must include a scientifically rigorous appraisal of all novel therapies developed internationally.

Any strategy towards the cure will require an assessment of existing knowledge, identifying gaps, a definition of the path forward with defined milestones and targets and the resources required to execute the strategy. The development of the Global Strategy to Cure must include consultation with experts in their respective fields and must include involvement from International representatives from various stakeholders such as people with SCI, regulatory agencies, ethicists, industry and policy makers. Finally, the success of the execution of the strategy will require collaboration from all stakeholders. The collaborations will encompass participation in International studies, sharing of research data, knowledge translation (KT) and ensuring that the trial patients all receive standardized care before and after initial treatment to reduce variability in study outcomes.

RHI recognizes that the development of a global cure strategy is an important first step towards meeting its vision. In the past five years, RHI has developed partnerships with international stakeholders, and with the RHI International Clinical Trials Network, is well positioned to facilitate strategy development and execution.

**The Need for Standardized Treatment of SCI in Canada**

At this time, although there are no known regenerative cures for the restoration of neurological function in people with chronic SCI (those currently living with paralysis from previously sustained injury), the newly injured have a greater chance of recovery due to advances in surgical interventions, the timing of these interventions after injury and advances in rehabilitation efforts. However, not all newly injured Canadians benefit from these advances as they are not universally available across the country. This disparity in care is due to a lack of institutional standards for SCI care across the country and limited clinical practice guidelines that are either available or have been implemented for the care of people with SCI across the health care continuum. In addition, there is limited consensus on the outcome measures that are necessary to evaluate the impact of treatment for people with SCI in the clinical setting.

Although there is still much that remains to be done for the newly and chronically injured to reduce paralysis after SCI, RHI recognizes that the success of future interventions and translation research findings around the cures will be limited if care across the country is not standardized with validated outcomes and mechanisms are not present for the dissemination of new knowledge. Therefore, our ability to better understand, measure and standardize the clinical environment will enable us to provide the cure to patients sustaining a SCI and measure the effects in clinical trials (i.e. improving the care for persons with SCI will prepare us for the cure). Treatments to minimize paralysis will need to be provided hours following injury and evaluated in multi-centre clinical trials. This will require a detailed understanding of the current health care system and the changes needed to provide treatments ‘out in the field’ hours following the injury.
Moving Research into Practice

As we strive towards developing a cure for SCI, it is important that the knowledge generated along the way is translated into practice. It was previously assumed that all research findings are incorporated and utilized by the intended users. However, in reality, it takes on average 17 years for new knowledge to be incorporated into practice and even when knowledge is translated, the utilization of the knowledge is inconsistent.¹

As described by the Graham et al ‘knowledge to action model,’ Knowledge Translation (KT) is a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the health care system.² KT takes place within a complex system of interactions between researchers and knowledge users that includes knowledge synthesis, dissemination, exchange and application. Knowledge users include other researchers, practitioners, administrators, policy makers and people with SCI. Implicit is the notion that evaluation and monitoring of KT initiatives, processes and activities are key components of the KT process. This overarching framework is critical to moving research into practice and will set the stage for the dissemination of the cure(s) for SCI when they are ready to be implemented. Furthermore, it will enable the impact of research initiatives to be evaluated and the successes and barriers to implementation into practice to be identified.

RHI recognizes that KT and the implementation of this knowledge into practice is as important as the research activities it undertakes to affect change towards the cure of SCI. Hence, RHI constantly strives to incorporate KT into all research activities with the ultimate goal of implementing best practices into the care of people with SCI. With this approach, RHI will shorten the 17 year time frame to achieve translation of knowledge into practice to ensure that all newly injured Canadians with SCI will have access to these cures as soon as they become available.

Economic and Sustainability Considerations for Best Practice Implementation

In Canada, we currently live in a time of limited government resources available for providing essential services to Canadians. Financial constraints in the health care system continue to be a major area of concern for health care providers and patients, particularly for SCI stakeholders where the annual economic burden of traumatic SCI is about $2.7 billion.³ Therefore, although improvements in care for people with SCI may become available through research, uptake of these improvements by the affected stakeholders may be limited if they do not offer cost savings to the health care system. It is therefore critical that economic sustainability be addressed for all research and best practices implementation endeavours at the onset to ensure uptake by stakeholders while providing benefit to people with SCI.

RHI recognizes the importance of economic sustainability of its BPI efforts and that these considerations are necessary during the design phase of all research studies that could lead to best practices. Therefore, RHI has identified economic sustainability as a major criterion for assessment of projects for investment.

**GOING FORWARD**

The objective moving forward is to refine RHI’s strategic research agenda towards a cure for paralysis, and focus on connecting the relevant national and International stakeholders to make this happen. Everything RHI does going forward must be focused on facilitating the efforts toward a cure and the translation of research results to ensure individuals with SCI receive the interventions they require.

RHF and RHI have recently received a commitment from the Canadian government for $35 million towards the continuation of its programs. RHI is submitting a new five-year business plan, details of which are included in this document, to guide activities towards meeting its objectives using these funds. RHI continues to recognize the importance of focusing on generating knowledge about SCI and the importance of translating the knowledge and affecting change in practice to result in better outcomes for people with SCI.

This five-year business plan reflects the commitment of RHI to build on its success and move closer to fulfilling RHI’s vision:

*A world without paralysis after SCI.*

*RHI’s mission is to lead collaboration across the global SCI community by providing resources, infrastructure and knowledge; and to identify, develop, validate and accelerate the translation of evidence into best practices.*

RHI recognizes that research must lead to action. For this reason, KT is integrated throughout the lifecycle of RHI research projects. This ensures that each project, from the design phase to best practice implementation, involves engagement of the appropriate stakeholders, and especially the ultimate consumers – people with SCI. This integrated approach towards knowledge development and application maximizes the general relevance of any project, while making sure that it incorporates translation strategies relevant to specific stakeholders.

This model – a national network with common goals, supported by infrastructure, resources and knowledge dissemination – is already making a difference, and will continue to result in better outcomes for individuals with SCI. This innovative model is unique in Canada and internationally for the SCI community. This model could also potentially be used for other health conditions such as traumatic brain injury or stroke.
Roadmap Towards the Cure: A 25-year Plan

In consultation with our stakeholders, RHI has developed 5, 10 and 25 year milestones to achieve its vision.

25 Year Milestones (2038)
By 2038, RHI envisions that all newly injured Canadians with SCI (traumatic and non-traumatic) will have access to novel therapies that will reduce paralysis and restore physical function in specific types of spinal cord injuries. There will be ongoing International collaboration working on a pipeline of other potential therapies being investigated through the RHI International Clinical Trials Network. In addition, all newly injured Canadians with SCI will receive comprehensive personalized treatments for their injury to minimize paralysis.

10 Year Milestones (2023)
By 2023, RHI envisions that there will be International collaboration on five promising neuro-restorative novel therapies [(i.e., neuro-regeneration, neuro-protection or neuro-plasticity) (e.g., stem cells)] in clinical trials utilizing the RHI International Clinical Trials Network that have been approved by the International SCI community. In Canada, 75% of all newly injured persons sustaining a traumatic SCI will be receiving standardized care in SCI Centres that are part of the RHI Network.

5 Year Milestones (2018)
By 2018, RHI envisions that there will be global collaboration among the International SCI Community based on a Global Strategy to Cure SCI. As part of this effort, RHI will be participating in two or more existing or new International clinical studies in neuro-restorative therapies. In Canada, 50% of all newly injured persons sustaining a traumatic SCI will be receiving standardized care in SCI Centres that are part of the RHI Network. RHI anticipates that a reduction of at least 11% in permanent paralysis could be achieved by providing available neuro-protective treatments such as early surgery and Minocycline for specific types of SCI.4

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The pathway to achieve RHI's vision through the aforementioned goals is depicted below.

**GOALS AND DELIVERABLES FOR THE NEXT FIVE YEARS**

**The Opportunity**

RHI is a catalysing, science-based institution with plans to lead collaboration on a global scale to help accelerate research in a wide range of clinical foci – from acute care to re-integration into the community – and encourage the application of new knowledge to improve health for people with SCI.

The SCI cure and care communities in Canada are invigorated, focused on priority areas of research, and engaged in national and International collaborations that are improving health outcomes for individuals with SCI, while reducing health care costs.

After only a few years of pursuing its mission, RHI has arrived at the intersection of unprecedented scientific progress in knowledge and transformative global communications technology. With its multi-faceted, integrated and collaborative strategies, RHI is galvanizing an army of people across this country and around the world to harness and share their collective knowledge and ability to deliver results at an astonishing rate.

RHI believes that rigorous implementation of this strategy to its fullest potential will have a far-reaching impact — not only for Canadians and our health care system, but for people around the world, and will further solidify Canada’s reputation as an inventive, global leader in SCI research and care.

At this time of unprecedented scientific progress and transformative global communications technology, a world without paralysis after SCI is possible.
RHI has identified the following four goals to be achieved by 2018:

1. Improved and standardized delivery of care across Canada and internationally
2. SCI research accelerated through greater access to data, increased researcher capacity, informatics support and leveraged funds
3. Lower re-hospitalization rates
4. Greater number of innovations brought to market

These goals will contribute towards achievement of the longer-term objectives in our mission: reduced incidence and severity of paralysis, improved health care outcomes, reduced long-term costs, and improved quality of life for those living with SCI. Ultimately, our work aims towards achievement of our Vision.

In order to meet these goals, RHI has identified the following five broad strategies to deliver on the WD funds for the years 2013-2018:

1. Support and undertake Translational Research Studies,
2. Support and undertake Best Practice Implementation Projects,
3. Engage in further Network Development in Canada and abroad,
4. Develop and accelerate the use of Informatics related to TR and BPI—based on the Global Research Platform (GRP) and
5. Support the next generations of SCI specialists, the Best and Brightest
As RHI moves towards achieving its goals, it has identified the following five functional strategies it will pursue in order to support these activities:

1. Support and undertake **Translational Research Studies**
2. Support and undertake **Best Practice Implementation Projects**
3. Develop and accelerate the use of **Informatics related to TR and BPI**—based on the RHI Global Research Platform (GRP)
4. Engage in further **Network Development** in Canada and abroad
5. Support the **Best and the Brightest** individuals in SCI related research.

This section describes the five strategies and the necessary infrastructure that will be developed to support the strategies.

**Strategy 1: Support and Undertake Translational Research (TR) Studies**

RHI supports and undertakes **translational research (TR) studies** to generate knowledge about SCI and to seek ways to improve outcomes for people with the injury. These research projects are therefore critical to the Core Business and ultimate outcomes of RHI. **Translational research** is a branch of medical research that attempts to more directly connect research with patient care by turning basic discoveries (developed, for instance, through multi-centre research studies) into new treatments and approaches that tackle the most pressing needs of individuals with SCI.

The following activities either directly align with or support RHI’s vision: A world without paralysis after SCI.

RHI will undertake the following Translational Research activities:

1. Develop a Global Strategy to Cure Paralysis after SCI
2. Participate in two or more new or existing neuro-restorative therapies (i.e., neuro-regeneration, neuro-protection or neuro-plasticity) (e.g., stem cells)
3. Continue existing clinical studies
4. Support at least two pre-clinical studies towards identification of readiness for clinical trials
5. Establish an International Biobank for SCI
6. Develop and/or validate outcome measures for clinical studies and treatment
7. Continue observational studies utilizing the Rick Hansen SCI Registry (RHSCIR) data and continue supporting the RHSCIR sites across Canada
8. Support emerging innovative technologies and interventions for SCI
9. Implement health economic evaluation for all translational research projects.

The details for each of these activities and the relevance to the vision are described herein.
1. **Develop a Global Strategy to Cure Paralysis after SCI**

*Relevance to RHI’s Vision: The Global Strategy to Cure Paralysis after SCI will guide all future International translational research activities related to curing SCI.*

*Deliverable: A Global Strategy to Cure Paralysis after SCI*

A cure for paralysis after SCI will involve an assessment of numerous therapies and technologies. Stem cells offer the most promising option for neuro-restoration and will be the centre piece of any cure strategy. Stem cells are undifferentiated cells that that have the ability to differentiate into specialized cells and form tissue depending on the site of implantation. Treatment involves the administration of transplanted stem cells at diseased or injury sites where tissue damage may have occurred. In SCI, it is envisioned that stem cells may help injured spinal cord tissue regenerate after treatment and restore neurological function (see Appendix 5 for more information on the use of stem cells in the treatment of SCI).

There are frequent published reports of animal and human studies that provide promise to people with SCI about restoring function (e.g. stem cells) but almost all of these studies are too preliminary for assessment due to the limited size of the studies or the lack of demonstrated repeatability. These potentially risky trials may further jeopardize the health and safety of Canadians living with SCI participating in these trials. Part of the Global Strategy to Cure Paralysis after SCI must include a scientifically rigorous appraisal of all novel therapies developed internationally.

Any strategy towards the cure will require an assessment of existing knowledge, identifying gaps, a definition of the path forward with defined milestones and targets and the resources required to execute the strategy. The Global Strategy will consist of methods to assess the readiness of emerging therapies for use in human clinical trials. An assessment of ongoing clinical trials and ways to address regulatory and funding hurdles will be included. The development of the strategy must include consultation with experts in the respective fields and must include involvement from International representatives from various stakeholders such as people with SCI, regulatory agencies, ethicists, industry and policy makers. Finally, the success of the execution of the strategy will require collaboration from all stakeholders. The collaborations will encompass participation in International studies, sharing of research data, KT and ensuring that the trial patients all receive standardized care before and after initial treatment to reduce variability in study outcomes.

2. **Participate in two or more new or existing neuro-restorative therapies**

*Relevance to RHI’s Vision: These studies will investigate the safety and efficacy of cure related therapies.*

*Deliverable: Participation in two or more International neuro-restorative clinical trials.*

Based on the aforementioned Global Strategy to Cure Paralysis after SCI, RHI intends to participate in two or more multinational multi-centre human clinical studies in neuro-restorative therapies. These therapies will include neuro-regeneration (interventions to replace lost neural tissue or induce growth of neural elements), neuro-protection (early interventions that will maximize neurological impairment by minimizing secondary injury) and neuroplasticity (activity-based interventions that maximize functional recovery).
Research in this area will include neuro-regeneration, neuro-plasticity and additional neuro-protection studies. RHI’s role in these studies may include co-funding, sponsoring (where RHI is the responsible partner) or by providing support through project management, data capture (using the RHI GRP) and data management services. RHI may also consider participating in existing International safety, proof of concept or pivotal trials.

RHI recognizes that there are significant ethical and legal issues surrounding the use of stem cell therapy. Therefore, RHI will only participate in stem cell studies within the context of ethical and legal confines. Wherever possible, RHI will seek funding partners for these studies and may leverage additional funding to support these trials. Because of the regulatory and recruitment challenges associated with these types of SCI clinical trials, RHI does not expect to complete any of the new clinical trials by 2018.

3. Complete two existing clinical studies

**Relevance to RHI’s Vision:** Results from these studies will inform the Global Strategy to Cure Paralysis after SCI.

**Deliverable:** Completion of two existing neuro-protection clinical studies.

RHI is currently supporting two neuro-protection studies, The Canadian Multi-Centre CSF Pressure Monitoring and Biomarker Study (CAMPER) and Minocycline (See Appendix 6 for details). The CAMPER study will provide important insight in the management of blood and intrathecal pressures in acute human SCI, and validate the use of cerebrospinal fluid (CSF) biomarkers to predict long term outcomes of SCI.

The Minocycline study will determine whether Minocycline (a generic antibiotic) is efficacious in the neuro-protection of the spinal cord after injury. These multi-centre studies are currently underway in Canada but RHI intends to expand them internationally and expects to complete them by 2018.

4. Support at least two pre-clinical studies towards identification of readiness for clinical trials

**Relevance to RHI’s Vision:** These studies will inform the Global Strategy to Cure Paralysis after SCI.

**Deliverable:** Support at least two pre-clinical studies towards identification of readiness for clinical trials.

The translation of studies from animal to humans needs to happen in both directions. Although pre-clinical animal studies are often forward translated to inform human clinical study designs, back translation from human to animal studies is often required to address questions raised in human studies.

RHI will therefore provide support for at least 2 pre-clinical animal studies related to promising neuro-restorative therapies or in understanding the molecular basis of SCI. The latter will
determine the feasibility of using intracellular genetics (genetic) or protein (proteomic) markers in predicting long-term outcomes of SCI and identifying targets for intervention in the treatment of SCI. (See description of genomics and proteomics in Appendix 5 below)

5. Establish an International Biobank for SCI

Relevance to RHI’s Vision: The Biobank will support the clinical studies towards personalization of the cure.

Deliverable: Establishment of an International Biobank for SCI.

Biobanks are centralized collections of human biological samples that often contain linked information about health, lifestyle, environmental factors, and family disease histories. Types of biological samples warehoused in a Biobank include blood, urine, biopsy samples, bone marrow, semen and cerebrospinal fluid (CSF). These samples may be used for in-vitro studies, transplantation, clinical care, health research, and a number of other uses, some of which have yet to be conceived.5

RHI intends to develop a Biobank of CSF from subjects in acute care studies such as the CAMPER and Minocycline studies. The CSF samples from the SCI patients may potentially be used for proteomic and/or genomic studies, or for future in-vitro assessment of promising pharmaceuticals for the treatment of SCI. An increasingly common practice in SCI research is to include biomarker analysis in order to obtain a better understanding of the biochemistry of injury and treatment. The development of a Biobank will enable SCI researchers worldwide to be innovative in their approach to this area.

The establishment of a Biobank will require the creation of governance, infrastructure and privacy requirements and will be done through partnerships with well-established Canadian organizations in this area, such as the BC BioLibrary,6 the Canadian Tumour Repository Network (CTRNet), and those embarking on similar endeavours, such as the Canadian Partnership Against Cancer (CPAC).7

6. Develop and/or validate five outcome measures for clinical studies and treatment

Relevance to RHI’s Vision: The development and/or validation of outcome measures are required to measure the efficacy of cure related studies and will be incorporated into the accreditation of SCI Centres in Canada.

Deliverable: Development and/or validation of five outcome measures for clinical studies and treatment.

Outcome measures are a means to establish the baseline impact of a disease on an individual and the changes experienced over time. In particular, they allow the effectiveness of an intervention to

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6 See http://www.bcbiology.icip.ca/.
7 See http://www.partnershipagainstcancer.ca/priorities/research/strategic-initiatives/canadian-partnership-for-tomorrow-project/.
be tested. There are currently more than 150 outcome measures that have been developed for use in individuals with SCI. These include assessment of the severity of neurological impairment following injury, physical body structure, physiological function, mobility, self-care, societal participation and quality-of-life. Despite the plethora of outcome measures, there is a general agreement within the SCI community that there is a need to validate as many of these measures for use in SCI clinical trials. (see Appendix 5 for additional details).

RHI will plan to support studies examining the psychometric properties of five outcome measures.

7. Continue observational studies utilizing the Rick Hansen SCI Registry (RHSCIR) data and continue supporting the RHSCIR sites across Canada.

Relevance to RHI’s Vision: The ongoing analysis of RHSCIR data will inform the Global Strategy to Cure Paralysis after SCI. The support for the RHSCIR sites will support the implementation of clinical trials and the implementation of accreditation standards.

Deliverable: Completion of 10 national studies utilizing RHSCIR data to include SCI epidemiology, modeling of health services, and health economics

The RHSCIR is the only Canadian prospective, observational, longitudinal study which follows people with traumatic SCI from the time of injury over their lifetime. It involves identifying eligible participants, obtaining consent, study enrolment, and data collection about the patient’s injury to follow-up data collection at one, two, five and then every five years thereafter from the date of their injury until the participant dies or withdraws from the RHSCIR study. In order to obtain a comprehensive picture of SCI in Canada, a minimal data set of all eligible patients is also collected as part of the study. There are currently 3,000 patients enrolled in RHSCIR increasing with an approximate rate of 45 patients per month. The overall objectives for creating the national RHSCIR study were to create a data repository to inform the Global Strategy to Cure Paralysis after SCI and support the effort to accredit SCI Centres.

It is our belief that the cure will come about in a non-linear fashion. All spinal cord injuries are not the same and we believe that a personalized approach to identifying those subgroups of injury patterns that are most amenable to dramatic outcome improvements will lead to a “cure”. RHI will encourage research that enhances our understanding of the injury and repair process in specific subgroups of injuries collected in the RHSCIR, particularly incomplete, central cord, high cervical, conus/cauda equina injuries. RHI will promote collaboration across disciplines and make patient data available so researchers can access (and link) clinical data to other innovative approaches that may lead to the cure. RHSCIR data will also continue to support studies such as the Access to Care and Timing (ACT, see Appendix 6) to model the pre-hospital phase of care, since this will inform the provision of cure related therapies that will need to be applied within hours following injury.

Given the importance of RHSCIR data and having a SCI network in Canada, RHI will continue to support the RHSCIR sites.
8. Support emerging innovative technologies and interventions for SCI

_Relevance to RHI’s Vision:_ New emerging innovations may support the translational research pipeline and will be consistent with the Global Strategy to Cure Paralysis after SCI.

_Deliverable:_ Not applicable as support of emerging innovations may occur in various forms depending on status of development and is therefore difficult to predict (e.g. product at proof-of-concept stage may require financial support only and products in clinical research may require extensive project or data management support).

In health care, there is a constant stream of novel technologies and interventions that are being developed which may have applicability to the treatment and care of people with SCI. RHI will support the development of select emerging innovations which are consistent with RHI’s 5 year goals. This support will also apply to innovations that have been proven effective in other indications and have sufficient rationale for testing in SCI.

9. Implement health economic evaluation for all translational research projects

_Relevance to RHI’s Vision:_ Economic evaluations of SCI and cure related therapies provide critical information for funders, policy makers and decision makers for the justification of RHI’s activities.

_Deliverable:_ Not applicable as this activity provides ongoing support.

Information on the lifetime economic burden following SCI is limited, especially in Canada. Much of the existing data on the economic burden of SCI is from the US, which limits comparison given the dramatic differences between the Canadian and US healthcare systems. RHI has recently completed the first study that attempts to model the current lifetime economic burden associated with traumatic SCI in Canada. All SCI studies should include a health economics evaluation to facilitate cost-effectiveness studies, which can inform future health care decision making. This research will inform healthcare decision-making with an aim to improving care at lowered costs.

**Strategy 2: Support and Undertake Best Practice Implementation Projects**

The success of cure strategies will be dependent on changes in practice within the existing the health care delivery system. The time to implement best practices is currently 17 years and this needs to be dramatically shortened to ensure Canadians with SCI will benefit in their lifetime.

RHI intends to become the world leader in promoting and implementing best practices for the care of people with SCI. With RHI’s network, we are uniquely positioned to influence behaviour change, and ultimately lead SCI research into action. The overall aim of RHI’s Best Practice Implementation projects is to lead the process of improving access to and adoption of knowledge, in order to help support evidence-based decision-making in SCI care in Canada and internationally.

The following activities either directly align with or support RHI’s vision: A world without paralysis after SCI.
RHI will undertake the following Best Practice Implementation activities.

1. Continue Existing BPI Efforts to identify needs of people with SCI, services available and validation of research evidence
2. Expansion of the Knowledge Mobilization Network
3. Develop three new clinical practice guidelines
4. Accreditation of SCI centres that are a part of the RHI Network
5. Develop a national program for SCI patient self-management
6. Facilitate investment into commercialization of innovative therapeutics, medical devices and diagnostics with applications to SCI.

The details for each of these activities and the relevance to the vision are described herein.

1. **Continue existing BPI efforts to validate research evidence**

   *Relevance to RHI’s Vision:* These previously funded RHI projects will provide the necessary evidence to further develop and support the accreditation of SCI Centres across Canada.

   *Deliverable:* Complete periodic updates of the research evidence resources as required.

Since 2007, RHI has supported a number of BPI projects that have centred around the rehabilitation services currently available to people with SCI [SCI Rehabilitation (E-Scan) Atlas Project] and synthesized research evidence for clinicians [SCI Rehabilitation Evidence (SCIRE) Project] (see Appendix 6 for the RHI Project Overview) for details of these projects). These projects will continue to receive support during the 2013-2018 period as they inform current and future BPI efforts.

2. **Expansion of the Knowledge Mobilization Network**

   *Relevance to RHI’s Vision:* The KMN will provide the necessary infrastructure required to implement best practices and support accreditation in Canada.

   *Deliverable: Expansion of the Knowledge Mobilization Network to include acute centres.*

RHI recognizes the importance of developing an infrastructure of leaders in KT for the effective dissemination and promotion of the uptake of knowledge and best practice guidelines. RHI has therefore initiated a pilot Knowledge Mobilization Network (KMN) comprised of six sites in Alberta, Ontario and Quebec. The network consists of leaders working collectively to implement guidelines in real-world practice. The scope of the KMN is to:

- Identify specific topics in the areas of acute, rehabilitation and secondary complications
- Identify the corresponding clinical practice change desired
- Identify which performance indicators to collect and assess (e.g. implementation process measures, clinical outcome measures at patient level, systems level changes such as
improved access to care, reduced length of stay, decreased economic burden of care and so on)

- Contribute to the body of knowledge on implementation science

Therefore, this project addresses multiple objectives from knowledge synthesis and infrastructure building to BPI.

During the period 2013-2018, RHI will undertake the following activities related to the KMN:

- Expand the KMN nationally to include British Columbia and the Atlantic provinces and implement the pressure ulcer guidelines previously developed for the pilot KMN project in Ontario, Quebec and Alberta.
- Implement at least five best practices relevant to implementation of the cure related therapies.

3. Develop three new clinical practice guidelines

Relevance to RHI’s Vision: These clinical practice guidelines will provide the necessary evidence to further develop and support the accreditation of SCI Centres across Canada.

Deliverable: Completion of three new clinical practice guidelines

During the 2013-2018 period, RHI will develop 3 clinical practice guidelines (CPG) for implementation through the KMN. These guidelines will be developed from existing guidelines developed internationally (e.g. by the Paralysed Veterans of America) and/or developed using Delphi surveys of subject matter experts or using existing RHI-funded resources such as SCIRE. These new CPG will address areas such as pain, bladder management or autonomic dysreflexia.

4. Accreditation of SCI Centres

Relevance to RHI Vision: Accreditation of SCI Centres in Canada will ensure Canadians receive standardized care which will maximize neurological function and facilitate the implementation of clinical trials.

Deliverable: Accreditation of 50% of SCI centres that are a part of the RHI Network.

Accreditation of health care facilities by a recognized body is a common approach to validate the implementation of best practices. This is due to the fact that accreditation is associated with validated and recognized best practices and accreditation provides credibility to institutions. In addition, in many countries, accreditation is required to obtain governmental funding and for licensing purposes.

Accreditation Canada (AC), a recognized and highly respected accreditation organization, in partnership with RHI, has developed Canada’s first accreditation standards for SCI institutions. Through this partnership RHI will accomplish the following:

- Wide and broad distribution of evidence based care standards for SCI through AC standards
- An accountability requirement for SCI institutions to demonstrate the compliance to AC standards to impact care
- Process to update and revised standards as new discoveries and knowledge become available.
- Opportunities to expand AC standards for SCI care to International SCI sites.

The development of the standards and a pilot implementation study involving 5 sites in Canada have recently been completed. By 2018, RHI intends to ensure that at least 50% of all SCI centres in Canada that are a part of the RHI Network have achieved accreditation. This corresponds to over 50% of all Canadians who sustain a traumatic SCI receiving standardized care. RHI will achieve this target through a strategic publicity and KT campaign and by providing resources and incentives to sites to achieve and to continue to maintain compliance to the accreditation standards.

5. Develop a national program for SCI patient self-management.

Relevance to RHI Vision: This program will complement cure related therapies, maximize quality of life for those living with SCI and concomitantly reduce health care costs.

Deliverable: A national pilot program for SCI patient self-management.

It is reasonable to expect that cures will encompass a spectrum from partial to complete full physical function. Those who regain partial function will still require lifelong care, albeit to a lesser degree than someone who experiences no recovery. These individuals who are partially cured will benefit from a self-management program to limit secondary complications (including urinary tract infections, pressure ulcers, and autonomic dysreflexia). These secondary complications result in repeated emergency visits and re-hospitalization for people with SCI and the associated cost and demands on the patients and the healthcare system in general.

It is believed that these secondary complications can be prevented, monitored or even managed in some cases by the patients themselves, through a self-management program. The key elements of such a program are education, delivery of the program and adequate resources for implementation and follow-up.

During the period 2013-2018, RHI intends to develop a strategy and implement a pilot SCI patient self-management program. This program will be developed and implemented in partnership with all stakeholders including clinician, people with SCI and consumer organizations. The successful implementation of this program will result in result in not only lower re-hospitalization rates, but an increase in the quality of life of people with SCI as they will be empowered to self-manage other issues as well such as physical activity, diet and sexual health.

6. Facilitate investment into commercialization of innovative therapeutics, medical devices and diagnostics with applications to cure-related therapies SCI

Relevance to RHI Vision: This program will support the development of cure related therapies for testing in clinical trials.

Deliverable: Sponsor annual Investor Forums.
Best Practices Implementation (BPI) includes the commercialization of new and innovative therapeutics, medical devices and diagnostics, into the delivery of healthcare. Due to the regulatory requirements of being able to market a new therapeutic, medical device or diagnostic, the product development pathway is lengthy and expensive. Many of these innovations are under development by small and medium enterprises (SMEs). SMEs typically must obtain funding from investors, such as angel investors or venture capitalists, in order to be able to progress through their innovation through the product development pathway. These investors will typically only invest into SMEs in which there is potential for a strong return on their investment. Obtaining this sort of funding, especially in a difficult economic climate, is extremely challenging and investors into the life sciences, biotechnology and healthcare industries have become increasingly conservative due to poor investment returns in recent years. This challenge is even more difficult for SMEs developing an innovation that has application to SCI as it lacks many of the hallmarks of an attractive investment opportunity, such as a large market size, and is often viewed as being too ‘niche’ a market to receive much attention from investors.

Therefore, SMEs developing SCI-related innovations need to demonstrate that their product or service does, in fact, represent a viable investment opportunity. The SME must be able to demonstrate the innovation provides a solution to a real problem faced by those with SCI and that the innovation can be effectively implemented into the delivery of healthcare of those with SCI.

RHI and its network of researchers and clinicians with expertise in SCI possess resources that can be leveraged to help these SMEs become a more attractive investment opportunity, thus facilitating the needed investment required to further advance the development of the innovation. In the 2013-2018 period, RHI will continue to develop and implement mechanisms that will facilitate greater investment into these companies in order to result in an increased number of new therapeutics, medical devices and diagnostics that will benefit those with SCI. These mechanisms include hosting SCI-focused investor forums in which selected SMEs will present their company and innovation(s) to potential investors and utilizing resources within RHI and its network to help validate the innovation’s utility with respect to SCI treatment and care. RHI will also consider providing funding to SMEs for well-defined projects that have promise for commercialization.

**Strategy 3: Develop and Accelerate Informatics Activities**

Access to a robust source of data on individuals with SCI is required to maximize the benefits of both TR studies and BPI projects. This sort of patient-specific information creates the foundation for high-powered clinical trials, and the potential for validating best practices as they are implemented with different subtypes of injuries to the spinal cord. Such a data set becomes increasingly useful as more individual patients are included, and their progress monitored over time as they pass through the health care continuum from acute to community-based care. Towards this end, RHI has developed a powerful web-based Informatics resource (the RHI Global Research Platform) that currently enables the electronic capture and warehousing of patient study data using an easy-to-use web platform. The web platform permits extensive connectivity between multiple sites and therefore enables multi-site, multi-national clinical studies.
In addition to the collection and managing SCI data, the informatics resource at RHI also develops information technological solutions for researchers and clinicians that facilitate research and BPI activities. These solutions include collaboration enabling and decision making tools based on ease of use and validated evidence.

Key support for Translational Research and BPI operations involves the ability to collect and synthesize pertinent data, particularly patient information. Informatics provides the tools and the services to RHI and RHI partners/customers to collect accurate patient health data, analyze that data, support the subject selection and analytic components of research projects, and ultimately maximize program adoption and patient outcomes.

The following activities either directly align with or support RHI’s vision: A world without paralysis after SCI.

RHI will undertake the following Informatics activities.

1. Expansion of the Global Research Platform (GRP) to support collection and analysis of proteomics, genomics and imaging data.

2. Develop clinical support tools to improve data quality for clinical trials and to facilitate the standardization of care

3. Data warehousing, reporting, statistical support and data management

The details for each of these activities and the relevance to the vision are described herein.

1. **Expansion of the Global Research Platform (GRP) to support collection and analysis of proteomics, genomics and imaging data.**

   *Relevance to RHI Vision: The expansion of GRP to collect molecular and imaging data will enable the development of new classifications and outcome measures that will assist in the prediction and evaluation of cure related therapies.*

   *Deliverable: The Global Research Platform (GRP) is collecting proteomics, genomics and imaging data.*

The Informatics group at RHI is responsible for developing and implementing all software and hardware solutions required to support RHI programs. The dominant expression of this effort currently is the RHI Global Research Platform (GRP), an SCI specific electronic data capture and warehousing system. The longstanding RHSCIR program and the collaborative networks of RHI now depend on the GRP as the technological infrastructure for managing data and SCI-related studies.

The RHI GRP currently enables the collection of standardized and high quality SCI data that includes demographic and clinical data. Although the data collected provide important information regarding the injury, it currently lacks critical non-clinical information to not only better understand the nature of the injury but also permit the evaluation of additional outcome measures for assessing recovery.

Examples of informative non-clinical data include molecular (proteins and DNA) data that predict outcomes after SCI and imaging data that provide a more detailed visualization of the injury (See Appendix B for details). Availability of such individualized information about a patient will enable a
personalized approach to the treatment and care, thus increasing the probability of improved outcomes. Such an approach to “personalized medicine” is considered to be an innovative approach to ensuring patient specific and thus optimal care in treatment of many diseases and adoption and analysis of some of the aforementioned data will benefit people with SCI.

During the 2013-2018 period, RHI intends to adapt the GRP to interface and capture data from external systems containing patient imaging, proteomics/genomics, and electrophysiology data. Collection of this data will enhance the value of RHSCIR to researchers as they will have access to more comprehensive data related to the patients’ injuries.

2. Develop clinical support tools

*Relevance to RHI Vision: The development of clinical support tools will improve data quality for clinical trials and will facilitate the standardization of care.*

*Deliverable: The release of the International Standards for the Neurological Classification of SCI (ISNCSCI) algorithm to the International SCI Community*

A number of other software solutions are under consideration by RHI that are complementary to the RHI GRP; for example, RHI is currently collaborating with American Spinal Injury Association (ASIA), and the International Spinal Cord Society (ISCoS) to develop a calculator for the International Standards for the Neurological Classification of SCI. The calculator will be compatible with a tablet or other mobile device that a clinician can use to capture and calculate neurological impairment using the standards with fewer errors than seen in manual calculation. This tool will be coupled with the GRP to allow for neurological assessment data capture for participating facilities and patients. During the 2013-2018 period, RHI will explore other needs from researchers and develop appropriate applications that support other evidence-informed practices.

3. Data warehousing, reporting, statistical support and data management

*Relevance to RHI Vision: Data warehousing, reporting, statistical support and data management will be critical to support the Global Strategy to Cure Paralysis after SCI and cure related therapies.*

*Deliverable: Not applicable as this activity provides ongoing support.*

The RHSCIR study activities and the support of clinical trials require the collection, warehousing, analysis and reporting of large sets of data that are collected as part of the studies.

The RHI GRP provides a robust technical solution for these needs. The data collection capability of the GRP, which is optimized for flexibility, allows the addition of multiple studies with different datasets from multiple sites and multilingual features.

The data warehouse capability of GRP, currently under development, will provide a facility for linkage between different data sources, the ability to analyze and report on data, and easily produce data extractions for research use.

All data extractions will be de-identified at the secure hosting facility before any research use. The use of this data will provide capabilities to enhance the understanding of and planning for individuals with SCI.
During the 2013-2018 period, RHI will continue a number of mission-critical services that support network activities. These comprise of the following:

- **Data Management**, including data collection form development, data linkage, data quality assurance, data transformation, data importing, managing requests for data access, and the creation of study metadata (e.g., data dictionaries) that support the TR and BPI needs of RHI project teams and RHI partners/customers.

- **Data Analysis**, such as statistics and reporting to TR and BPI needs, provided to RHI project teams and to RHI partners/customers.

- **Program/Project Consulting**, to support partners/customers in implementing their own research programs or projects. Informatics services available to partners/customers include: project management; study/registry design; privacy protection solutions and information technology (IT) support.

- **Other Support Services**, such as ongoing IT support to internal and external customers using RHI technical solutions in their registries, research studies, etc.

RHI’s informatics support will enable Canadian SCI researchers and clinicians to access the RHSCIR and other study data (through RHI Data Use and Disclosure policy and procedures) for analysis and reporting. These capabilities will also enable the linking of RHSCIR data with other International datasets, thus providing a means of International collaborations on SCI related studies.

**Strategy 4: Engage in Further Network Development**

RHI recognizes that the engagement of key stakeholders across areas of practice and geography is important to achieve its mission. Therefore, RHI will continue the development of networks of SCI stakeholders to facilitate research collaborations and best practice implementation nationally and internationally. RHI recognizes that it needs to forge strategic partnerships with various entities, nationally and internationally, for the purposes of funding and otherwise facilitating TR and BPI activities as part of enhancing the network. These entities include governments, granting bodies, corporations, research and health care organizations, and accreditation agencies.

From its inception, RHI has recognized the importance of collaboration to advance the cause of SCI research, and the implementation of best practices in SCI care. RHI has since succeeded in creating a highly collaborative and productive national network of SCI stakeholders.

Although the network was originally built through the expansion of the RHSCIR study, it now enables researchers to work collaboratively on numerous research projects including multi-site clinical trials. The use of the web-based RHI GRP facilitates interactions within the network by centralizing the data collection and warehouse capabilities.

During the 2013-2018 period, RHI will continue to support the national network and expand it internationally to create a truly global network of SCI researchers for collaboration in research endeavours, including multi-site clinical trials.
**The Rick Hansen International Clinical Trials Network**

The Rick Hansen SCI Registry (RHSCIR) study was established in Vancouver in 2004 and since has expanded to 31 facilities across Canada, effectively creating a clinical research network. This collaboration – largely due to the need to increase the number of participants available for clinical trials, and to enable interactions between researchers world-wide is now expanding internationally. This network will foster collaboration in the following manner:

- Utilize the RHI Global Research Platform as the primary clinical data collection tool
- Collect standardized International SCI Data Sets, which aim to standardize the collection, sharing and reporting of clinically-relevant information
- Recruit participants into clinical trials that would result in a substantial increase in the number of multi-centre and single site clinical trials being conducted world-wide
- Identify and select the most promising therapeutic interventions with the best chance of advancing to clinical trial, irrespective of country of origin
- Advance the adoption of best clinical practices at the international sites through appropriate accreditation processes.

RHI is already in discussions with SCI research and clinical institutions around the world to collaborate on international research activities. The countries that RHI has engaged include Australia, China, the United States, countries in the European Union and Israel.

**Benefits of the RHI Global International Clinical Trials Network to Canada**

Expanding the existing Canadian SCI research network globally will offer the following benefits to Canadian SCI stakeholders:

- The international network will provide access to a large population of people with SCI enabling the recruitment of more participants into an increased number of clinical trials
- The network of International scientists and clinicians will be able to collaborate with Canadian researchers to determine and validate the most promising discoveries in the world which should must then be assessed in clinical trials
- The International network of scientists and clinicians will be able to include participants from diverse populations, cultures, and socioeconomic groups
- The International network will enable the dissemination and adoption of standardized best practices in treatment and care of people with SCI, throughout all countries. Canadians with SCI will therefore benefit from best practices from other countries. Conversely, Canadian best practices may be adopted internationally, thus promoting the reputation of Canada as a global leader in SCI care
- The International network will enable financial support from multiple jurisdictions to be focused on the most pressing challenges and opportunities in the field of SCI
- Due to the increased interaction with International partners, Canadian researchers and people with SCI will be able to participate in high profile International SCI trials.
The following activities either directly align with or support RHI’s vision: A world without paralysis after SCI.

RHI will undertake the following Network Development activities.

1. Participate in 1 or more International prospective SCI data studies involving 4 or more countries
2. Organize and sponsor network conferences and meetings
3. Set up SCI knowledge management system
4. Develop a central patient recruitment model for clinical studies
5. Develop and nurture strategic relationships with national stakeholder organizations
6. Seek co-funding and leverage funding opportunities for RHI projects nationally and internationally

The details for each of these activities and the relevance to the vision are described herein.

1. Participate in 1 or more International prospective SCI data studies involving 4 or more countries

   Relevance to RHI Vision: International SCI Dataset studies will enable sites to connect and share standardized data and cure related clinical trial data as part of the RHI International Clinical Trials Network.

   Deliverable: Participation in 1 or more International prospective SCI data studies with data from a minimum of 4 countries.

RHI recognizes the value in collecting standardized and prospective health data about people with SCI. Towards this end, RHI is currently collaborating with the US National Institute of Health, International Spinal Cord Society and other International SCI institutions in identifying a standardized dataset that could be used to collect International data sets using the RHI-GRP. This collaborative effort will facilitate the collection and analysis of standardized, comprehensive health care datasets about people with SCI across the globe. In addition, the collection of standardized datasets on a single platform (GRP) will facilitate collaboration on International clinical trials. During the 2013-2018 period, RHI will participate in 1 or more International prospective data studies.

2. Organize and sponsor network conferences and meetings

   Relevance to RHI Vision: Bringing international experts together will help to develop a Global Strategy to Cure Paralysis after SCI and regular meetings will facilitate the sharing of data, ideas and develop collaborations.

   Deliverable: Host annual RHSCIR site coordinator meetings and one International SCI meeting.

RHI recognizes the importance of face-to face meetings and conferences to enable KT and collaborations. Since 2010, RHI has been hosting annual RHSCIR site coordinator meetings and in May 2012, RHI and RHF co-hosted a successful International meeting in Vancouver, interdependence 2012 (i2012) that brought together over 500 members of the Canadian RHI clinical research network, International partners, representatives from regulatory agencies, companies focussed on SCI products, investors, and people with SCI.
Progress in research, KT and best practice implementation projects, (many of which were funded by RHI) was shared. Feedback from the participants meeting expressed that value of such meetings in fostering collaborations and uniting the global SCI research and care agenda. Participants have expressed interest that RHI should continue to host them on a periodic basis.

During the 2013-2018 period, RHI will continue to host the annual RHSCIR site coordinators in conjunction with an annual meeting of the RHI Canadian Clinical Research Network across the country; host a i2012-like event; and sponsor other smaller but focused meetings internationally that bring together key SCI key stakeholders for discussions relevant to RHI’s vision. A meeting to bring together world experts working a cure for paralysis after SCI is an example of such a meeting.

3. Set up SCI knowledge management system

Relevance to RHI Vision: Bringing International experts together will facilitate the development of a Global Strategy to Cure Paralysis after SCI as well as the sharing of data and ideas.

Deliverable: Launch of a SCI knowledge management system

A key component of a successful network is the ability of share and disseminate knowledge effectively between researchers, clinicians and other stakeholders, including people with SCI. Knowledge can include published papers, study protocols, clinical study documentation, standard operating procedures, training materials, conferences/meeting related information, updates on RHI and network member’s initiatives and clinical practice guidelines.

RHI currently utilizes Sharepoint to share knowledge across the SCI network. During the 2013-2018 period, RHI will maintain and update this platform to include other modules to meet knowledge dissemination needs as the RHI network expands to International jurisdictions. The additional modules may include social media (to create a real-time Community of Practice), virtual meeting tools and e-learning modules (to limit travel-related costs).

4. Develop a central patient recruitment model for clinical studies

Relevance to RHI Vision: The development of a central patient recruitment model for clinical studies will facilitate the implementation of International clinical trials on cure related therapies.

Deliverable: Complete the pilot of a central patient recruitment model for clinical studies

One of the major challenges faced by SCI researchers worldwide is the inability to recruit sufficient patients for clinical research studies. This can be attributed to a number of reasons which include an overall low number of people with SCI compared to other indications (e.g., cancer and cardiovascular disease) and limited ability of people with SCI to get to clinical research sites due to transportation, accommodation and Canadian distance issues. However, one of the main reasons for limited participation in clinical studies is the lack of awareness of the existing clinical research studies by people with SCI willing to participate in such studies.

During the 2013-2018 period, RHI intends to develop a patient recruitment model that will focus on creating an inventory of all SCI related clinical research studies and informing potential participants about the study that they are eligible to participate in. of these trials.
In Canada, people with SCI who have participated in RHI-sponsored projects are asked to consent to future contact for new clinical research studies. RHI will explore the development of an International inventory, similar to the Canadian method, of patients who have consented to being contacted by clinical study researchers with the intention of bringing patients and the sponsors of clinical research and trials together. RHI will ensure that all features of this recruitment model will meet appropriate privacy and security standards.

5. Develop and nurture strategic relationships with national stakeholder organizations

**Relevance to RHI Vision:** The development and nurturing of relationships with national stakeholder organizations will be critical to the development of a Global Strategy to Cure SCI and accredit SCI Centres.

**Deliverable:** Formal partnerships with at least 5 new national stakeholder organizations to include funding agencies, non-SCI disease related organizations, consumer organization and research organization.

The success of RHI in its efforts to achieve its mission is dependent on the productive relationships it enjoys with all its strategic partners. The partners include consumer organizations (e.g. provincial Canadian Paraplegic Associations, SCI Canada), professional organizations (e.g. Canadian Medical Association, Canadian Spine Society), funding agencies (e.g. Michael Smith Foundation of Health Research), accreditation organizations (e.g. Accreditation Canada) and other disease related organizations and networks (e.g. Ontario Brain Institute, Canadian Stroke Network).

A Strategic Partnership is a formally-documented relationship with an individual or organization with the intent of accelerating RHI’s vision and goals through collaboration or funding support. Strategic partnerships will be established with individuals, governments, non-governmental organizations, trade associations, research and healthcare institutions, or corporations, and are developed locally, nationally and internationally.

To achieve its mission, RHI endeavours to lead such collaborations that will accelerate finding a cure and improving health care outcomes for people with SCI. RHI has identified the following four areas in which it has forged and continue to forge strategic partnerships:

1. Research Activities
2. Best Practice Implementation and
3. Policy Change

The following list outlines potential strategic partnership development opportunities (Please note that some of the proposed partnerships are already in exploratory stages of discussions).

**Research Activities**

- **The Canadian Institute of Military and Veterans Health Research (CIMVHR)**
  Tasked by the federal government and Veterans Affairs, this new institute is dedicated to improving care and treatment for military personnel veterans and their dependents (over 700,000 Canadians). CIMVHR works closely with Veterans Affairs since Veterans Affairs responsibilities are met through various compensation programs and commemoration. Research varies from primary care and clinical research to mental health and societal issues.
Knowledge acquired from research may be used to guide efforts in support of the health and well-being of Veterans Affairs clients.

- **The Collaboration on Repair Discoveries (ICORD).** ICORD is an inter-disciplinary research organization focused on SCI, and affiliated with Vancouver Coastal Health and the University of British Columbia. ICORD is co-located with RHI at the Blusson Spinal Cord Centre (BSCC) in Vancouver. ICORD and RHI are increasingly working together towards developing expertise at the BSCC in pre-clinical validation of novel basic science discoveries to identify promising areas of research that have the highest likelihood and impact of success to advance through clinical studies, trials and evaluations.

- **Canadian Spine Society (CSS).** The CSS is an organization composed of spine surgeons and health care workers focussed on advancing care for spine patients, and supports research in spine care. A strategic partnership will enable CSS-funded researchers to utilize the RHI GRP for research purposes.

**Best Practice Implementation**

- **Accreditation Canada.** A not-for-profit, independent organization that provides health organizations with an external peer review to assess the quality of their services based on standards of excellence. Participating in accreditation demonstrates an organization’s commitment to quality health care. Thousands of health organizations voluntarily participate in Accreditation Canada’s programs each year.

- **Canadian Medical Association (CMA).** A national, voluntary association of physicians that advocates for access to high quality health care, and provides leadership and guidance to physicians. The CMA aims to improve health status by educating and equipping the public, and advocating for effective disease prevention and health promotion, in addition to the treatment of disease, injuries and disabilities. There are 12 provincial and territorial medical associations that are divisions of the CMA but are autonomous, with specific responsibilities in their jurisdictions.

**Policy Change**

- **Provincial and national SCI associations (SCI Canada and provincial associations).** With divisions in all 10 provinces and 47 regional offices, SCI Canada, their affiliated provincial chapters and other SCI –consumer advocate organizations provides a wide variety of services to their membership. SCI Canada and their provincial chapters have a membership of more than 30,000 Canadians who have a SCI or other mobility impairment. Efforts from these organizations have helped in creating policies, legislation, and public awareness to remove barriers that exclude people with SCI from fully participating in society. These organizations are currently working closely with RHI to use the results of the RHI-sponsored SCI Community Survey to not only shape their strategic plans, but to actively create policy briefings to improve the conditions for people with SCI within their jurisdiction.

- **Health Authorities (e.g., Vancouver Coastal Health, Alberta Health Services).** Health authorities in Canada are tasked with providing health services to the public in various jurisdictions, RHI will work with health authorities to implement operational and health care practice policies for the care of people with SCI.

Significant effort is required to develop and nurture these relationships through co-sponsorship and co-hosting of events, advertising, and face-to-face meetings, co-funding activities of mutual benefit and collaborating on efforts for policy changes.
During the 2013-2018 period, RHI will actively continue its relationship with existing partners and develop new ones with those that align with its objectives.

6. Seek co-funding and leverage funding opportunities for RHI projects nationally and internationally.

Relevance to RHI Vision: Co-funding and leveraging funding opportunities to support RHI projects nationally and internationally is important to ensuring the sustainability of the Institute and Network.

Deliverable: Funding leveraged format least 5 provinces, one of the national tri-council agencies and one International source.

RHI recognizes that the importance of leveraging Government of Canada funding to seek funding from other sources to ensure its sustainability and the sustainability of its network. In partnership with the Rick Hansen Foundation, RHI will seek funding from provincial governments, persons of high net worth and corporations. RHI will also actively seek opportunities of co-funding projects with provincial funding organizations (e.g. Michael Smith Foundation of Health Research) and other SCI organizations and governments around the world. RHI has significant experience in this area and was successful in leveraging the original Government of Canada funding for the period 2007-2012 ($30 Million) for an additional total of $38.7 million from provincial governments. RHI was also successful in co-funding several projects with other organizations (e.g. Ontario Neurotrauma Foundation and Alberta Paraplegic Foundation and British Columbia Institute of Technology).

During the 2013-2018 period, RHI, with the leadership of the Rick Hansen Foundation, will seek to obtain funding from aforementioned entities. The efforts required to obtain funding involve travel and meetings with key individuals, attending conferences and network events, hosting events showcasing RHI and network accomplishments and the use of consultants.

Strategy 5: Support the Best and Brightest

Relevance to RHI Vision: Building research capacity in Canada related to stem cell research towards the cure and its implementation into clinical practice supports RHI’s Vision.

Deliverable: Support two post-doctoral scholars.

Although Canada has several world class researchers in SCI, there is an on-going need to increase the amount of SCI research capacity in Canada and to encourage promising young researchers to pursue research in SCI. Towards this goal, RHI intends to co-fund academic Post-doctoral Scholars in research areas of SCI. The intention is to encourage young Canadian researchers by leveraging funding from RHI’s national partnerships with academic, granting, industry, professional and accreditation institutions. These proposed RHI Scholars will offer significant benefit to the SCI research field in Canada that include:

- Developing leadership and expertise in targeted areas of science that are critical to RHI being able to make progress on its Mission and Vision
• Creating opportunities to generate additional resources from research funding organizations
• Developing the capacity in SCI research in Canada

RHI will therefore provide matching funds (in collaboration with the aforementioned partners) for one Post-Doctoral scholar in each in the following fields:
• Late stage preclinical stem cell research in the treatment of SCI, and
• Implementation and KT sciences

During the 2013-2018 period, RHI will fund the aforementioned scholars for a minimum of two years, depending on co-funding availability.

Although RHI has committed direct funding for 2 scholars only, it is important to note that many of the project grants described in this document will include support for graduate students and post-doctoral fellows. Therefore, RHI’s efforts will result in the indirect and direct support of several young researchers in SCI over the 2013-2018 period.

**Corporate Infrastructure**

Administration costs are distinguished between those that are directly related to running a program and those that are support functions.

Direct Program Administration costs include the program employees, specialist consultants from programs, review committees, memberships of associated organizations, attendance and presentations at program specific conferences, and meetings with current and potential partners nationally and internationally. These costs are included in the program costs.

Leadership, coordination and program support incorporates the corporate infrastructure and support services and costs. These include the staff costs and expenses relating to the internal leadership and support staff, governance (boards and committees), and external consultants and contractors (including legal and audit). The support services include accountability, finance, human resources, operations, compliance, resource development, communications, marketing and IT needs. The costs include legal, audits, insurance, bank and management fees, occupancy (rent, utilities, leasehold improvements, etc.) telecommunications, computer and office equipment and supplies, licenses, and other office overheads.

Over the next five year period the Rick Hansen Foundation (RHF) and RHI will continue to collaborate in support of the goal to accelerate progress to find cures for SCI. RHI will lead on the scientific program while RHF will lead in the provision of shared services, including support for International outreach, Finance and Accountability, Marketing and Communications and Resource Development.

Under the shared services agreement, which is designed to bring efficiencies with the Rick Hansen organizations and alignment with Rick Hansen’s vision of cures after SCI, the support for accountability, finance, resource development, communications and marketing will be provided by RHF under a shared service agreement. All other support and overhead expenses will be incurred directly by RHI.
APPENDICES:

APPENDIX 1. PERFORMANCE MEASUREMENT AND EVALUATION

RHI is committed to the principles of monitoring and evaluating the performance of its projects and programming, in order to better understand the factors affecting how evidence leads to practices that will improve the lives of people with SCI. The reported results of RHI monitoring and evaluation activities will be used in four ways:

1. They will provide RHI Project Managers and Program Directors with the information they need to manage well, by informing them of what works and what does not.

2. They will provide important evidence to RHI Senior Management and the Board on the success of strategic plans, thereby informing decisions about changes required to better meet the objectives of the organization.

3. They will give RHI donors, network members, and the broader community information on how well RHI is continuing to meet their needs and priorities.

4. Through publication of the findings, they will contribute to the growing body of knowledge on specific areas of focus, and thereby help to guide other organizations carrying out similar SCI interventions, KT projects, etc.

Performance measurement and evaluation within RHI are inextricably tied to a commitment to KT, as described earlier in the overview of Best Practice Implementation. All of RHI’s activities, from research to network development, find their value in the planning aspects and execution steps related to KT. The usefulness of evidence created from RHI’s research activities, for example, is defined by the ways in which that evidence informs how people with SCI are cared for in practice. For this reason, a substantial component of RHI evaluation will focus on KT Science, or the study of the factors influencing how best to encourage adoption of evidence into clinical practice or policy.

RHI has developed a logic model describing its theory of change in the SCI environment. Based on this, the organization will develop a performance measurement framework to outline how achievement of results will be measured, and will ensure all projects collect performance data in alignment with this framework. Finally, a multi-year evaluation plan will be developed early in 2013.

Logic Model

RHI’s logic model, shown below, demonstrates the link between its strategies, outputs and expected outcomes and, ultimately, with its Vision. Within the outcome statements, the numbers in parentheses correspond to the strategies that contribute to achievement of those outcomes.
RHI Logic Model

**Strategies:**

**Outputs:**

1. **Translational Research**
   - Global SCI cure strategy
   - Clinical and pre-clinical studies, research on technologies and interventions
   - R/SCIR and biobank
   - Validated outcome measures
   - Health economic evaluation of research

2. **Best Practice Implementation**
   - Knowledge Mobilization Network
   - Validation of evidence and development of best practices
   - SCI Centre accreditation
   - Patient self-management program
   - Commercialization of therapeutics, devices, diagnostics

3. **Network Development**
   - Network conferences and meetings
   - Strategic relationships with national stakeholder organizations
   - SCI knowledge management system
   - International prospective SCI data set study
   - Central patient recruitment model
   - Co-funding and leverage funding

4. **Informatics**
   - Adaptation of GRP to support new types of studies
   - Clinical support tools
   - Data warehousing, reporting, statistical support and data management
   - GRP as data collection tool for international clinical trials network

5. **Best and Brightest**
   - Support to PhDs and post-doctoral scholars

**Immediate Outcomes:**

- Knowledge created on neuro-restitution (1)
- Improved evidence-based standards for SCI (1, 2)
- Canadian sites are accredited (2)
- Improved patient self-management (2)
- Increased investor funding for innovations (2)
- Increased collaboration of key stakeholders across areas of practice, nationally and internationally (1, 2, 3, 4)
- Informatics needs of research studies are met (4)
- Research capacity built in Canada (5)

**Intermediate Outcomes:**

(to 2018)

- Improved and standardized delivery of care across Canada and internationally (1, 2, 4)
- Lower rehospitalization rates (2)
- Greater number of innovations brought to market (2)
- SCI research accelerated through greater access to data, increased researcher capacity, informatics support and leveraged funds (1, 2, 3, 4, 5)

**Ultimate Outcomes:**

(beyond 2018)

- Reduced incidence and severity of paralysis, improved health care outcomes, reduced long-term costs, improved quality of life for those living with SCI (1, 2, 3, 4, 5)

**RHI Vision:**

A world without paralysis after spinal cord injury
Performance Measurement

RHI has integrated performance measurement into everything that it does. The senior staff have developed and implemented policies, procedures and practices to ensure performance measurement is incorporated into daily organizational activities. Once an organization-wide performance measurement framework is developed, each project will have a specific logic model developed during the planning stage, with performance indicators identified that are pertinent to that project. Data collected during project/program implementation are entered into a performance measurement database for the purposes of aggregation and analysis. There is regular and active communication with grant recipients on performance measurement and evaluation requirements, and reporting on grant projects is reviewed to ensure accuracy, validity and comprehensiveness. Finally, workshops and other communications to RHI staff and our Board encourage use of performance measurement and evaluative information. The table below identifies some of the performance measures to be collected by RHI.

<table>
<thead>
<tr>
<th>Result</th>
<th>Examples of Performance Indicators</th>
</tr>
</thead>
</table>
| Outputs | Percent of project milestones achieved  
Number of research studies supported, by type  
Degree of consumer engagement informing development, design, and evaluation of RHI projects  
Number of sites participating in key projects (RHSCIR, KMN)  
Number of publications, conference presentations, other knowledge products  
Number of outputs supported by the outcomes of other RHI work |
| Outcomes | Results of peer review  
Level of satisfaction  
Number of citations of publications  
Number of awards won for research |
| Accelerated research | Number of new research studies enabled by RHI products/services (data accessed from RHI sources, data linkage enabled by GRP, etc.)  
Cost-effectiveness of research studies enabled by RHI |
| Increased collaboration of key stakeholders | Number of stakeholders engaged, by type and by region  
Level of cooperation and collaboration |
| Canadian sites accredited | Percent of sites accredited among RHI network sites |
| Improved and standardized delivery of care | Percent of Canadians sustaining a traumatic SCI receiving standardized care  
Level of adoption of standards among accredited sites  
Level of adoption of RHI-identified best practices in targeted sites |


<table>
<thead>
<tr>
<th>Result</th>
<th>Examples of Performance Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of clinicians self-reporting use of evidence-based practices</td>
<td></td>
</tr>
<tr>
<td>Improved self-care by people with SCI</td>
<td>Percent of people with SCI self-reporting use of evidence-based self-management practices</td>
</tr>
</tbody>
</table>

**Evaluation Methodology**

RHI will evaluate the extent to which its projects were effectively translated into conceptual, instrumental, and/or strategic use, and the contextual factors influencing this translation. The organization will employ a number of evaluation approaches, including economic assessment and case study methodology. Where possible, evaluations will adopt a quasi-experimental design for maximum rigour in a field setting (recognizing that in most cases a fully randomized design will not be possible for ethical or practical reasons). Evaluation processes will be as participatory as possible, involving both immediate RHI stakeholders (researchers, clinicians, policymakers), and ultimate beneficiaries (people with SCI and their families) in all stages of the evaluation design and implementation.

Other concepts and models are anticipated to be of use in RHI’s evaluation. In order to capture its engagement of external stakeholders, models of collaboration and network evaluation will be exploited. When evaluating ongoing multi-centre clinical studies, the notion of process use (which is drawn from the field of evaluation) will be employed to conceptualize early outcomes.

Early in 2013, RHI will develop a multi-year evaluation plan covering the period from 2013 to 2018, which will identify evaluation coverage, scope, and timelines. Evaluation coverage at the project level will prioritize pilot projects as well as more innovative or higher-risk projects. Organization-wide evaluations will be conducted twice in the five-year period, for the purposes of strategic decision-making and accountability to donors and the broader community. These evaluations will be partially informed by meta-evaluation involving synthesis and analysis across the aforementioned project evaluations.
RHI’s Vision

Rick Hansen’s guiding vision has remained steady over more than 25 years, and has consistently informed the direction and work of the various organizations he has helped to found and lead.

Vision: A world without paralysis after SCI.

History of the RHI

25 years ago, Rick Hansen had a dream – to make the world more accessible and inclusive and to find a cure for paralysis after SCI. Inspired by a deep-seated belief that anything is possible, Rick’s “big dream” took shape in the form of the Man In Motion World Tour. For 26 months, he and his team wheeled more than 40,000 km through 34 countries, raising awareness of the potential of people with disabilities.

Following the Tour, Rick established the Rick Hansen Foundation (RHF) to continue his quest for an accessible and inclusive society and a cure for paralysis after SCI (SCI). Under Rick’s leadership, the Foundation functions as a social innovator, finding collaborative solutions to challenges in the community and the resources necessary to implement those solutions. It was also Rick’s vision to create the Institute that bears his name, and it continues to motivate all those working together to reduce the impact of SCI and improve the quality of health of those living with a SCI.

The RHI (RHI), as a program of the Rick Hansen Foundation, works to reduce the incidence and severity of paralysis after SCI and maximize quality of health for people living with SCI while reducing long-term costs.

RHI exists today because of Rick’s leadership and tenacity and his unparalleled ability to achieve “the impossible.”

The diagram below traces the organizational evolution leading from various predecessors to RHI.
The Reality of SCI

Spinal cord injuries have a devastating impact on the health and well-being of individuals. Many would categorize SCI as one of the greatest survivable catastrophes experienced by a human being. Health care needs for people who sustain a SCI are highly specialized and complex. Regardless of cause or age at injury, SCI has far-reaching consequences for individuals and their families.

Some facts on SCI in Canada:

- There are an estimated 86,000 people living with SCI in Canada, and millions more worldwide.
- An estimated 4,300 new cases of SCI occur each year in Canada.
- Traumatic SCI occurs most commonly in males between the ages of 16–30, although as the population ages, more injuries will occur from falls and illnesses.
- The economic burden of traumatic SCI is estimated at $2.7 billion a year in Canada (i.e., spending on health care, equipment and modifications, long-term care as well as indirect costs associated with morbidity and premature mortality).
- The economic burden over a lifetime for each individual can vary from $1.6-million for a person with paraplegia to $3.0 million for a person with tetraplegia.
- The financial burden is further compounded by the fact that the unemployment rate for those with SCI is as high as 60%.
Compared to the general population, Canadians with SCI:

- Are re-hospitalized 2.6 times more often
- Require three times more contact with a physician
- Require 30 times more hours of home care services
- And have a far shorter life expectancy, from 15 to 30 fewer years.

**Progress to Date in SCI Care and Treatment**

In 1973, Rick Hansen, then 15 years old, shattered his spine after being thrown from a truck. He spent seven months in recovery and rehab in Vancouver. Most of the first two months was spent in a bed to hold his spine in place in the hope it would heal. He soon learned he would never walk again. Returning home to Williams Lake, BC, he found a home and community with many accessibility barriers.

Today, new research is revolutionizing the treatment of SCI in the hospital and the community. In addition, new breakthroughs and discoveries, progressive drug therapies, and advanced surgical techniques are helping people to better manage quality of life issues associated with SCI, such as chronic pain, bladder and bowel complications, pressure ulcers, sexual dysfunction, and increased susceptibility to respiratory problems.

It is now known that:

- **Timely and early intervention after injury is a critical success factor.** A Canadian clinical trial, the RHI-supported Surgical Treatment for Acute SCI Study (STASCIS), is showing **20% improvement in outcome and reduction in impairment** after early surgical intervention.

- **The damaged central nervous system has the potential to rewire and adapt.** Rehabilitation strategies that utilize electrical stimulation can improve functional recovery. Dr. Milos Popovic, in an RHI-supported study, has shown that electrical stimulation to the hand can improve grasping function in individuals with SCI. In another RHI-funded study, University of Alberta Professor Arthur Prochazka developed technology that is now a commercial product in North America, Europe and awaiting regulatory approval in Asia that will allow individuals with tetraplegia to **maximize their hand function** in the comfort of their own homes.

- **Better understanding of underlying mechanisms of SCI is enabling development of new drugs and treatments.** Reducing the incidence and severity of secondary complications such as neuropathic pain will improve quality of life. Recent research has identified the importance of evaluating new treatments for SCI-related pain syndromes. For example, in an RHI-funded study, early findings indicate pregablin may act as a preventative measure to **reduce pain** signals that are sent out by damaged nerves in the body.
APPENDIX 3. THE QUEST FOR THE CURES IN SCI

Despite the progress, there is still a long way to go, and there are several significant challenges to overcome before we obtain a cure for SCI (SCI). The concept of “cure” is complex in medicine and health care as a whole. The specific definitional challenge varies by disease and discipline. In SCI, the “holy grail” of all inquiry is to identify approaches to repair and regeneration of the spinal cord; that is, a reversal of the damage to the neurological tissue, accompanied by avoidance of all consequences and complications flowing from such damage. For any and all severities of SCI, this essentially requires new, functioning nerves to bridge the gap where the cord was injured.

In the early 1990s, the well-known SCI leader Sam Maddox wrote The Quest for Cure: Restoration of Function after SCI in which the connection between cure and restoration of function was described. It was already clear, 20 years ago, that “cure” encompassed something beyond repair per se, that is, some form of functional recovery which will help improve quality of life. The following table summarizes targets that are now recognized in SCI research and care. These targets encompass restoration of motor function, but more importantly highlight how that a cure may also help to mitigate or abolish the secondary conditions such as bladder and bowel dysfunction which impact the lives of those living with SCI.

<table>
<thead>
<tr>
<th>Functional Target</th>
<th>Disorder</th>
<th>Cure as Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breathing</td>
<td>Ventilator-Dependent</td>
<td>Unassisted breathing</td>
</tr>
<tr>
<td>Motor Control</td>
<td>Paralysis</td>
<td>Full use of upper and lower limbs</td>
</tr>
<tr>
<td>Urination</td>
<td>Incontinence</td>
<td>Control over voiding</td>
</tr>
<tr>
<td>Sexual Performance</td>
<td>Impotence</td>
<td>Erections</td>
</tr>
<tr>
<td>Reproduction</td>
<td>Infertility</td>
<td>Successful assisted fertility</td>
</tr>
<tr>
<td>Reflex System</td>
<td>Spasticity</td>
<td>Prevention of episodes</td>
</tr>
<tr>
<td>Mental Health</td>
<td>Depression</td>
<td>Positive mood</td>
</tr>
<tr>
<td>Self-care</td>
<td>Dependence</td>
<td>Domestic independence</td>
</tr>
<tr>
<td>Physical Activity and Health</td>
<td>Obesity</td>
<td>Decreased cardiovascular risk factors</td>
</tr>
<tr>
<td>Community Integration</td>
<td>Isolation</td>
<td>Social involvement</td>
</tr>
</tbody>
</table>

In other health conditions, such as cancer, it has been shown that a cure can occur in a stepwise fashion. Small advances in pain management, a modest, but significant increase in life expectancy, and in some cases, remission (e.g. Hodgkin’s lymphoma) are more easily attainable rather than a single treatment that “cures” all cancers. Similarly, in SCI, any reduction in extent and severity of paralysis may be incremental—sometimes involving improvements at specific segments of the spinal cord. Researchers are on the verge of identifying subgroups of individuals with SCI where varying degrees of their paralysis can potentially be cured. In particular, nerve regeneration that would allow a patient to come off a

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ventilator or control their bladder is a target that is coming within reach. In summary, dealing with each affected body system could involve celebrating many tactical victories, even while the “war” against the injury to the cord tissue remains unfinished. Therefore it is envisioned that there will be cures rather than a single cure for people with SCI.
APPENDIX 4. DISTINCTIONS AND DIRECTIONS OF RHI

The RHI (RHI) evolved from the SCI Translational Research Network, which was established in 2007, primarily to foster greater collaboration across the SCI community with a view to accelerating progress towards a cure for paralysis after SCI. While there are many institutions working in the area of SCI, RHI’s focus has always been in specific clinical areas, such as increased restoration of physical function following SCI.

As a catalyst, RHI brings together the all the relevant stakeholders (e.g. researchers, clinicians, people with SCI, policy makers, funders) focussed on its vision. This is important to ensure the model is relevant, cost effective, collaborative and the outcomes have an increased probability of uptake and implementation.

Canada’s Emergence as a Global Leader in SCI Research & Care

Canada has taken a leading role in many of the advancements that have been translated from discovery into improved clinical treatment and services. The Rick Hansen Foundation and its partners have worked closely with government to build this leadership position, culminating in SCI expertise, technological innovation and a unique, inter-disciplinary approach that is widely admired around the world.

This leadership – through multiple investments in capacity and infrastructure – has resulted in:

- The creation of SCI Solutions Network in 2008, the predecessor to the RHI, representing a merger of three core components, the Rick Hansen SCI Registry (RHSCIR), the SCI Solutions Alliance, and the SCI Translational Research Network. The SCI Solutions Network renamed the RHI to better acknowledge the vision that Rick has championed from the start, and the work being undertaken to realize that vision.

- Being a catalyst in Canada and globally, with RHI combining leading-edge translational research and direct links to clinical best practice. Towards this end, RHI has established important partnerships with organizations focused on the implementation of standards of care and best practices such as Accreditation Canada. Several of the important projects being guided and sponsored by RHI are summarized and updated in the Current Project Update section of this document.

- The implementation of RHSCIR, the first and only Canadian prospective cohort study dedicated to collecting and sharing standardized SCI data. It has created a national network of SCI researchers and clinicians who recognize the importance of following standardized clinical practices. Representative of all of Canada’s major SCI trauma units and rehabilitation hospitals, the number of participants enrolled is now over 3000.

- The development of the RHI Global Research Platform (GRP). This is a state-of-the-art, web-based, secure data collection that enables easy and efficient capturing of data, readily accessed for research purposes. The GRP is highly adaptable: it can be used as a spine data collection tool supporting local as well as multi-centre clinical studies. The GRP is now being implemented internationally.
• The establishment of the International Collaboration on Repair Discoveries (ICORD) at the University of British Columbia and Vancouver Coastal Health as one of the largest interdisciplinary SCI research programs in the world. With 43 faculty and more than 300 trainees and staff, ICORD is leading numerous regional, national and International initiatives related to the treatment and care of people with SCI.

• The opening of the Blusson Spinal Cord Centre, an 11,000 square metre state-of-the-art facility housing ICORD, the RHI, the Vancouver Coastal Health Spine Clinic, and other service providers all under one roof. Centralizing these entities has allowed for increased efficiency by sharing administration and program supports, and by facilitating interagency meetings, as well as the intangible benefit of fostering high levels of informal access to colleagues.

**Translational Research**

Research that focuses on the application of ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease is termed Translational Research (TR). At RHI, TR ranges from translating knowledge gained in the laboratory into human-based studies through to applying knowledge from other disciplines, such as health economics, to health care. In the research realm, this process of translation is sometimes colloquially described as moving “from bench to bedside.” Building upon basic science or cross-disciplinary insights and building up a real-world knowledge base are ultimately aimed at generating new treatments and programs that will have an impact on the lives of Canadians with SCI.

**Categories of Translational Research**

RHI supports SCI-related translational research that reflects three categories or levels (as originally specified by the U.S. National Institute of Health’s *Roadmap for Medical Research*).⁹

- **T1**: Translation of basic research related to human studies
- **T2**: New tests and treatments that lead from T1 research and result in improvements in clinical practice for the benefit of people with SCI, as well as identification of gaps in care
- **T3**: Dissemination, implementation, and incorporation of recommended care and impact measurement. Note that the T3 level of work overlaps strongly with the work of the Institute categorized under best practice implementation

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The following diagram illustrates the relationships between the three levels:

Beyond the general categories described above, Translational Research at RHI has the following specific targets:

- Breakthroughs in treatments (i.e., cures, as defined in the preceding section) given to patients immediately following injury in order to reduce the level of paralysis or cures that restore function and reduce the impact and incidence of secondary complications, specifically pressure ulcers, pain, and bladder problems.
- The development and validation of best practice guidelines that can improve the care of persons with SCI in a sustainable manner.

**Operating Principles**

The principles that currently guide Translational Research efforts at RHI include:

1. **Applying a transparent process and relevancy criteria to the selection of clinical studies**

   The selection of projects at RHI undergo a rigorous external peer-reviewed assessment to determine relevancy to RHI objectives. The criteria utilized for assessment include:
   - Choosing the highest quality clinical trials based on the best available science
   - Engaging relevant stakeholders during the design and operational phases of all projects
   - Selecting studies that have a high impact for individuals with SCI
   - Considering the probability of uptake of the study outcomes by stakeholders
   - Assessing whether the study includes an integrated KT strategy
   - Determining whether the study will benefit from the RHI clinical trials infrastructure
   - Considering issues of sustainability related to the research itself and the potential care improvements
   - Assessing whether or not the study will help build research capacity in Canada.

2. **Focus on T2/T3 types of Translational Research**

   RHI will primarily focus on research that has a high probability of directly benefitting individuals with SCI. RHI will only support basic discovery research as it pertains to animal studies towards novel neuroprotection and/or neuroregeneration (e.g. stem cells) therapies.
In addition, the primary and secondary outcome measures must be aligned with the objectives of RHI, and there must be clearly identified translational research partners for an imminent clinical trial.

3. Supporting a personalized medicine approach applied to SCI

Personalized medicine is a growing perspective in many areas of health care. It involves the use of “in-depth biologic information about an individual patient to make decisions about [his or her] care.” In the context of SCI, the aim is to understand the differences in the extent and severity of each injury to the spinal cord, as well as its local, regional, and global consequences to the individual. This will allow for tailored interventions. All spinal cord injuries are not the same. The expectation is that a personalized approach to identifying specific patterns of injury that are most amenable to dramatic outcome improvements will lead to incremental movement towards a more comprehensive “cure.” For this reason, RHI will support TR that:

- Enhances understanding of the injury and repair process in specific subgroups of injuries, particularly incomplete, central cord, high cervical, conus/cauda equina injuries, as well as some forms of non-traumatic spinal cord impairment
- Develops and validates clinical practice guidelines that will assist clinicians in providing evidence-based care and to ensure people with SCI are getting the best available treatment for their type of SCI
- Relates to emerging fields that may be pertinent to personalized SCI care, including stem cells, genomics, proteomics, imaging, and outcome measures (e.g., electrophysiology-based, patient-reported measures, etc.)

4. Integrating a health economics component to all projects

The RHI will engage health economists and specialist SCI researchers, leveraging academic expertise and peer review systems to answer key research questions about the economic costs of SCI. This will enable RHI to understand the economic burden of SCI and related health conditions, and the economic benefits of certain treatments and prevention strategies.

Best Practice Implementation

Best practices are interventions, programs/services, strategies, or policies which have demonstrated desired changes through the use of high-quality, well-documented evaluation research. They have the ability to be replicated, and the potential to be adapted for use and transferred between institutions. A best practice is one that is most suitable given the available evidence and particular situation or context. In the context of SCI, such practices are used to demonstrate what works for enhancing the health of people with SCI, throughout their interaction with the healthcare system.

The term Best Practice Implementation (BPI) at RHI refers to the use of strategies to adopt and integrate best practices into the care of people with SCI. The focus of the BPI Program is to influence practice – level changes, resulting in altered behaviour of clinicians and patients towards better care of people

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with SCI. Therefore, the BPI Program aims to identify, validate and lead processes to ensure that best practices are used by clinicians and consumers towards achieving the aforementioned objectives of RHI.

BPI activities at RHI are closely aligned with Translational Research activities, and include leading and participating in all associated KT activities. RHI integrates KT throughout the course of TR projects, and seeks to ensure that users of the knowledge will be linked to the researchers conducting the research. Furthermore, emphasis is placed on the potential end outcome of the research studies, and how this will serve to impact the health outcomes of people with SCI. Therefore RHI utilizes a series of KT strategies to ensure research conducted in Translational Research has the greatest potential for use.

One of the key aspects of the BPI Program is the identification of the target audience (knowledge users) so that the activities can be customized appropriately to ensure effective uptake. This involves:

- Identifying the demographic and social profile of the audience
- Understanding the values, beliefs, attitudes, norms of the audience
- Understanding the factors or elements required to influence the audience
- Identifying the components required to determine the readiness for change

RHI is effectively able to obtain and assess this information through the RHI network of researchers and health care providers, across the SCI health care continuum.

A major challenge in current BPI efforts in SCI is the insufficient knowledge regarding the factors that determine the successful utilization strategies for the adaptation of best practices by specific audiences. This is due to the fact that Implementation Science—the study of BPI applications and techniques— is in its infancy with limited research data available for use in making informed decision in BPI efforts. RHI recognizes this deficiency and intends to play a leadership role in supporting SCI-related Implementation science nationally and internationally. The approach RHI intends to take in this effort is described later in this document.

**Operating Principles**

The **principles** that currently guide BPI work at RHI include the following:

1. **Using relevancy criteria to select projects for implementation**

   The selection of projects at RHI will undergo a rigourous assessment to determine relevancy to RHI objectives. The criteria used to determine relevancy are identical to the ones utilized for TR projects and address the following:

   - Choosing the highest quality projects based on the best available science
   - Engaging relevant stakeholders during the design and operational phases of all projects
   - Selecting projects that ultimately have a high impact for individuals with SCI
   - Considering the probability of uptake of the project outcomes by stakeholders
   - Assessing whether the project includes an integrated KT strategy
   - Considering issues of sustainability related to the research itself and the potential care improvements
   - Assessing whether or not the project will help build research capacity in Canada
2. **Evaluation of effectiveness will be integrated into all BPI activities**

RHI is committed to continually improving the reliability of best practice guidelines for the SCI population, and expanding their adoption. RHI will be evaluating all projects to identify the characteristics of successful implementation, and intends to utilize **participatory action research methodology** (an iterative process between planning, action, evaluation and reflection that includes continuous interactions with affected stakeholders throughout the project) to understand the effectiveness of various approaches to KT and BPI, and adjust, as needed, to ensure optimal uptake. We will incorporate methodologies developed by leaders such as the National Implementation Research Network (NIRN), an organization that has provided expert advice and consultation to the RHI-sponsored network set up to focus on BPI\(^\text{12}\) , to better understand the process of implementation.

3. **Fostering strategic relationships**

Developing an integrated KT approach requires significant investment in building relationships and formal partnerships. It requires bringing people together who normally do not have regular interactions so that they might openly share their respective knowledge in a trusting environment. RHI will foster relationships across various cultures and attitudes, aimed at recognizing norms that may be increasingly shared by all. Strategic relationships, relevant to BPI, will continue to be nurtured and leveraged with professional associations (e.g. Canadian Medical Association), accreditation organization (e.g. Accreditation Canada), KT and BPI focussed institutions (e.g. National Implementation Research Network), and funding agencies (e.g. Canadian Institute of Health Research and Michael Smith Foundation of Health Research).

4. **Promoting sustainable change**

Behavioural change in clinical practice is a long term endeavour requiring many years of investment; otherwise, both adoption and utilization tend to erode. Therefore, all implementation approaches must consider the mechanisms of sustainability, including a consideration of the different challenges at an individual and organizational level that may come into play. In most cases, a combination of interventions will be needed to achieve lasting change at both patient care and system levels.

5. **Integrating a health economics component to all projects**

As mentioned earlier, RHI will engage health economists and specialist SCI researchers, leveraging academic expertise and peer review systems to answer key research questions about the economic costs of SCI. This will enable RHI to understand the economic burden of SCI and related health conditions, and the economic benefits of certain treatments and prevention strategies.

APPENDIX 5. LEADING EDGE IN SCI RESEARCH

In addition to past and existing efforts, the frontline of SCI research continues to shift and expand. Four arenas have been identified as leading edges, offering exciting opportunities for new focal work led and sponsored by RHI. These four arenas are introduced in the following subsections:

Stem Cells

The term stem cell denotes a cell that can divide, give rise to more stem cells, and ultimately differentiate into diverse specialized cell types. Stem cell therapy is a potential treatment for SCI that has been a focus of scientific and clinical research for some time.\(^\text{13}\)

There are various types of stem cells that have been transplanted into the spinal cord after SCI, with the main goal being to promote organic repair and/or functional recovery from the injury. The therapeutic strategies of such transplantation include replacement of lost or damaged nerve cells, and promoting nerve cell regeneration. These strategies have demonstrated success in animal models of SCI, and therefore have potential for clinical application in humans.

While clinical trials have been initiated in this area, as yet, there is limited evidence of benefits. As a result, no stem cell therapies are currently approved for SCI. However, some strategies being explored show great promise and are deserving of more intensive study. For example, stem cells derived from mice have similar characteristics to human embryonic stem cells, while creating fewer ethical and political issues. Techniques for generating these types of stem cells continue to be developed. As well, studies are being conducted on their application in reversing neurologic disorders in animals other than mice.\(^\text{14,15}\)

Another area of interest is remyelination of damaged nerve cells at the injury site. Myelin is a coating surrounding nerve cells that facilitates signal conduction. Degradation or loss of this myelin sheath may occur as a result of SCI, thereby disrupting signals between the brain and other parts of the body. Repairing or replacing the myelin may improve signal conduction and thus reduce the consequences of SCI. Stem cells are currently being studied to determine whether they promote remyelination, which in the short term may prove to be a more realistic therapeutic goal than complete nerve cell regeneration. For example, Geron Corp. received FDA approval in 2010 to conduct a human clinical trial where SCI patients will receive injections of progenitor cells from a human embryonic stem cell line, between seven and 14 days post-injury.\(^\text{16}\)

Much research is still needed in the stem cell field, opening the door to multiple opportunities for RHI initiatives. For example, while many laboratories around the world are studying stem cell transplantation therapies, there is a great deal of uncertainty about what types of cells will enjoy the most utility. Other gaps in stem cell research include: differential effects in the rarer laceration-type


\(^{16}\) Kwon BK, Sekhon LH, Fehlings MG. Emerging repair, regeneration, and translational research advances for SCI. Spine. 2010; 35[21 Suppl]: S263-70.

injuries compared with contusion injuries to the spinal cord, a lack of studies in larger animals, and very limited investigations among subjects with long-term SCI.\textsuperscript{17}

**Proteomics and Genomics**

An initial impact or disease causes the primary injury to the spinal cord, but the loss of nerve cells and other tissue destruction does not end there. Subsequent injury to the spinal cord can continue for hours, days, and weeks after the initial lesion, mediated by various biochemical molecules at the cellular level. Indeed, a number of intra- and inter-cellular processes involving complex molecular cascades occur post-trauma. Understanding how these cascades are initiated and how they influence recovery following injury is a focal point of SCI research. With the recent advent of tools related to the fields of proteomics and genomics, researchers are now able to investigate molecular-level changes, and harness the resulting insights to improve the health outcomes of individuals with SCI.

Following traumatic injury a multitude of proteins are up- or down-regulated, with effects such as inhibiting cell death, promoting survival, and mediating regeneration of damaged neurons.\textsuperscript{18} The investigation of proteins in this sort of context is known as proteomics. The proteins involved may be explored as potential therapeutic targets, with the goal of accelerating natural recovery processes, initiating repair mechanisms, and promoting regeneration. Proteome analysis can also identify biomarkers that might help in classifying injury severity, predicting neurologic recovery, and monitoring improvements following interventions. Currently, functional measures are used for most of these purposes, but applying such approaches is impossible in many patients. Furthermore, the variability in spontaneous recovery among people, with the same functional classification, is quite high. Biological markers may be able to more precisely determine the extent of injury, and would thus be an important tool in conducting clinical trials of novel SCI therapies.\textsuperscript{19}

Similarly, research is ongoing to understand potential genetic determinants of the processes of neuro-protection, neural repair, and/or spinal cord regeneration. Some patients seem to recover from their paralysis faster or to a greater extent than others. Is this variation due to the unique genetic response of each individual to their injury? There is evidence to suggest this is the case. Some individuals express genes that appear to be connected to enhanced recovery. Researchers are attempting to identify these genes, and understand how they may be regulated as part of an acute intervention following injury. This key agenda in the field of genomics may be accomplished by assessing gene expression patterns. In such studies, researchers compare gene expression in healthy and damaged tissues to identify how the pattern has changed following a lesion. Genes that have markedly different expression in the two types of tissue are of interest as they may be influenced by the trauma, and therefore play a differential role (either positive or negative) in the recovery process. Researchers may then investigate how these specific genes are regulated. A therapeutic intervention will require either up-regulating genes involved in neuro-protection and/or repair, or down-regulating genes involved in extending neural damage.\textsuperscript{20}


Although manipulating the function of existing genes is a therapeutic approach that is arguably more within reach, there are more technically challenging therapeutic targets. For example, gene transfer using viral vectors to direct the host to promote healing in the spinal cord has shown promise in clinical trials. Further research is being conducted in areas such as improved vector systems with longer duration of expression and lower immunogenicity, regulation of gene expression, and identification of candidate genes for enhancement of spinal cord regeneration. These represent exciting research opportunities that could significantly impact future SCI recovery and rehabilitation interventions.

Proteomics and genomics are two cutting-edge and highly interrelated fields where RHI could help to make important breakthroughs that would identify intervention research targets and tools. RHI researchers have already been involved in bridging these two arenas by demonstrating the feasibility of coupled genomics and proteomics analyses (i.e., both performed on the same biological sample). Advances such as these will keep Canada, its research networks, and its International partners at the forefront of SCI-related science.

**Imaging**

In addition to magnetic resonance imaging (MRI), there are several other imaging technologies that have been developed over the past decade. Goldberg and Kershah have observed that these approaches have “enabled the non-invasive visualization of the spinal cord in a manner previously unimaginable in the living person.” This is important, as accurate diagnosis of the extent and severity of SCI is a cornerstone of effective treatment and rehabilitation. A clinical evaluation using the American Spinal Injury Association (ASIA) scale is common practice following SCI, offering a baseline measure of functional status. However, functional status is not explicitly correlated with the organic injury of the spinal cord. Two injuries that are similar upon clinical evaluation can have different organic causes, and thus require different treatment strategies (see figure below). This phenomenon is representative of the complexity of the spinal cord, which includes cell bodies, lengthy nerves (axons), and various supporting structures. Injuries to the cord can be isolated to a very small segment or can extend over many segments. Only advanced imaging techniques such as MRI can reveal the true extent and severity of the physical damage to the cord itself.

Kim et al. have noted that, for the first six hours following traumatic SCI (a period known as “spinal shock”), neither neurological exams nor electrophysiological measurements (see subsection on outcome measures below) accurately predict long-term functional impairment. In this and other clinical situations, imaging may provide an objective method with which to evaluate tissue damage. This modality can also help to guide surgery, and has also been shown to predict post-surgical outcomes.

Each different imaging method has specific advantages and disadvantages, driving researchers to refine current modalities and develop innovative approaches. Some of the newer modalities that have shown promise in improving the diagnostic assessment of SCI include diffusion tensor imaging (DTI) and myelin water imaging. In comparing DTI with traditional MRI, Chang et al. found that the “injured cervical spinal

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cord can be evaluated in more detail and more precisely using DTI...for which findings are correlated with clinical findings such as neurological impairments.\textsuperscript{25} When evaluating this imaging technique in mice, Kim et al found that, within three hours of SCI, DTI “accurately predicts long-term locomotor behavioural recovery.”\textsuperscript{26} If successfully translated to human subjects, the modality could help validate acute interventions, monitor efficacy of treatment, and allow more accurate prognosis to be assigned to SCI patients. DTI continues to be a rapidly developing technology, as evidenced by its positioning on the agenda of the 2011 ASIA/ISCoS symposium.\textsuperscript{27} Clearly, it represents a field of potential interest in a future RHI research agenda.

Myelin water imaging is a MRI-based technique that exploits the differential properties of water in various microenvironments of the central nervous system in order to better visualize tissue. A recent study applied this technology to the cervical spinal cord of healthy patients, with the investigators finding “excellent contrast between grey and white matter.”\textsuperscript{28}

Imaging represents a critical tool in the SCI continuum of care, informing clinicians about improved outcomes during the acute, rehabilitation and chronic phases, and thereby guiding development and dissemination of best practices. Continued investment in investigating the various techniques is required. Further progress, sponsored by RHI, will allow for the refinement of classical imaging methods, and the development of new modalities that will overcome limitations of current technologies.

**Enhancing Outcome Measures**

Outcome measures are a means to establish the baseline impact of a disease on an individual and the changes experienced over time. In particular, they allow the effectiveness of an intervention to be tested. To date, more than 150 outcomes measures have been developed for use in individuals with SCI.\textsuperscript{29} Some of the earliest examples served to classify the severity of neurological impairment following injury. Since then, they have expanded to cover various aspects of physical body structure, physiological function, mobility, self-care and, most recently, societal participation and quality-of-life.\textsuperscript{30} While creating new outcome measures is a key first step, they must be validated in real-world settings to promote their adoption in clinical settings. The SCI research community has been unanimous in calling for further validation studies of potential outcome measures.\textsuperscript{31}

Outcome measurement tools vary greatly, ranging from patient questionnaires to more elaborate technologies. Patient-reported measures in medicine are constantly undergoing refinement. For instance, the National Institutes of Health in the U.S. have adopted the Patient Reported Outcome

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\textsuperscript{25} Chang Y, Jung TD, Yoo DS et al. Diffusion tensor imaging and fiber tractography of patients with cervical SCI. *Journal of Neurotrauma*. 2010; 27(11): 2033-40.
\textsuperscript{30} Ditunno JF. Outcome measures: evolution in clinical trials of neurological/functional recovery in SCI. *Spinal Cord*. 2010; 48(9): 674-84.
Measurement Information System, an item bank that will influence the protocols for future clinical trials (including studies related to SCI treatments), sponsored by that agency.  

One category of measurement involves the field of electrophysiology, which offers an objective and reliable means to determine which neural circuits are firing in a damaged area of the nervous system. Electrophysiological monitoring is an umbrella term that includes a number of measurement techniques, each covering specific aspects of the central and peripheral nervous systems. It generally involves stimulating neurons to fire through electrical or magnetic stimulation and measuring the response. The resulting data can help to determine the level and density of injury, establish a baseline measure of physiological function, and monitor any recovery generated by natural processes and/or interventions. The approach is useful in SCI because neurological status is something that physicians, nurses, and other therapists routinely consider in order to monitor the severity of and progressive recovery from paralysis following SCI. Electrophysiology has particular value because it reflects improvements at the biological or “organic” level. Such changes have a higher probability of representing persistent and pervasive improvements for the SCI patient.

Xie and Boakye cite other advantages of electrophysiological approaches, including:  

1. The generation of quantitative, objective data that can be analyzed by blinded researchers.  
2. Flexible and environment-independent approaches, for example, allowing measurements on unresponsive, uncooperative, or comatose patients.  
3. The ability to target specific spinal segments and peripheral nerve tracts, including those below the level of injury.

Traditionally, electrophysiology has been employed to track neurological conditions in real time during surgery, partly to avoid causing further damage. More recently, the applications have expanded. In 2009, electrophysiology techniques were used in a longitudinal study to measure the effectiveness of stem cell treatment over the course of 2.5 years. In 2008, a novel electrophysiology method was described that may be able to assess muscle function in individuals with SCI, thereby demonstrating potential utility in guiding and evaluating rehabilitation programs.

Knowledge gaps in this arena have been identified, the most notable being that electrophysiological measures have yet to be fully standardized and validated in a clinical setting. Consequently, detailed guidelines for the use of electrophysiology-based measures have not been produced. However, progress continues to be made, creating a platform upon which RHI-supported research may build. For example, a recent paper published by ICORD researchers found that two electrophysiology modalities can reliably monitor changes in sensory function after a cervical SCI.

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The study authors state that these electrophysiological modalities may be “useful to monitor the safety of a therapeutic drug or cell transplant in early-phase clinical trials, as well as document the potential efficacy of interventions where the standard neurological assessment might not detect subtle changes in therapeutic effects.” The promise of electrophysiologic measurement in RHI research and treatment remains to be fully explored.

APPENDIX 6. RHI PROJECT OVERVIEW

Please see this booklet for information on some of RHIs priority projects.