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From Evidence to Practice: A Systematic Approach to Implementing Electrical Stimulation Therapy for Treating Pressure Injuries in Community Dwelling Individuals with Spinal Cord Injury

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Graduate Program in Health and Rehabilitation Sciences

A thesis submitted in partial fulfillment of the requirements for the degree in Doctor of Philosophy

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Abstract

Pressure injuries are a common secondary health complication among individuals with a spinal cord injury (SCI) and can have a profound effect on quality of life. Unfortunately, pressure injury care in community dwelling individuals with SCI is often fragmented and inconsistent across Canada. Current best practice guidelines strongly recommend the use of electrical stimulation therapy (EST) to manage pressure injury in this population; however, there is little uptake of EST, and is not considered as a first-line treatment by many clinicians. Therefore, the objective of this dissertation is two-folds 1) to determine the impact of pressure injuries on individuals with SCI (Chapter 2), and 2) to utilize a systematic approach to implementing EST for managing pressure injuries in community dwelling individuals with SCI living in South West Local Health Integrated Network (LHIN) in Ontario (Chapters 3, 4, and 5). The first study highlighted the importance of implementing pressure injury prevention and management programs in this high-risk population by reporting the negative effect that pressure injuries has on the ability of individuals with SCI to participate in activities of daily living and recreational activities, and the significant impact on quality of life and health care utilization. In studies 2 and 3, a pressure injury model of care involving EST was developed based on the barriers and facilitators identified by local stakeholders. The model was later adapted to fit the local environment by a team of local experts and a SCI consumer in a two-day workshop. The final study used iterative plan, do, study, act (PDSA) cycles to implement the adapted model of care into current practices. Multiple issues associated with key implementation activities were identified to limit the sustainability of EST for treating pressure injuries in community dwelling individuals with SCI, despite the numerous strategies put in place to solve the issues. However, these studies not only provide a clear approach to implementing pressure injury best practices, but the findings provide important insight to future researchers or clinicians interested in implementing EST for managing pressure injuries in community dwelling individuals with SCI.
Keywords

Pressure ulcers, participation, electrical stimulation therapy, spinal cord injury, implementation, knowledge translation
Co-Authorship Statement

The studies contained in this dissertation were collected, analyzed and written by the author, Deena Lala. Studies from Chapters 2 and 3 have been published, while Study from Chapter 4 has been submitted. Several co-authors have contributed to these studies and their impact is summarized below.

Study 1 (Chapter 2): The conception of this study, development of the consumer survey, and the data collection was performed by Luc Noreau. Frederic S. Dumont and Jean Leblond analyzed the data with the assistance of Deena Lala (DL). Data interpretation and the written manuscript was completed by Deena Lala and reviewed by Dr. Pamela Houghton and the other co-authors.

Study 2-4 (Chapters 3-5): These studies were conceptualized, collected, analyzed and written by Deena Lala. Specifically, Deena Lala interviewed the stakeholders and created the conceptual model of barrier and facilitators of EST implementation according to NIRN framework. Deena also collaborated with the steering committee to develop the model of care (Chapter 3). She organized the ADAPTE process, collected meeting notes and collated responses that resulted in the the initial adapted model of care in the form of a process map (Chapter 4). Deena worked closely with the specialized team (SCIPUT/PICS) at Parkwood Institute, SJHC, to create a process and data collection forms and communication processes on the customized electronic platform (CHAYA). Deena collected and analyzed all feedback from participants and providers that was collected via surveys throughout 5 the plan do study act (PDSA) cycles (Chapter 5). Dr. Pamela Houghton provided significant feedback in the construction of the studies and assisted in data collection for Chapter 5. Drs. Dalton Wolfe and Paul Holyoke provided significant guidance in the study design and methodology of these studies. Anna Kras-Dupuis provided input on the methodology and analysis of data from Chapters 3 and 5, while Lyndsay Orr assisted in data collection in Chapter 5. The manuscripts were reviewed by the co-authors of each manuscript.
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I would like to thank my co-supervisors Dr. Pamela Houghton and Dr. Dalton Wolfe for providing me with the guidance, support, and resources over the last five years to complete this thesis. Dr. Houghton and Dr. Wolfe also taught me the importance of balancing work and play, and always give time for myself.

Thank you to Dr. Paul Holyoke who took a great deal of effort in helping me understand different implementation methodologies and developing my skills in mixed methods analysis.

I would also like Anna KrasDupuis for not only providing great insight in the project, but always supporting me and giving me great advice. To my partner in crime, Lyndsay Orr, thank you for lending your ear during my frustrations, and constantly providing moral support.

To my parents, thank you for your unconditional love, supporting me throughout my life decisions, and always encouraging me to pursue further education. I would like to thank my sisters, for always being there when I needed you most. Finally, I would like to thank my husband, Nirav Rathod, for being my best friend, always supporting me and enduring all my ups and downs. I can’t thank you enough for all the times you made me laugh when I was overwhelmed and stressed.
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# List of Abbreviations

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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADL</td>
<td>Activities of daily living</td>
</tr>
<tr>
<td>AIF</td>
<td>Active implementation framework</td>
</tr>
<tr>
<td>AIS</td>
<td>American Spinal Injury Association Impairment Scale</td>
</tr>
<tr>
<td>BPG</td>
<td>Best practice guidelines</td>
</tr>
<tr>
<td>CBPR</td>
<td>Community based participatory research</td>
</tr>
<tr>
<td>CCAC</td>
<td>Community Care Access Centre</td>
</tr>
<tr>
<td>EST/E-Stim</td>
<td>Electrical stimulation therapy</td>
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<tr>
<td>KT</td>
<td>Knowledge translation</td>
</tr>
<tr>
<td>KTA</td>
<td>Knowledge to action</td>
</tr>
<tr>
<td>iADL</td>
<td>Instrumental activities of daily living</td>
</tr>
<tr>
<td>LHIN</td>
<td>Local health integrated network</td>
</tr>
<tr>
<td>ONF</td>
<td>Ontario Neurotrauma Foundation</td>
</tr>
<tr>
<td>NIRN</td>
<td>National Implementation Research Network</td>
</tr>
<tr>
<td>NPUAP</td>
<td>National Pressure Ulcer Advisory Panel</td>
</tr>
<tr>
<td>PAR</td>
<td>Participatory action research</td>
</tr>
<tr>
<td>PDSA</td>
<td>Plan Do Study Act</td>
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<tr>
<td>PIC</td>
<td>Pressure injury consultation</td>
</tr>
<tr>
<td>PU</td>
<td>Pressure Ulcer</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>RHI</td>
<td>Rick Hansen Institute</td>
</tr>
<tr>
<td>SCI</td>
<td>Spinal cord injury</td>
</tr>
<tr>
<td>SCI KMN</td>
<td>Spinal cord injury knowledge mobilization network</td>
</tr>
<tr>
<td>SCIPUT</td>
<td>Spinal cord injury pressure ulcer team</td>
</tr>
<tr>
<td>SW</td>
<td>Southwest</td>
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</tbody>
</table>
Chapter 1

1 Introduction

This dissertation focuses on understanding the significant impact that pressure injuries have on individuals with spinal cord injury (SCI) and describing a systematic approach to implementing pressure injury best practices, specifically electrical stimulation therapy (EST), in treating the pressure injuries in community dwelling individuals with SCI. This chapter provides the readers with the necessary background knowledge to prepare for the four subsequent chapters.

1.1 Pressure Injuries

According to the National Pressure Ulcer Advisory Panel (NPUAP), a pressure injury, is defined as a “localized injury to the skin and/or underlying tissue usually over a bony prominence or related to a medical or other device. Pressure injury has previously been referred to as pressure ulcers; however, in 2017, the NPUAP recommended a name change to more accurately describe pressure injuries occurring in both intact and open ulcers. Throughout this thesis pressure ulcers and pressure injuries will be used interchangeably since subsequent chapters represent articles that were written before or after the NPUAP name change.

Pressure injuries can be quite extreme, varying in size and severity, from mild redness of the skin to severe tissue damage affecting the muscle and bone. In 2016, the NPUAP developed a revised pressure injury staging system (Table 1), based on the initial staging proposal by Shea in 1975, in order to classify and describe wound severity.

Pressure injury develops when soft tissue is compressed against bony prominence usually while sitting in a chair or lying in a bed for prolonged periods of time. This pressure is enough to compress blood vessels and decrease or completely obstruct blood flow to the local and surrounding soft tissue, resulting in local ischemia. Local ischemia impedes the transportation of oxygen and essential nutrients for maintaining healthy tissue. However,
the tissue cells continue to metabolize and produce waste by-products that cannot be removed by the lymphatic system and accumulate locally. Ultimately, cell death occurs, resulting in necrosis of the skin and underlying tissues. Capillary walls can also be damaged, allowing fluid and red blood cells to enter the interstitial space leading to skin induration and erythema.

Relieving the pressure to the tissue allows for improved cell profusion and the removal of the waste by-products. Unfortunately, due to their lack of sensation and mobility, individuals with SCI are unable to experience the pain secondary to ischemia and fail to respond to applied pressure. Therefore, they are subject to tissue hypoxia and increased risk of pressure injury development.

1.2 Spinal Cord Injury and Pressure Injuries

Over the years, the life expectancy for individuals with SCI has increased dramatically, reaching approximately 25 to 30 years beyond their injury due to advances in SCI rehabilitation. Despite these improvements, individuals with SCI continuously experience secondary health complications, including pressure injuries. The most common areas of pressure injury in individuals with SCI include the ischium, sacrum, and trochanters, which corresponds to the areas in direct contact with the wheelchair. The prevalence of pressure injuries among individuals with SCI varies from 31% and 50%. Pressure injuries are one of the top five reasons for rehospitalization and reduced life expectancies in this population, unfortunately little is known about the impact that pressure injuries have on an individual’s ability to participate in their daily routine or recreational activities.

1.3 Canadian Best Practice Guidelines for the Prevention and Management of Pressure Injuries in People with SCI

In 2009, the Rick Hansen Institute (RHI) and the Ontario Neurotrauma Foundation (ONF) provided funding to a panel of experts from different disciplines to develop best practice guidelines (BPG) for the prevention and management of pressure ulcers in the SCI population under the leadership of Dr. Pamela Houghton and Dr. Karen Campbell. A
total of 112 recommendations were developed “to provide a common framework for spinal cord experts and wound care specialists to enhance pressure ulcer prevention and management strategies for people with SCI across the continuum of care”. This guideline is unique in that they itemize practices for occupational therapists and physiotherapists to help manage pressure injuries and protect the skin from pressure-related injuries. The partnership of ONF, RHI and the Alberta Paraplegic Foundation has created the Spinal Cord Injury Knowledge Mobilization Network (SCI KMN) to promote the implementation and sustainability of these BPG in SCI care to improve pressure ulcer outcomes.

Among the 112 recommendations for pressure injury management in individuals with SCI, there were only two recommendations that reported the highest level of evidence (i.e. 1A – evidence from meta-analyses or systematic reviews of randomized controlled trials) – adequate daily protein intake and electrical stimulation therapy (EST) use. EST with standard wound care has significant evidence to promote the closure of stage III and IV pressure injuries. EST involves delivering low levels of electrical current directly to the pressure injury or surrounding tissue using specialized electrodes and equipment.

EST can accelerate healing and enhance wound closure by mimicking the natural current of the skin when it is injured and facilitating the galvanotaxic attraction of cells required for healing. Otherwise wound repair process would be arrested and wound will fail to heal. EST promotes cellular and physiological action in most phases of wound healing. In vitro studies have demonstrated that EST can induce fibroblastic activity by increasing DNA and protein synthesis and increasing calcium influx; promote migration and activation of macrophages; and promote myofibroblast transdifferentiation. Some in vitro studies have also suggested that EST have both bacteriostatic and bactericidal effects on infected wounds. In vivo animal and human studies have demonstrated that EST can enhance angiogenesis by increasing capillary density causing increased blood flow and tissue oxygenation. EST has also been shown to improve tissue tensile strength by increasing collagen deposition.
1.4 EST and Pressure Injuries in SCI Population

To date, there have been three systematic reviews\textsuperscript{28–30} and three meta-analyses\textsuperscript{31–33} that have illustrated the benefits of using EST for treating chronic wounds. In addition, a meta-analysis and systematic review was conducted that pooled the effects of EST on healing pressure injuries specific to individuals with SCI.\textsuperscript{34} A total of eight studies\textsuperscript{35–42} compiled into two different meta-analyses reported accelerated healing by 1.32%/day and improved closure rates by 1.55 times in pressure injuries treated with EST compared to sham EST or standard wound care.

Although EST has frequently been shown to be an effective therapy for treating wounds, there is a lack of uptake for its use by clinicians.\textsuperscript{43} In 2010, Houghton et al.\textsuperscript{38} in collaboration with South West CCAC conducted a multi-centered controlled trial that demonstrated that EST could be applied successfully in a non-clinical environment, such as the patient’s home, with improved clinical outcomes and the assistance of care providers in the community.\textsuperscript{38} Despite these findings, EST remains overlooked by both patients and healthcare providers, particularly in the community for managing pressure injuries.

1.5 Implementation Frameworks: KTA and NIRN

Implementing evidence-based clinical best practice guidelines, such as EST, is challenging and therefore the recommendations are often not used effectively\textsuperscript{44} leading to a decrease in patients’ quality of care.\textsuperscript{45} In the United States, studies have reported that only about 55% of patients receive the recommended care.\textsuperscript{46,47} However, this is not surprising given the fact that it can take an average of 17 years for research knowledge to be incorporated into practice.

Knowledge translation (KT), also known as knowledge transfer or knowledge exchange, is a methodological strategy to avoid some of the challenges associated with implementation. CIHR identifies two different categories of KT: end-of-grant KT and integrated KT.\textsuperscript{48} End-of-grant KT is the most common road for sharing results, where the researcher develops and implements a plan for potential users to be aware of the
knowledge though simple communication activities. Common methods of end-of-grant KT include passive dissemination or distribution of research to practice; however, these methods are often ineffective to promote the uptake of recommendations and induce change to achieve optimal care.\textsuperscript{44,49}

Integrated KT engages stakeholders and potential users through the entire research process from development to dissemination of the research results. In theory, this integrated approach should produce findings that are relevant and used by end-users due to the active attention required during the coordinated practice of dissemination and implementation of guidelines.\textsuperscript{49} Unfortunately, translating knowledge is not an easy task and is often faced with many challenges. A one-year pilot study integrating a computerized ordering system for diagnostic imaging reported low acceptance, with only 2\% following the guideline’s recommendations.\textsuperscript{50} The group highlighted the importance of adequate resources, timing, funds and early involvement of key users and stakeholders.

Over the years, multiple frameworks have been developed to promote effective implementation. Many considerably overlap, and any construct missing from one is compensated in another. Two frameworks that have been widely recognized are Knowledge to Action (KTA)\textsuperscript{51} and the National Implementation Research Network (NIRN).\textsuperscript{52} KTA is an iterative, complex and dynamic process that consists of two concepts – knowledge creation and knowledge application.\textsuperscript{51} Knowledge creation consists of 3 levels and represents the process through which knowledge is created, distilled, refined and tailored to the meet the needs of the intended users such as consumers, health care providers, or decision makers. The action phase represents the process by which knowledge is implemented or applied. It consists of seven steps: (1) identify the knowledge gap, (2) adapt the knowledge to the local context, (3) assess barriers to knowledge use, (4) select, tailor, and implement interventions, (5) monitor knowledge use, (6) evaluate the outcomes, and (7) sustain knowledge use. This cycle is dynamic; therefore, each step may be influenced by the step preceding it and there may also be interactions and feedback between the phases.
Similarly, NIRN describes 5 Active Implementation Framework (AIF) including usable innovation, implementation stages, implementation drivers, implementation teams and improvement cycles to facilitate successful implementation. More specifically, the implementation stages include Exploration, Installation, Initial Implementation, and Full Implementation. During exploration, the implementation team assesses the readiness of all participating organizations and members. If the parties are not ready, the implementation team is responsible for helping achieve readiness. During installation, the implementation team will ensure that all the necessary structural supports are in place including funding, human resource strategies, policy development, staff and personnel, technology, and training. Initial implementation is when the intervention or recommendation is used for the first time. Organizations and staff are learning new skills, and trying to accommodate and support the change in their practice through iterative plan-do-study-act (PDSA) cycles. Finally, full implementation is reached when effective practices are maintained (i.e. 50% or more staff are using the program) and good outcomes have been achieved. The program is generally fully operational in 2-4 years with referrals coming in, full client load, health care professionals carrying out the program, supports are in place, and community has adapted to the new program. Eventually, the program becomes the accepted practice.

1.6 Thesis Objectives

This introductory chapter revealed the importance of understanding how pressure injuries can affect the day-to-day life of individuals with SCI and how clinical best practice guidelines can be implemented using the KTA and NIRN framework. The work that will be presented in this thesis was part of a larger best practice implementation project conducted in collaboration with the Spinal Cord Injury Knowledge Mobilization Network (SCI KMN) group at Parkwood Institute and the researchers at Saint Elizabeth Home Health Care and Western University. The overall objective of this thesis was to develop and field-test an intervention that incorporates the application of pressure injury best practices that includes EST for persons with SCI.
1.7 Layout of Thesis

The subsequent chapters are divided into four studies. Chapter 2 evaluates the impact of pressure injuries on individuals with SCI. Chapters 3 and 4 illustrate the preparation undertaken to support the implementation process, while Chapter 5 evaluates the initial implementation of the pressure injury best practice in the local community.
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Table 1: National Pressure Ulcer Advisory Panel Pressure Ulcer Staging System

<table>
<thead>
<tr>
<th>Stage:</th>
<th>Description:</th>
</tr>
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<tbody>
<tr>
<td>Suspected Deep Tissue Injury</td>
<td>Localized intact but discolored skin or blood-filled blister due to underlying soft tissue damage from pressure or shear.</td>
</tr>
<tr>
<td>Stage I</td>
<td>Intact skin with non-blanchable redness of a localized area (usually over a bony prominence)</td>
</tr>
<tr>
<td>Stage II</td>
<td>Partial-thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough.</td>
</tr>
<tr>
<td>Stage III</td>
<td>Full-thickness tissue loss with visible subcutaneous fat but bone, tendon, and muscles are not exposed.</td>
</tr>
<tr>
<td>Stage IV</td>
<td>Full-thickness tissue loss with exposed bone, tendon, or muscle.</td>
</tr>
<tr>
<td>Unstageable</td>
<td>Full-thickness tissue loss in which the base is covered by slough and/or eschar in the wound bed.</td>
</tr>
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Chapter 2

2 Impact of Pressure Ulcers on Individuals Living with a Spinal Cord Injury

2.1 Introduction

After a spinal cord injury (SCI), it is not uncommon for individuals with SCI to experience a health complication related to their injury. Pressure ulcers, for example, are one of the most common issues that may arise after injury, with a prevalence of approximately 30% in community dwelling SCI Canadians\(^1,2\). The lifetime prevalence of a pressure ulcer in individuals with SCI is approximately 85%\(^3\), which places a significant burden on the healthcare system. In Canada, the added cost for caring for a community dwelling individuals with SCI with a pressure ulcer is approximately $4800 monthly or almost $57,000 annually\(^4\).

Among individuals with SCI, pressure ulcers most commonly occur in the ischial and sacral regions\(^5,6\) and many risk factors have been identified. These include 1) SCI-specific factors such as age at onset\(^7\), completeness of injury\(^8\), longer duration of SCI\(^8,9\), urinary incontinence\(^10\), and severe spasticity\(^11\); 2) behavioural factors such as smoking\(^12\); 3) sociodemographic factors including aging\(^9\), marital status\(^12\), low level of education\(^9\) and unemployed\(^13,14\); and 4) medical factors including poor nutrition\(^6,12\), cardiovascular disease\(^3,15\), pulmonary disease\(^16\), diabetes mellitus\(^3,15\), and pressure ulcer history\(^7\).

Pressure ulcers are a serious secondary health complication in individuals with SCI that not only negatively affects their health, but can also have a profound impact on their quality of life (QOL)\(^17\). In a cross-sectional survey of 320 individuals with traumatic SCI living in Stockholm, Sweden, Westgren and Levi\(^18\) found that individuals with a pressure ulcer had reduced quality of life and limitations in physical and social activities. Unfortunately, this study did not specify what activities were limited and to what they were limited as a result of their pressure ulcer. Another survey conducted by Krause et
al.\textsuperscript{19} found that individuals with SCI with pressure ulcers indicated lower levels of well-being and activity, and greater health problems. Studies in individuals without SCI have also demonstrated the impact of pressure ulcers on QOL\textsuperscript{20,21}. For example, a case control study among the able-bodied population receiving community nursing found that pressure ulcers significantly impacted health-related QOL\textsuperscript{22}. They reported having increased difficulty in performing activities of daily living (ADL).

Given the significant burden of pressure ulcers on everyday activities in individuals without SCI, it is plausible that pressure ulcers in individuals with SCI would have an overwhelming implication to their day-to-day life. Unfortunately, there have been no studies that have examined the influence of pressure ulcers on the daily life of individuals with SCI living in Canada. Therefore, the objective of this study is to describe the impact of pressure ulcers on individuals living with SCI in Canada. Specifically, 1) determine the extent to which pressure ulcers limited activities in the last 12 months; 2) compare satisfaction rates with participation in main activity and paid employment in those with and without pressure ulcers; 3) compare the overall QOL between those people with and without a pressure ulcer 4) report differences in community participation in those with and without pressure ulcers; and 5) compare the health care utilization in those people with and without a pressure ulcer.

\section*{2.2 Methods}

\subsection*{2.2.1 Participants}

This study involved both men and women living in the Canadian community for at least one year after being discharged from the hospital or rehabilitation facility due to SCI. Individuals were eligible if they had a traumatic SCI, were of 18 years of age or older, and could speak English or French. Data obtained from individuals with non-traumatic or medically acquired SCI were not retained in the scope of this publication.

All participants gave written informed consent for participation. Approval to conduct this study was obtained from the Institutional Review Board Services and the Research Ethics Committee at Laval University.

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2.2.2 Procedure

All data was collected through a National SCI Community Survey using measures developed for the Rick Hansen Spinal Cord Injury Registry Community Follow-up Version 2.0\textsuperscript{23}.

Individuals with SCI living in all provinces and territories across Canada were invited to participate in an online or telephone survey through a national consumer awareness campaign that included national and local media advertisements and a survey-specific website. Information packages were also distributed with the assistance of Rick Hansen Institute (RHI) partners (Rick Hansen Foundation, SCI-Canada, and Wheelchair Sports). Overall, 90\% of participants completed the survey online, while 10\% completed the survey over the phone. There were no responses from individuals living in Yukon, Northwest Territories or Nunavut. According to Statistics Canada\textsuperscript{24}, these territories represent 0.3\% of the Canadian population. Therefore, the lack of response from these individuals would most likely not affect our findings. The survey was provided in both official languages of Canada (English and French). A gift certificate of $25 and a complimentary subscription to Solutions magazine was provided to all participants who completed the survey.

2.2.3 Outcome Measures

The Community Follow-up Questionnaire Version 2.0 is a comprehensive follow-up questionnaire designed specifically for individuals with SCI\textsuperscript{23}. A subset of information collected in the Community Follow-up Questionnaire Version 2.0 was used to develop this comprehensive national survey including: demographics, spinal cord injury classification (type and severity of injury), secondary complications (pressure ulcers), community participation, activities and employment, health care utilization measure, and overall quality of life rating.

Demographic data included age, gender, race, first language, relationship status, education level, employment status, and postal code. Participants were also asked to

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identify the location (i.e. neck, and upper, middle or lower back), classification (i.e. tetraplegia or paraplegia) and cause of their injury, parts of the body with motor and sensory loss, and mode of mobility.

Participants were asked to identify the number of pressure ulcers they had experienced in the last 12 months: none, one, two, three, four, more than 5, or don’t know. Individuals who reported developing a pressure ulcer in the past 12 months were asked about the extent to which the condition limited their activity (1 = not at all; 2 = very little; 3 = to some extent; 4 = to a great extent; and 5 = completely).

Participants were asked to write down a specific activity on the survey that they value most or spend the most time doing (main activity) over the last 12 months. They were then asked how satisfied they were with their main activity (1 = very dissatisfied; 2 = somewhat dissatisfied; 3 = neither satisfied nor dissatisfied; 4 = somewhat satisfied; and 5 = very satisfied). Participants were also asked how satisfied they were with their employment situation (1 = very dissatisfied to 5 = very satisfied).

The community participation section of the survey had 26 questions regarding activities (ADLs and iADLs, social roles) that they participated in the home or in the community on a regular basis. Response options included: 1) yes, as much as I want; 2) yes, less than I want; 3) no, but I would like to do it; and 4) no, and I don’t want to do it.

The health care utilization section of the survey is an adaptation of the Canadian Community Health Survey\textsuperscript{24} that measures the number of times participants saw or talked with a specific health care practitioner in the past 12 months. Participants were instructed to exclude any interaction with healthcare professionals they encountered during overnight hospital stays.

Overall quality of life was measured using a five point Likert scale where 1 (very bad), 2 (bad), 3 (fair), 4 (good), or 5 (very good).
Results from individuals with pressure ulcers (cases) over the past 12 months were compared to those without a pressure ulcer (controls).

2.2.4 Statistical Analysis

Statistical analysis was performed using SPSS version 21.0 (SPSS, Chicago, Illinois) and R software version 3.0.0 (R Foundation for Statistical Computing, Vienna, Austria). We used descriptive statistics to describe participant characteristics. Categorical and dichotomous variables were presented as frequency (%), while continuous variables were presented as mean ± SD. Participants were divided based on presence and absence of pressure ulcers and 95% confidence intervals were reported for each group. A paired, 2-tailed t-test was used to determine statistical significance between those with and without pressure ulcers. Activities presented in the community participation section of the survey were presented as relative risk index (RR) and 95% CI for each of the activities and was calculated by comparing the category ‘yes as much as I want’ to the combined categories ‘yes, but less than I want’ and ‘no, but I would like to do it’ among those with and without a pressure ulcer. RR>1 indicates that individuals with pressure ulcers had reduced ability or greater difficulties to perform activities compared to those without. Participants who selected the category ‘no, and I don’t want to do it’ were excluded from this specific analysis, as pressure ulcers most likely were unrelated to their ability to perform the activities. Statistical comparisons of relative risk indexes were performed to determine whether the American Spinal Injury Impairment Scale Classification (AIS) and level of injury (tetraplegia AIS A-C versus paraplegia AIS A-C versus all AIS D) influence community participation in individuals with pressure ulcers. Crosstabs were used to estimate the effect of pressure ulcers on activity level, satisfaction with main activity, and overall quality of life, such that Chi² tested the statistical significance (p-value). Bonferroni correction was applied to adjust for multiple comparisons. Further analyses were conducted to determine the relationship between the presence of pressure ulcers and health care utilization. Kolmogorov-Smirnov test was used to examine the distribution differences in the number of consultations between those with and without a pressure ulcer. P values <0.05 were considered statistically significant.
2.3 Results

2.3.1 Participants
One thousand thirty-seven individuals with traumatic SCI participated in this study (table 2). The mean age of individuals that had developed a pressure ulcer was 47.8 ± 12.8 years, while the average duration of injury was 19.5 ± 13.0 years. Among our sample with pressure ulcers, 39.8% of individuals had tetraplegia with AIS grade A, B or C; 55.6% had paraplegia with AIS grade A, B or C; and 4.6% had AIS grade D. AIS D included those with tetraplegia (n = 90) and paraplegia (n = 81). There were significantly more individuals with paraplegia AIS A, B or C than AIS D (p < 0.0001). Furthermore, individuals with paraplegia AIS A, B, or C had longer duration of injury than AIS D (P = 0.029). The majority of individuals who had a pressure ulcer were Caucasian (93.4%), married (39.1%), and well educated beyond post-secondary education (65.4%).

2.3.2 Pressure Ulcers Prevalence
There were 381 (33.5%, 95% CI = 30.8% - 36.3%) individuals reported developing at least one pressure ulcer in the last 12 months. More than a quarter of the individuals (n = 308, 27%) reported developing one or two pressure ulcers, while 73 (6.4%) individuals reported developing three or more pressure ulcers.

2.3.3 Pressure Ulcers and Activity Level
Of the 381 individuals with pressure ulcers, approximately two thirds (65.3%) reported that their pressure ulcer reduced their activity at least to some extent.

Among individuals with 1 or 2 pressure ulcers, 32% reported that pressure ulcers limited their activity to a great extent or completely, while a higher percentage (53%) of those with ≥3 pressure ulcers reported their activity level was limited to a great extent or completely (P = 0.0007) (table 3).
2.3.4 Pressure Ulcer and Satisfaction with Main Activity
The activities in which the individuals with pressure ulcers indicated they spent most of their time performing (main activity) over the past year were the following: employment (21.8%); homemaker including unpaid work (12.3%); self-employment and volunteer work (6.8% each); student (3.4%); looking for paid work (2.1%); and vocational rehab program (0.8%). Moreover, 46% of individuals with pressure ulcers described themselves as being retired or having no main occupation.

The average number of hours reported participating in their main activity in those with pressure ulcers was 30.8 ± 24.0 h/wk, which was similar to the 33.8 ± 25.9 h/wk in those without pressures ulcers (P = 0.157). With regards to their satisfaction with their main activity over the last year, individuals with one or two pressure ulcers are more dissatisfied with their ability to participate than individuals with no pressure ulcers (P = 0.0077) (see table 3). No significant difference with satisfaction level of main activity was found between those with 1 or 2 pressure ulcers and those with ≥3 (P = 0.4848) or those with ≥3 pressure ulcers and those without pressure ulcers (P = 0.1514).

2.3.5 Pressure Ulcer and Overall Quality of Life
Approximately 12% of individuals with pressure ulcers reported their QOL as very bad or bad, 26.8% reported it as fair, while 61.7% stated that it was good or very good.

Individuals with ≥3 pressure ulcers reported significantly lower QOL compared to those without pressure ulcers (P = 0.0003) (see table 3). Fifty-two percent of individuals with ≥3 pressure ulcers reported their QOL as very bad or bad or fair compared to 26.1% in individuals with 1 or 2 pressure ulcers and 29.5% in individuals without pressure ulcers. A significant difference in QOL was not found between individuals with 1 or 2 pressure ulcers and those without pressure ulcers or those with ≥3 pressure ulcers.

2.3.6 Pressure Ulcer and Community Participation
All risk ratios were >1, indicating that individuals with pressure ulcers had more difficulty participating in community activities than those without pressure ulcers. The

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presence of at least 1 pressure ulcer had a significant impact on 19 (73%) of 26 activities presented in the survey (figure 1). Individuals with pressure ulcers have a 52% and 54% reduced ability to groom (RR = 1.52; 95% CI, 1.22-1.91) and feed themselves independently (RR = 1.54; 95% CI, 1.19-2.00) as much as they wanted, respectively, compared to those without a pressure ulcer. Furthermore, those with pressure ulcers are 66% less likely to communicate with others by electronic means (RR = 1.66; 95% CI, 1.18-2.35) as much as they want to when compared to those without a pressure ulcer.

Additional analyses revealed that 22 of 26 activities were not affected by injury level and severity among individuals with pressure ulcers. Four activities were influenced by injury level and severity and affected their ability to participate in community activities. Individuals with tetraplegia (AIS grades A-C) had greater difficulties performing 3 out of the 4 activities compared to individuals with paraplegia (AIS grades A-C) and AIS grade D. Individuals with tetraplegia (AIS grades A-C) were more restricted in their ability to feed themselves (p = 0.028) and move from one place to another using transportation (P = 0.025) compared to individuals with paraplegia (AIS grades A-C). In addition, individuals with tetraplegia (AIS grades A-C) with pressure ulcers had reduced ability to move from one place to another in their own home and in nearby surroundings (P = 0.038) compared to those with AIS grade D with pressure ulcers. Contrary, individuals with AIS grade D had greater difficulties grooming themselves compared to individuals with paraplegia (AIS grades A-C, P = 0.05).

2.3.7 Pressure Ulcer and Satisfaction with Paid Employment

Individuals with pressure ulcers reported working an average of 20.2 ± 14.4 h/wk compared to 22.8 ± 14.7 h/wk in those without pressure ulcers. There was no statistically significant difference in satisfaction rate with employment between those with and without pressure ulcers (P = 0.894).

2.3.8 Pressure Ulcers and Health Care Utilization

A significantly higher number of overnight hospital stays in the last 12 months were reported among individuals with pressure ulcers. Compared with 4.0 ± 22.3 nights by
individuals without a pressure ulcer, those with 1 or 2 pressure ulcers reported $8.8 \pm 27.2$ nights ($P = 0.003$), while those with three or more pressure ulcers reported $17.0 \pm 45.4$ nights ($P = 0.002$).

Excluding overnight hospital stays, the most common health care professionals seen among individuals with pressure ulcers in descending order were family doctors/general practitioners, occupational therapists, nurses, urologists, wound care nurse/specialist, physiotherapists, case manager, and physiatrist (table 4). A significantly higher percentage of consultations for occupational therapists ($P < 0.011$) and wound care nurse/specialists ($p < 0.0001$) were reported among those with pressure ulcers compared to those without. Individuals with $\geq 2$ pressure ulcers reported a significantly higher percent of consultations with a nurse compared to those without a pressure ulcer ($P < 0.0001$). Among individuals with 1 pressure ulcer ($P = 0.005$) and $\geq 3$ pressure ulcers ($P = 0.007$), a significantly higher percent of consultations with the family doctor/general practitioner were seen when compared to those without a pressure ulcer.

### 2.4 Discussion

In our study of 1137 community-dwelling individuals with traumatic SCI, 33.5% of individuals reported a pressure ulcer in the last 12 months. We found that approximately 65% of individuals with pressure ulcers were limited in their ability to participate in their main activity. Furthermore, a greater proportion of individuals with pressure ulcers were more dissatisfied with their ability to participate in their main activity. We also found that individuals with pressure ulcers report a lower QOL $^{22}$ and higher outpatient health care utilization.

#### 2.4.1 Activity Level and Quality of Life

To our knowledge, this is the first documented study in Canada to examine the impact and extent to which pressure ulcers affect the ability of individuals with SCI to perform their main activity. Our findings demonstrate that those with and without pressure ulcers have difficulties performing tasks; however, those with pressure ulcers have greater deficit in participating in ADL and community activities. Our results compare well with a

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case-control study by Frank et al. who examined the impact of pressure ulcers in individuals receiving community-nursing care in the United Kingdom. They found that those with pressure ulcers had significantly reduced ability to eat, dress, groom, control bladder and bowel, transferring, and bathing. Interestingly, we found that pressure ulcers did not impact the ability of an individual with SCI to carry out activities that are paid for (i.e. employment). This contradicts results by Krause et al. who found that pressure ulcers are related to employment status such that a greater proportion of individuals without a pressure ulcer reported working compared to those with pressure ulcers. Krause et al. also found that the proportion of individuals who worked was reduced with the presence of multiple pressure ulcers. Because we did not ascertain pressure ulcer location nor severity in our study, this might explain the lack of impact of pressure ulcers on their ability to carry out activities that are paid for.

We did not find that injury severity influenced an individual’s ability to participate in community activities. Only 4 of 26 activities showed significant differences in RRs in individuals with pressure ulcers based on injury level and severity. This may be because participation in activities is not an absolute assessment. It is relative to what people expect while taking into account their physical, psychological and social conditions. Therefore, an individual with tetraplegia may indicate to participate as much as they wanted even though their capabilities are limited.

In addition, we found that individuals with pressure ulcers are more dissatisfied with their ability to perform activities they enjoy compared to those without pressure ulcers. Similar findings were summarized by Gorecki et al indicating that pressure ulcers interfered with ADLs and individuals with SCI became dependent upon healthcare professionals to assist with wound care and ADLs. In a qualitative study by Langemo et al., a male with paraplegia and stage IV sacral pressure ulcer also reflected our findings of restrictions in activity participation by stating that his pressure ulcer prevents him from “…getting to go out, go fishin’ or nothin’, or doin’ whatever you want to do…You’re more confined.”
Other secondary health complications among individuals with SCI, including neurogenic bladder, have also been shown to reduce the ability to perform activities. Oh et al\textsuperscript{28} interviewed 132 individuals with neurogenic bladder and 150 individuals without (controls) to determine their health related-QOL using the Medical Outcomes Study 36-Item Short Form General Health Survey. They found that individuals with neurogenic bladder had significantly lower scores in all domains of the questionnaire compared with the controls. Based on the aforementioned study and the fact that individuals with SCI are predisposed to multiple complications, careful interpretation of our findings is warranted. In addition to other secondary health complications, the reduced ability to participate in activities and the dissatisfaction may be due to other issues such as bed rest. Bed rest is frequently recommended as a treatment modality for pressure ulcers preventing individuals with pressure ulcer from engaging and participating in activities.

In terms of the overall QOL, our findings are similar to previous reports\textsuperscript{18,19} that pressure ulcers in individuals with SCI are associated with lower QOL. In our study, approximately 10% of individuals with 1 or 2 pressure ulcers and 16% of individuals with \( \geq 3 \) pressure ulcers reported their QOL as very bad or bad, compared to only 6.9% of individuals without pressure ulcers.

### 2.4.2 Prevalence

Pressure ulcer prevalence in our study was slightly lower than Krause et al.,\textsuperscript{12} who reported a pressure ulcer prevalence rate of 40.2% per year, but was aligned with other studies that ranged from 36-39.3% annually\textsuperscript{14,15}. The design of these studies was similar to our self-reported survey, but the studies were conducted in the United States. Our prevalence rate was higher than other studies conducted in Canada\textsuperscript{1,2}.

### 2.4.3 Health Care Utilization

As anticipated, our study found significantly longer overnight stays in individuals with \( \geq 3 \) pressure ulcers compared to those with 1 or 2, or those with no pressure ulcers. We also identified high outpatient health care utilization among individuals with pressure ulcers. Our results are consistent with several previous reports that have demonstrated that
individuals with SCI have a high health care utilization pattern\textsuperscript{29–31}. However, this is the first study that identified specific services required by those with pressure ulcers.

Canada has a universal publicly funded health care system that provides hospital and medical care to all residents within their province. Therefore, it’s interesting that our study found that individuals with pressure ulcers visited family doctor/general practitioner and nurses more than a physiatrist or wound care nurse/specialist to assist in managing their pressure ulcer. Physiatrists have greater expertise in secondary health complications and medical needs associated with individuals with SCI than family doctors, while wound care nurses are more knowledgeable in standard wound care, including debridement, cleansing, and dressing and adjunctive therapies to wound care compared to general regulated nurses.

Although individuals with SCI are utilizing nutritionist/dietician and physiotherapy services, there is not a significant difference in these service utilization between those with and without pressure ulcers. We would expect these services to be used more frequently among individuals with pressure ulcers especially because malnutrition has frequently been reported to be a significant risk factor for pressure ulcers\textsuperscript{12,32,33}. Results in our study suggest that more individuals with SCI with pressure ulcers sought services from occupational therapists rather than physiotherapists. This is interesting given that physiotherapists provide similar services as occupational therapists, and physiotherapists can provide direct wound care\textsuperscript{34}.

2.4.4 Study Limitations

We acknowledge that there are limitations to our study. As previously mentioned, all outcome measures were based on patient self-report. Therefore, the participant’s classification of their SCI may be inaccurate. Furthermore, our participants were asked to identify any pressure ulcers they may have experienced over 1 year. Pressure ulcers may have been underestimated as a result of recall bias or the ability of participants to identify less severe ulcers; therefore, our findings must be interpreted carefully. Secondly, individuals with traumatic SCI living in the Northwest Territories, Nunavut, or Yukon
did not complete the survey; thus, these results may not be generalizable to individuals with SCI living in those Nordic regions of Canada, those living outside of Canada or individuals with non-traumatic SCI. Third, we did not collect data on the site or stage of the pressure ulcer. Larger and more severe pressure ulcers located around the pelvic region may impact an individual’s ability to perform activities more significantly than less severe pressure ulcers located elsewhere. Fourth, the healthcare utilization section of the survey did not include access to plastic surgeons. If pressure ulcers are severe and chronic, patients may be referred to a surgeon for a second opinion and to determine their eligibility for surgical closure. Finally, since this was a survey study, those who completed the study may feel more comfortable expressing their views regarding their health. Responses to these surveys may have attracted one of the following types individuals with SCI – those who are self-motivated and well aware of their health or those who are less self-motivated and completely dissatisfied with their care. This could have resulted in underestimations or over estimations, respectively, in the overall impact of pressure ulcers on the daily life of individuals with SCI.

2.4.5 Conclusion

This is the first nation-wide survey to document the impact that pressure ulcers have on individuals living with SCI. We found that pressure ulcers in individuals with SCI have a profound impact on community and daily activities by limiting their ability to participate in these activities. A greater proportion of individuals with pressure ulcers are also more dissatisfied with their ability to participate in their activities compared to those without pressure ulcers. Pressure ulcers were found to increase their health care utilization in particular visits to the family doctor or general practitioner. Our findings highlight the importance of implementing pressure ulcer prevention and management programs for this high-risk population. Future studies should examine other secondary health complications and factors, other than pressure ulcers that may impact an individual with SCIs’ ability to perform community activities.
2.5 References


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Table 2: Demographics and SCI characteristics of the 1137 participants according to the presence or absence of pressure ulcers

<table>
<thead>
<tr>
<th>Variable</th>
<th>Participants with a Pressure Ulcer* (n = 381)</th>
<th>Participants without a Pressure Ulcer* (n = 756)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>47.8 ± 12.8 (19-90)</td>
<td>48.6 ± 13.6 (18-86)</td>
<td>0.3459</td>
</tr>
<tr>
<td>Duration of Injury (years)</td>
<td>19.5 ± 13.0 (1.1-57.5)</td>
<td>17.9 ± 13.2 (1.0-75.2)</td>
<td>0.0579</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>279</td>
<td>73 (68-78)</td>
<td>0.2445</td>
</tr>
<tr>
<td>Women</td>
<td>102</td>
<td>27 (23-32)</td>
<td>0.2445</td>
</tr>
<tr>
<td>Total</td>
<td>381</td>
<td>756</td>
<td></td>
</tr>
<tr>
<td>Type of Injury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tetraplegia AIS grades A-C</td>
<td>138</td>
<td>39.8 (34.6-45.1)</td>
<td>0.1346</td>
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<tr>
<td>Paraplegia AIS grades A-C</td>
<td>193</td>
<td>55.6 (50.2-60.9)</td>
<td>0.0001</td>
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<tr>
<td>AIS grade D</td>
<td>16</td>
<td>4.6 (2.7-7.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total</td>
<td>347</td>
<td>667</td>
<td></td>
</tr>
<tr>
<td>Origin</td>
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<tr>
<td>Caucasian</td>
<td>356</td>
<td>93 (90-96)</td>
<td>0.6714</td>
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<td>Living Setting</td>
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<tr>
<td>Own Home</td>
<td>257</td>
<td>67 (62-72)</td>
<td>0.2604</td>
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<tr>
<td>Rental – Apartment, condo, basement suite</td>
<td>79</td>
<td>21 (17-25)</td>
<td>0.3270</td>
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<tr>
<td>Total</td>
<td>336</td>
<td>673</td>
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<tr>
<td>Relationship Status</td>
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</tr>
<tr>
<td>Single, Never Married</td>
<td>124</td>
<td>33 (28-38)</td>
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<tr>
<td>Married</td>
<td>149</td>
<td>39 (34-44)</td>
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</tr>
<tr>
<td>Common Law</td>
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<td>8.9 (6-12)</td>
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<td>Total</td>
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<tr>
<td>At least Postsecondary</td>
<td>129</td>
<td>34 (29-39)</td>
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<tr>
<td>More than Postsecondary</td>
<td>249</td>
<td>65 (60-70)</td>
<td>0.9379</td>
</tr>
<tr>
<td>Total</td>
<td>378</td>
<td>754</td>
<td></td>
</tr>
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</table>

NOTE: Values are n, % (95% CI), mean ± SD (minimum-maximum), or as otherwise indicated. For continuous variables, t tests (SPSS version 22.0) were used; for categorical variables, tests for the equality of proportion (R version 3.0.0) were used.
*In the last 12 months
### Table 3: Activity level, satisfaction with main activity and overall quality of life among individuals with and without pressure ulcers

<table>
<thead>
<tr>
<th>No. of Pressure ulcers</th>
<th>None (n = 756)</th>
<th>1-2 (n = 308)</th>
<th>≥3 (n = 73)</th>
<th>P*</th>
<th>P†</th>
<th>P‡</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activity Level</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limits to some extent, very little, or not at all</td>
<td>N/A</td>
<td>209 (67.9)</td>
<td>34 (46.6)</td>
<td>NA</td>
<td>NA</td>
<td>0.0007§</td>
</tr>
<tr>
<td>Limits to a greater extent or completely</td>
<td>N/A</td>
<td>99 (32.1)</td>
<td>39 (53.4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Satisfaction with Main Activity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very dissatisfied or somewhat dissatisfied</td>
<td>184 (24.3)</td>
<td>88 (28.6)</td>
<td>25 (34.2)</td>
<td>0.0077</td>
<td>0.1514</td>
<td>0.4848</td>
</tr>
<tr>
<td>Neither satisfied nor dissatisfied</td>
<td>100 (13.2)</td>
<td>58 (18.8)</td>
<td>10 (13.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very satisfied or somewhat satisfied</td>
<td>472 (62.4)</td>
<td>162 (52.6)</td>
<td>38 (52.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Overall Quality of Life</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very bad or bad</td>
<td>52 (6.9)</td>
<td>32 (10.4)</td>
<td>12 (16.4)</td>
<td>0.0901</td>
<td>0.0003§</td>
<td>0.0264</td>
</tr>
<tr>
<td>Fair</td>
<td>171 (22.6)</td>
<td>76 (24.7)</td>
<td>26 (35.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good or very good</td>
<td>533 (70.5)</td>
<td>200 (64.9)</td>
<td>35 (47.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Values are n (%) or as otherwise indicated

Abbreviations: NA, not applicable

*Comparison between those with 1 to 2 pressure ulcers and those with none
†Comparison between those with ≥3 pressure ulcers and those with none
‡Comparison between those with 1 to 2 pressure ulcers and those with 3 or more
§P ≤ 0.0071 considered statistically significant when Bonferonni correction is applied.
## Table 4: Percentage of individuals with SCI with a pressure ulcer who met with a health care practitioner

<table>
<thead>
<tr>
<th>Health Care Utilization</th>
<th>No pressure ulcers (n=756)</th>
<th>1 pressure ulcer (n=205)</th>
<th>2 pressure ulcers (n=103)</th>
<th>≥ 3 pressure ulcers (n=73)</th>
<th>Average in those with pressure ulcer (n = 381)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Doctor/General Practitioner</td>
<td>77.9</td>
<td>83.9 (p=0.005)*</td>
<td>75.7</td>
<td>89.0 (p=0.007)‡</td>
<td>82.8</td>
</tr>
<tr>
<td>Nurse</td>
<td>29.0</td>
<td>40.0</td>
<td>54.4 (p&lt;0.0001)†</td>
<td>46.6 (p=0.0001)‡</td>
<td>46.9</td>
</tr>
<tr>
<td>Occupational Therapist</td>
<td>29.6</td>
<td>44.9 (p=0.011)*</td>
<td>46.6 (p=0.008)†</td>
<td>49.3 (p=0.003)‡</td>
<td>46.9</td>
</tr>
<tr>
<td>Wound Care Nurse/Specialist</td>
<td>9.8</td>
<td>38.0 (p&lt;0.0001)⁄</td>
<td>38.8 (p&lt;0.0001)⁄</td>
<td>47.9 (p&lt;0.0001)⁄</td>
<td>41.5</td>
</tr>
<tr>
<td>Urologist</td>
<td>36.0</td>
<td>40.5</td>
<td>46.6</td>
<td>49.3</td>
<td>45.5</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>25.7</td>
<td>25.9</td>
<td>24.3</td>
<td>30.1</td>
<td>26.8</td>
</tr>
<tr>
<td>Case Manager</td>
<td>16.4</td>
<td>22.4</td>
<td>26.2</td>
<td>28.8</td>
<td>25.8</td>
</tr>
<tr>
<td>Physiatrist (Rehab Doctor)</td>
<td>20.0</td>
<td>21.5</td>
<td>19.4</td>
<td>20.5</td>
<td>20.5</td>
</tr>
<tr>
<td>Nutritionist/Dietician</td>
<td>9.4</td>
<td>13.2</td>
<td>17.5</td>
<td>20.5</td>
<td>17.1</td>
</tr>
<tr>
<td>Social Worker</td>
<td>7.7</td>
<td>7.8</td>
<td>14.6</td>
<td>19.2</td>
<td>13.9</td>
</tr>
<tr>
<td>SCI Peer Support Person</td>
<td>10.2</td>
<td>11.2</td>
<td>15.5</td>
<td>11.0</td>
<td>12.6</td>
</tr>
<tr>
<td>Psychiatrist/Psychologist</td>
<td>8.5</td>
<td>7.3</td>
<td>8.7</td>
<td>19.2</td>
<td>11.7</td>
</tr>
<tr>
<td>Spine Surgeon</td>
<td>8.5</td>
<td>9.3</td>
<td>6.8</td>
<td>13.7</td>
<td>9.9</td>
</tr>
<tr>
<td>Respiratory Therapist</td>
<td>2.9</td>
<td>3.4</td>
<td>6.8</td>
<td>12.3</td>
<td>7.5</td>
</tr>
<tr>
<td>Respirologist</td>
<td>2.9</td>
<td>2.9</td>
<td>3.9</td>
<td>12.3</td>
<td>6.3</td>
</tr>
<tr>
<td>Orthotist/Prosthotist</td>
<td>4.4</td>
<td>4.9</td>
<td>2.9</td>
<td>9.6</td>
<td>5.8</td>
</tr>
<tr>
<td>Recreational Therapist</td>
<td>5.0</td>
<td>4.4</td>
<td>7.8</td>
<td>4.1</td>
<td>5.4</td>
</tr>
<tr>
<td>Vocational Counsellor</td>
<td>2.5</td>
<td>2.9</td>
<td>1.0</td>
<td>9.6</td>
<td>4.5</td>
</tr>
<tr>
<td>Drug and Alcohol Counsellor</td>
<td>0.4</td>
<td>1.0</td>
<td>1.9</td>
<td>5.5</td>
<td>2.8</td>
</tr>
<tr>
<td>Sexual Health Clinician</td>
<td>2.2</td>
<td>2.4</td>
<td>1.9</td>
<td>4.1</td>
<td>2.8</td>
</tr>
<tr>
<td>Speech-Language Pathologist</td>
<td>0.8</td>
<td>0.5</td>
<td>0.0</td>
<td>0.0</td>
<td>0.2</td>
</tr>
</tbody>
</table>

**NOTE:** Values are percentage or as otherwise indicated. P values are reported when P ≤ 0.05.

*Significant difference between those with one PU and those with no PU

†Significant difference between those with two PU and those with no PU

‡Significant difference between those with three or more PU and those with no PU

A version of this chapter has been published for publication: Lala D, Dumont FS, Houghton PE, Noreau L. Impact of pressure ulcers on individuals living with a spinal cord injury. Arch Phys Med Rehabil 2014;95:2312-9. DOI: 10.1016/j.apmr.2014.08.003.
Figure 1: Association of community participation between individuals with (n = 381) and without (n = 756) pressure ulcers within the last 12 months expressed as RR (square) and 95% (lines). Participation “yes, as much as I want” category versus “yes, less than I want” and “no, but I want to do it” categories (■, P < 0.05).

Chapter 3

3 Developing a Model of Care for Healing Pressure Ulcers with Electrical Stimulation Therapy for Persons with Spinal Cord Injury

3.1 Introduction

The ability to provide appropriate health care services to individuals with chronic and/or disabling conditions in the community is frequently unmet and dissatisfactory\(^1\)\(^-\)\(^3\), and often lags behind acute and rehabilitation services\(^4\). The disparities in services between these settings are often the result of the complex nature of these conditions. Individuals with chronic and/or disabling conditions are more vulnerable to comorbidities and risk factors that lead to secondary health complications\(^5\)\(^-\)\(^7\), which may require specific services and longer treatments\(^8\). However, when attempting to gain access to health care services in the community, they frequently encounter an array of barriers including physical, communication, and systemic barriers\(^9\)\(^-\)\(^12\).

Individuals with spinal cord injury (SCI) are an example of a subpopulation that experiences this fragmented care system\(^13\). Lack of knowledgeable health care providers, ineffective communication among providers and with the patient, and inaccessible facilities and equipment are common barriers they experience when accessing health care services in the community\(^14\),\(^15\). Given these findings, it is not surprising that individuals with SCI generally prefer receiving services from SCI outpatient services than in the community\(^1\), as they are better equipped and have the capacity to address many of the health issues.

Given the significant number of secondary health complications associated with having a SCI\(^16\), it is imperative that improvements be made in health care services in the community to reduce hospitalizations and reduce the burden on the healthcare system\(^17\). Pressure ulcers are one of many secondary health complications that can develop following SCI\(^18\),\(^19\), due to physiological changes to the skin\(^20\), reduced sensations and

limited mobility. In Canada, approximately 25% of individuals with SCI have a pressure ulcer in acute care\textsuperscript{21}; however, the prevalence increases in the community setting\textsuperscript{22}.

Multiple best practice guidelines\textsuperscript{23,24} and reviews\textsuperscript{22,25,26} recommend the use of electrical stimulation therapy (EST) to promote the closure of pressure ulcers. Despite the extensive evidence of the efficacy of EST in healing pressure ulcers in this population, there is a lack of uptake of this therapy particularly for managing those living in the community\textsuperscript{27}

An attempt to standardize the application of EST to manage pressure ulcers in a client's home or nonclinical setting was conducted by Houghton et al\textsuperscript{28}; even though positive outcomes in terms of healing and limited adverse events were reported, the change in practice was not maintained due to barriers not fully understood.

Implementing evidence-based practices, such as EST, is challenging and requires a significant amount of time and commitment\textsuperscript{29}. Fortunately, there are a variety of methodological approaches that can be employed in implementation research that can enhance the likelihood of practice change.

The Knowledge-to-Action (KTA) and National Implementation Research Network (NIRN) frameworks are two systematic approaches that were designed to guide implementation by facilitating the translation of knowledge into practice and informing effective implementation of evidence-based practice\textsuperscript{30,31}. Key commonalities/processes outlined in each of these frameworks include clearly defining the practice/recommendation being implemented, identifying barriers and facilitators that would enable the implementation of the practice (i.e. action plan), and adapting the practice to the local environment.

During the initial attempt to incorporate the use of EST for managing pressure ulcers in community dwelling persons with SCI\textsuperscript{28}, these processes for successful implementation were not initiated. Therefore, without identifying potential barriers that could impede the uptake of this intervention and establishing a process for adapting the practice, the change in practice was inclined to fail.

As such, the overall objective of this initiative is to implement the use of EST for managing pressure ulcers in community dwelling persons with SCI. The specific objective addressed in this paper is to develop a pressure ulcer model of care that clearly defines the EST practice and is adapted to the local environment by understanding the perceived “facilitators” and “barriers” that may impede or promote the uptake of this therapy. Furthermore, given the limited literature that exists describing the specific methods to achieve these key processes, this paper also outlines a methodology that can be undertaken to complete the initial phases of implementation.

### 3.2 Methods

This initiative is a collaborative effort between Western University, South West Community Care Access Centre (CCAC), and Parkwood Institute. The South West CCAC is one of 14 regionally based CCACs in the province of Ontario and co-ordinates publicly funded home care providers to seniors, individuals with disability, and/or individuals requiring assistance to live independently in the community. They provide community-based services ranging from supportive care, nursing and/or rehabilitation. Parkwood Institute is a large tertiary rehabilitation center in Ontario that specializes in the rehabilitation of individuals with SCI.

#### 3.2.1 Step 1: Developing Partnerships with Stakeholders

To improve the uptake of practice change and facilitate implementation, it is critical to engage local stakeholders. Community-based participatory research (CBPR) or participatory action research (PAR) was an approach that was undertaken to facilitate involvement and create a partnership and mutual trust among researchers and community. Studies suggest that it can enhance both the quality of the research and the potential for addressing major concerns in the community. Therefore, the researchers at Western University convened a representative panel of 11 individuals including other researchers, administrators, regional managers, program coordinators, a clinical nurse specialist, and a SCI consumer. The panel (i.e. the Steering Committee) was drawn from public and private health sectors, and from the community (i.e. South West CCAC and
contracting agencies) in London, Ontario. The group appreciated and valued the importance of this initiative to improve the local management of pressure ulcer care, and thus it was very receptive in engaging in a research-clinical partnership. The group was mandated to review the perceived “facilitators” of and “barriers” to EST implementation, make key decisions around the model of care, and seek approval from administrative leaders within their organization/institution. The principal investigator (PEH) and study coordinator (DL) facilitated each of the meetings and distributed minutes following each meeting. The meetings were held between April and October 2014.

3.2.2 Step 2: Gathering Information on Barriers and Facilitators

Members of the Steering Committee identified and engaged key stakeholders who were willing to contribute their thoughts, perspectives, and attitudes towards EST. Direct invitations via email were made to these individuals. There were 3 types of stakeholders interviewed for this phase of the project: 1) hospital and community administrators and practice leaders; 2) hospital and community frontline care providers including registered nurses, occupational therapists, physiotherapists, social workers, physicians, and a registered dietician; and 3) SCI consumers with recent or prior experiences with pressure ulcers. The study coordinator met with 29 stakeholders face-to-face or via telephone to examine the potential facilitators of and barriers to implementing EST. The interviews were semi-structured with a set of open-ended questions to facilitate discussion, but remaining focused and organized. The coordinator recorded key descriptions and concepts that emerged during the conversation. There was no audio recording during these conversations.

3.2.3 Step 3: Examining Barriers and Facilitators using the NIRN Framework

Following the stakeholder interviews, the study coordinator followed a qualitative method for data analysis; the notes were repeatedly reviewed and concepts related to the stakeholders’ perceived facilitators of and barriers to implementing EST were identified. The responses were then collated and in an attempt to examine the concepts, they were categorized into implementation drivers according to the NIRN framework.31 These
drivers are part of a structured process to inform and facilitate implementation action planning\textsuperscript{38}. There are 9 key drivers divided into the following 3 categories: competency, organizational, and leadership. Competency drivers are activities that develop, improve, and sustain one’s ability to put the program into practice. The three competency drivers include selection, staff training, and coaching. The skills that are achieved in the selection criteria, taught in training, and supported in the coaching process are monitored using performance assessments. Organizational drivers are activities that help develop the supports and infrastructure needed to create an environment for the new practices. The 3 organizational drivers include decision support data systems, facilitative administrative support, and systems interventions. Leadership drivers focus on providing effective leadership strategies for challenges that arise when the program is put in place. The 2 leadership drivers include technical and adaptive leaderships\textsuperscript{31,39}. To achieve effective implementation, it is important to achieve a balanced approach by ensuring that the activities (i.e. the barriers and facilitators) are distributed across several drivers. The drivers are integrated, complementing one another, but also compensate when challenges arise.

These findings were then presented to the Steering Committee and reviewed thoroughly. The Steering Committee noted that the majority of the stakeholders lived in urban areas, and they recognized that these findings may not be consistent with those living in the rural areas. The Committee discussed the potential facilitators and barriers to implementing a new program in rural areas with less access to resources. Any differences of opinion about aligning the facilitators or barriers with the implementation drivers were openly discussed and edits were made.

3.2.4 Step 4: Developing the Model of Care

The perceived facilitators of and barriers to EST implementation were later provided to a working group. This group, comprised of researchers, frontline providers, and administrators, including a few members of the Steering Committee, focused on developing a model of care for treating pressure ulcers with EST. The goal was to
incorporate EST as a treatment method for managing pressure ulcers, while also addressing the key themes that were discovered during the stakeholder interviews.

The working group met 3 times for 2 hours between June and September 2014. Following the first meeting, the working group developed a preliminary model of care, which was presented to the Steering Committee by the study coordinator. The Steering Committee reviewed the model in detail and provided their feedback. The model of care went through 2 more revisions until a final model of care was reached, with the endorsement from the Steering Committee.

3.3 Results

3.3.1 Perceived Facilitators and Barriers

Figure 2 outlines the perceived facilitators of and barriers to implementing EST for treating pressure ulcers in individuals with SCI living in the community categorized into the implementation drivers. There were 3 key barriers that emerged between all of the interviews: 1) lack of interdisciplinary collaboration and communication; 2) inadequate training and education; and 3) the lack of funding, time and staff.

3.3.1.1 Lack of Interdisciplinary Collaboration and Communication

The stakeholders frequently reported ineffective interdisciplinary collaboration and communication as a barrier. Individuals with SCI often have a number of underlying issues associated with their pressure ulcers including co-morbidities, nutritional deficiencies, prolonged sitting and immobility, and psychosocial concerns. The stakeholders familiar with EST identified the importance of addressing these concerns with the appropriate providers prior to or concurrently with receiving EST in order for the treatment to present positive healing benefits. Therefore, the stakeholders reported the significance of having interdisciplinary collaboration amongst providers such as nurses, occupational therapists, physiotherapists, social workers, and dietitians, which is often missing or infrequent in community care. Lack of communication at all levels across the organization and between organizations was cited. Specifically, providers in the community identified that there is a lack of consistent and available means to

communicate basic information about a client’s care plan and health status to the client’s circle of care especially if they are from a different provider agency. The stakeholders also described that there were frequent conflicts and power struggles between providers in the community and those in the hospital regarding what the best and most appropriate treatment plan would be for the client. For example, one community stakeholder indicated that they sometimes did not follow dressing instructions provided by wound specialists or physicians. The stakeholders highlighted the importance of creating a trusting environment amongst members of the client’s circle of care, including the client.

3.3.1.2 Inadequate Training and Education

Many stakeholders stated that there was lack of awareness, knowledge, training, and skills surrounding the use of EST in managing pressure ulcers across the continuum of care. They emphasized that prior to implementation of this therapy, it is important to incorporate improvement strategies, such as education and training sessions that are focused on introducing EST as a feasible therapy for improving pressure ulcer healing. Stakeholders expressed a preference for open educational resources that would be freely accessible online and available for print, in addition to hands-on demonstrations on how to use EST. They also indicated that not every provider would be receptive and willing to participate in the training sessions offered to them.

3.3.1.3 Lack of Funding, Time and Staff

The most commonly reported barriers expressed by providers, particularly those working in the community, were the lack of funding, time and staff for implementing strategies that may result in a change in practice. To obtain funding for EST delivery, the stakeholders stressed the importance of acquiring complete buy-in and ongoing support and feedback from administrators and/or practice leaders. When interviewing the stakeholders, many were unfamiliar with the EST literature to date and, therefore, were unaware that EST with standard wound care can be more cost-effective compared to standard wound care alone40. All community stakeholders reported the issue of high turnover, resulting in fewer staff, higher workloads, and lack of time to consider learning a new practice. Many providers felt overloaded and burdened as a result of concurrent

projects or competing initiatives. Self-management by the client was identified as a possible solution. However, the need to recognize family/caregiver ‘burnout’ was emphasized, resulting from highly complex care needs of their loved ones and high stress levels.

3.3.2 Pressure Ulcer Model of Care with EST

Figure 3 illustrates the model of care that was developed with consideration of the facilitator of and barriers to implementing EST in treating pressure ulcers in individuals with SCI living in the community. To summarize, referrals for individuals meeting the inclusion criteria would be sent to a local EST coordinator. The coordinator would schedule an appointment for the client to meet with a specialized interdisciplinary pressure ulcer team at a rehabilitation centre to address the wound and its underlying causes. A treatment recommendation with EST protocol (if appropriate) would be developed and shared with the patient’s care team including both public and private providers. A community care coordinator or champion in the private or public sector will coordinate any additional care, and order necessary equipment and resources to execute the patient-specific treatment recommendation. The client’s care team in the community including regulated and unregulated care providers will lead the care plan at the client’s home. If the wound has not reduced by 50% after three months, the client may need to be reassessed by the specialized team again. Specific details within the model of care are summarized below.

There are three features to this model that make it unique within the context of the current practices that occur in this region. These include 1) a specialized SCI pressure ulcer team that provides consultation and specific recommendations about feasibility of EST therapy, 2) provision of tools that enable ongoing collaboration and communication between community and rehabilitation providers, and 3) a focus on capacity-building and enhancing expertise in the community.
3.3.2.1 Specialized SCI Pressure Ulcer Team

The model proposed that there be a specialized interdisciplinary team located within a tertiary SCI rehabilitation centre (i.e. St. Joseph’s Health Care London, Parkwood Institute), where community dwelling individuals with SCI with a new or existing pressure ulcer may be referred. Members of this specialized team should have collective knowledge and expertise in preventing and managing common conditions in persons with SCI as well as a firm understanding of best practices in wound care. The Canadian best practice guidelines recommend that the team consist of a physician (preferably a physiatrist specialized in SCI), a nurse specialized in wound care, an occupational therapist, a physiotherapist, a dietician, a social worker or psychologist. It was also suggested that each discipline would contribute to a comprehensive assessment and that the team would develop a preliminary interdisciplinary treatment plan, including recommendations for EST, if appropriate. These recommendations would be shared with the client and community care providers.

3.3.2.2 Constant Collaboration and Communication

Ideally, successful implementation and effective care delivery occur when all stakeholders caring for a client share a sense of collaborative team, despite representing different organizations or settings. Although not clearly evident in the figure, one of the key aspects of this model is the need for ongoing collaboration and communication among the client’s care team. This includes communications between the specialized SCI team and the providers in the community caring for the client. Ideally, successful implementation and effective care delivery would be facilitated by a shared sense that all stakeholders are part of the collaborative team approach for a given client – no matter if they represent different organizations or settings.

Before the treatment plan is initiated in the community, the specialized SCI team negotiates it with the client and/or their caregiver, the care coordinator, and community care providers. It is important to determine if the treatment is acceptable and feasible within the community environment. Once finalized, the community providers would execute the treatment plan. They would then share the client’s progress with the entire
care team through follow up care conferences. The unregulated care providers involved in the client’s care should also be part of the care team, as they tend to interact with the client most frequently.

3.3.2.3 Building Capacity and Enhancing Expertise

Another primary component of the model of care was to build capacity and enhance expertise in both the community and the rehabilitation setting. Therefore, it was felt that the specialized SCI team should also have an outreach component in which they would support community providers by providing education and training. On the other hand, the community providers have a clear understanding of home care and can educate the specialized SCI team on community processes and practices. By creating this 2-way flow of knowledge, we hope to strengthen the relationship between organizations and improve the quality of care we provide individuals with SCI.

3.4 Discussion

To our knowledge, this is the first study to develop an adapted pressure ulcer model of care for healing pressure ulcers with EST by initially understanding the perceived facilitators and barriers to implementation. A significant number of perceived facilitators and barriers emerged following the stakeholder interviews, highlighting the complexities involved with implementing EST in the community. Several barriers identified in this study are comparable to other studies investigating implementation of evidence-based practice in health care, such as lack of time, problems with staffing including workload and understaffing, inadequate training and education, lack of resources, ineffective communication among team members, poor attitudes and beliefs towards practice change, incongruent polies and procedures, and difficulties reaching rural areas\textsuperscript{41-47}. This initiative did find some facilitators that could help foster implementation including having a clinical champion who could advocate for EST and obtaining complete buy-in from all team members from both rehabilitation and community to the patient themselves. These have been confirmed as necessary factors by other SCI-related implementation studies\textsuperscript{48,49}.
By classifying these items within the implementation drivers outlined by the NIRN model, we were able to visualize that changes are not only required at the individual and patient level, but also at the organizational and system levels in order to successfully implement and sustain a practice change.\textsuperscript{41,42} This is noteworthy, as these implementation drivers are part of a structured (ideally facilitated) process to inform implementation action planning as part of the NIRN framework.\textsuperscript{38} These issues can be carried forward into the implementation action planning with the success of these approaches assessed during the testing phase of this initiative.

When developing the model of care, the Steering Committee and Working Group agreed that not every barrier to implementation could be addressed. However, there were many discussions on possible options to manage the major barriers such as lack of communication and inadequate training and education. Improving communication amongst providers between or across setting and organizations may be achieved via teleconferences, videoconferences, and perhaps existing or newly developed electronic platforms. Once communication strategies are in place, it is likely that providers from rehabilitation and community can share their skills and expertise with one another to build capacity for pressure ulcer management. Alternatively, knowledge and skills related to EST can be gained through online resources and hands on experiences provided by experts within the field.

As the model of care was being created, the Working Group proposed different models for integrating rehabilitation and primary care that would benefit persons with SCI, including a clinic approach, self-management program, outreach services, and a case management approach. These different approaches to care were then combined to create our pressure ulcer model of care. Although each of these approaches has its advantages and disadvantages, together, these models create a unique program to treat pressure ulcers in individuals with SCI living in the community. Interestingly, these models have all been previously shown to be feasible when managing persons with disabilities and chronic illnesses.\textsuperscript{50} Therefore, this SCI pressure ulcer model of care or aspects of the model is an...
exemplar for other conditions, especially those with movement disorders, who are at risk for developing ulcers.

This paper also described in detail a method for gathering key initial implementation processes outlined by the KTA and NIRN framework. Using a CBPR approach seemed to be a good tactic given that the issue of pressure ulcers in the community was important to the team members and the assurance of collaboration resonated with the Steering Committee. More importantly, as researchers, we gained valuable insight to the advantages of using a CBPR approach including the ability to create a trusting partnership with community members with diverse backgrounds, being able to gain an understanding of the culture and dynamics of different communities and how a practice change such as implementing EST may not apply to other local circumstances, and to use community members as a primary resource to gain insight to how practices are run in different settings and organizations.

3.4.1 Limitations
There are limitations that need to be addressed. When interviewing the stakeholders to gather the barriers and facilitators, the conversations were not audio recorded. Therefore, the meetings were not transcribed word for word and appropriate coding could not be performed to complete a qualitative analysis. However, this phase of the initiative is intended to be exploratory and only requires an understanding of the issues that may be faced as the therapy is implemented into practice.

Another limitation faced was that there was poor representation from personal support workers, community dietitians and occupational therapists in the stakeholders group that were interviewed. Fortunately, an administrator and clinical leader from a local nonprofit organization that provides attendant care services to individuals with disability participated in the Steering Committee and Working Group, respectively.
3.4.2 Summary and Next Steps

This article outlines a structured plan and collaborative approach between researchers and community members in developing a pressure ulcer model of care while taking into account perceived facilitators and barriers to implementing EST for managing pressure ulcers in the community dwelling individuals with SCI. Using a similar stakeholder engagement approach, the next phase of the implementation planning will include further adapting the recommended practice in a two-day ADAPTE workshop, where frontline providers will operationalize the model of care by taking into account the barriers to create process maps detailing steps needed to initiate EST in the local community. This will be followed by a field-test using iterative Plan, Do, Study, Act (PDSA) cycles on a sample of community dwelling individuals with SCI and pressure ulcers.
3.5 References


A version of this chapter has been published: Lala D, Hougthon PE, Kras-Dupuis A, Wolfe DL. Developing a model of care for healing pressure ulcers with electrical stimulation therapy for persons with spinal cord injury. Topics in Spinal Cord Injury Rehabilitation 2016;22:277-87; Doi:10.1310/sci2204-227
Figure 3: Model of care for healing pressure ulcer with electrical stimulation therapy (EST) in community dwelling persons with SCI. AX = assessment; CCAC = Community Care Access Centre; OT/PT = occupational therapist/physical therapist; RD = registered dietitian; RN = registered nurse; SW = social worker; WSA = wound surface area.

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Chapter 4

4 Using a modified ADAPTE Process to Enable Effective Implementation of Electrical Stimulation Therapy for Treating Pressure Ulcers in Person with Spinal Cord Injury

4.1 Introduction

Good clinical practice guidelines deliver research evidence to care providers and health settings (e.g. hospitals, community agencies) in a format that is usable. However, to ensure the likelihood that the guidelines will be used, it is important and necessary to adapt the guideline or specific recommendations to the local context, which requires significant involvement of end-users. Adapting practice guidelines/recommendations to a particular environment has many advantages; it enhances the applicability so the adaptation "fits" the local environment, it ensures relevancy and improves the acceptance and adherence to the recommendations, it facilitates users in effective implementation planning, it optimizes the use of existing resources, and it engages knowledge/end-users resulting in greater chance of uptake.

Frameworks such as Knowledge-to-Action (KTA) and the National Implementation Research Network (NIRN) both refer to adaptation as a critical step to knowledge translation and implementation. KTA recommends selecting and tailoring the intervention to identified barriers and end-users. Although the KTA provides useful guidance for implementation, it does not provide concrete direction on how adaptation to the local context should occur. Comparatively, NIRN recommends a process for local self-assessment and identification of core components to implementation, known as drivers, which would generate change in a specific organization or setting.

In 2009, a group of international researchers, guideline developers, implementers, and users developed the ADAPTE process, a systematic approach for adapting guidelines in order to enhance the use of evidence-based research. The ADAPTE process consists of...
three phases including set-up, adaptation, and finalization. The set-up phase outlines the required tasks to be completed before the adaptation process begins, including identifying necessary resources and skills, and organizing a panel. The adaptation phase contains the core components of adaptation, including selecting a topic, searching and assessing guidelines, making decisions around how to adapt the guidelines, and drafting an adapted guideline document. Lastly, the finalization phase includes an external review in which the feedback of the adapted guidelines is obtained from relevant stakeholders and an updated version would be created. The ADAPTE process is supported by a Web-based toolkit that includes a manual and related tools to help facilitate the process.

The ADAPTE process was designed to be flexible, where knowledge/end-users are encouraged to customize the process to their own needs and context. Aside from a few studies that illustrated practical examples of how one may use the ADAPTE process for guideline adaptation, there has not been any clear initiative that incorporates the ADAPTE process as part of the implementation planning process for a local context, with a variety of healthcare providers, working across the care continuum within a regional system of care. However, the elements and approach of the ADAPTE process are compatible with achieving an objective of designing a successful implementation process as it can encourage users to detail the practice by operationalizing it to the local environment.

In December 2013, a group of researchers centered at Western University in London, Ontario, Canada, undertook an initiative with Parkwood Institute (a local healthcare organization focused on physical and mental health, with a specialty in spinal cord injuries), the South West Community Care Access Centre (“SW-CCAC”, a regional health agency that coordinates publicly-funded home and community care) and local healthcare providers to improve the management of pressure injuries (previously known as pressure ulcers or pressure sores) in community dwelling individuals with spinal cord injury (SCI). The use of electrical stimulation therapy (EST) for treating pressure injuries in this population was selected from the Canadian pressure injury best practice guidelines as the therapy to adapt and implement. EST involves applying low levels of
electrical current to the wound and/or surrounding tissues. Numerous clinical trials and meta-analyses have shown that EST can speed healing and promote wound closure of pressure injuries.\textsuperscript{19–21} Despite strong evidence and recommendations by many best practice guidelines, the therapy continues to be unused by frontline community providers due to a number of perceived barriers expressed by a group of local stakeholders.\textsuperscript{22} Given these findings, it became apparent that the adaptation process could facilitate the necessary details to enable effective implementation and ensure that the adaptation reflects the local context.

Therefore, the objective of this initiative was to apply a modified ADAPTE process to adapting best practice, with a focus of using EST as a treatment for healing pressure injuries in community dwelling individuals with SCI in South Western Ontario. A summary of the findings is briefly reported including the challenges and opportunities with implementing EST, identifying task-specific EST duties, and a detailed process map for providing EST to community dwelling individuals with SCI with pressure injuries. Furthermore, the lessons learned from using a modified ADAPTE process within implementation planning are summarized.

\section*{4.2 Methods}

This initiative was guided by the 3 phases of the ADAPTE process\textsuperscript{12}: set up, adaptation, and finalization, including the steps within each. The specific components of each phase and the ordering of the steps were modified to meet the requirements for the EST implementation planning.

Ethics approval was obtained from the Western University Research Ethics Board and the Lawson Health Research Institute. Because the adaptation process formed part of a research study, it was a requirement of the University Ethics Board that all participants of the adaptation process provide written informed consent for their participation.
4.2.1 Set up phase

4.2.1.1 Step 1: Check whether adaptation is feasible and select a topic

For this exercise, the organizing committee combined steps 1 and 3 of the formal ADAPTE Set Up Phase into an initial Step 1. The feasibility of the adaptation (formal step 1) and the selection of the specific topic for adaptation (formal step 3) were informed by a previous extended exercise, known as the “exploration phase” in the NIRN framework. The process and results of that work have been reported in a previous publication. An expert panel of consumers, healthcare providers, healthcare system managers, and researchers reviewed the opportunities presented by EST best practices for the treatment of pressure injuries, and then identified the barriers to and facilitators for EST implementation. Further, a preliminary pressure injuries model of care using EST as a treatment for healing was developed by the expert panel.

4.2.1.2 Step 2: Establishing an organizing committee, and adaptation team

An organizing committee comprised of 6 researchers from Western University, Lawson Health Research Institute, and Saint Elizabeth Health Care led the adaptation initiative. The committee’s responsibilities included identifying members to be a part of the local interdisciplinary adaptation team, organizing the adaptation process (i.e. ADAPTE workshop), and overseeing the entire project.

The adaptation team was selected to be representative of key stakeholders across the region that could potentially address and advise on the opportunity for EST implementation and the barriers and facilitators identified in Step 1. The team consisted of 17 individuals, of which 12 were from the community including a client service manager from a provincial health agency that coordinates community care (SW-CCAC), a regional service coordinator from Spinal Cord Injury Ontario (a non for profit organization dedicated to providing services and advocacy for people living with spinal cord injuries), a clinical lead for the regional wound care program, 2 physiotherapists (PT), a occupational therapist (OT), a registered dietitian (RD), 2 registered nurses in which one was an enterostomal therapy nurse, a personal support worker supervisor, and

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a team leader for senior supports for daily living. An individual with SCI was involved to ensure that the consumer’s perspective was represented. In addition there were four members of the Pressure Injury Consultation (PIC) team (previously known as the Spinal Cord Injury Pressure Ulcer Team (SCIPUT)) from Parkwood Institute including a PT, OT, RD, and an advanced practice nurse. PICS is a specialized interdisciplinary team that was specifically developed after an EST model of care was created during the exploration phase of this study. Specific clinicians were chosen to be members of the PICS team given their experience working with one another and their expertise in working with individuals with SCI.

The adaptation team were invited to commit to 2 consecutive 8-hour days to attend the ADAPTE workshop. The entire PICS team (9 members) were required to attend 3 additional, 1- to 2- hour sessions to adapt the process of rehabilitation services within Parkwood Institute to complement the EST implementation.

4.2.1.3 Step 3: Organizing the ADAPTE workshop – the preparatory phase
Over a 3-month period, the organizing committee prepared for the two-day ADAPTE workshop at Western University, and for subsequent meetings with the PICS team. Information regarding the initiative, including the barriers and facilitators to implementing EST that were collected in phase 1, and resources related to the application of EST were shared with the group to review in advance. The workshop was held on May 17-18, 2015. The additional PIC meetings were held in June 2015.

4.2.2 Adaptation
In the formal ADAPTE process, most of the Adaptation phase is focused on collecting, assessing and coalescing various existing best practices and clinical guidelines (Steps 7-14), and the fifteenth step – “Assess acceptability and applicability of the recommendations” – addresses the questions specific to this initiative (Figure 4). Since Steps 1 & 3 of the Set Up stage had identified the best practices that would be the subject
of this exercise, the work of the Adaptation phase in this study was on the fifteenth step and called Step 4.

4.2.2.1 Step 4a: The ADAPTE workshop
Two organizing committee members trained in facilitation delivered the workshop. Two members of the organizing committee independently took notes and compared their records after each day to identify critical observations. The workshop was audiotaped for field note verifications. At the end of each day, the organizing committee met and discussed the field notes and observations of progress, contentious issues, and overall progress toward the objectives. Three weeks after the ADAPTE workshop, the organizing committee met again to review the findings, and confirm the lessons learned from the workshop. Similarly, a trained facilitator led the PIC team meetings, and gathered and consolidated the learning after each meeting. The findings were shared and reviewed with the PIC team within 2 weeks of the final meeting in July 2015.

On the first day, the adaptation team was provided with an overview of the overall research study, with a significant focus on the evidence for the use of EST in pressure injury management. Each member of the adaptation team was then asked to articulate the challenges and opportunities with working in their health care setting and how it may affect the implementation of EST. The team then reviewed the model of care and discussed issues that might arise as the community aspects of this model is operationalized, with the goal of developing a process map.

At the end of the first day, the task of creating the process map had been delayed due to an extensive debate related to clarity of roles of healthcare providers who might be involved in EST. The debate centred on whether the providers should be designated in terms of discipline (e.g., PT or nurse) or on the basis of a specific skill set acquired by an individual (e.g., experience in EST).

On day 2, task-focused assistance was provided by the facilitators to support the adaptation team in mapping out a process illustrating the flow of activities of community
providers in initiating EST as a treatment modality for pressure injury management in community-dwelling individuals with SCI. Once a draft process was complete and confirmed by the team, the team worked through a simulated case that had been prepared by the organizing committee in advance. The purpose of the case simulation was to validate the appropriateness of the process map.

4.2.2.2 Step 4b: The PIC team meetings

The meetings with the PIC team were similarly organized with the objective to develop a process that will guide how the team would work together to provide a comprehensive assessment of the patient with SCI with a pressure injury to provide client-specific recommendations and support to the healthcare providers who would be involved in delivering the community-based EST.

To test the PIC's process map, a test patient with a pressure injury was recruited to evaluate a simulated clinical experience. Unfortunately, the test patient had a severe wound infection and was admitted to a local acute hospital for a few weeks to receive treatment. However, the team did learn some valuable lessons and insight from undergoing part of the simulated clinical experience and revised their initial process map accordingly.

Following the workshop and the meetings, the organizing committee reviewed the meeting notes and recordings, and categorized and refined the challenges and opportunities to implementing EST in the local environment. The committee also further refined the sequential process maps and created a visual interpretation of the activity flow.
4.2.3 Finalization

4.2.3.1 Step 5: Drafting a document for local adaption of EST
A summary of the issues discussed and resolved in the ADAPTE workshop and the PIC team meetings was merged with the sequential process maps in a draft document and shared with the PIC team and the adaptation team for content verification.

4.2.3.2 Step 6: External review by local stakeholders
The draft document for local adaptation of EST was also shared with a broad group of local stakeholders. This group included regional managers of SW-CCAC, regional directors and managers of local community agencies, local vendor for EST devices, and the director of rehabilitation and the coordinator of SCI rehabilitation at Parkwood Institute. The local stakeholders were asked to review the document and provide specific feedback. Because the SW-CCAC stakeholders had an extensive list of comments on the draft documents, additional face-to-face and teleconference communications were facilitated over a 4-month period until consensus was reached.

4.3 Results

4.3.1 Challenges and Opportunities to EST Implementation
Seven challenges and opportunities with implementing EST in the local environment emerged from the discussions during the ADAPTE workshop (Table 5). The challenges reported included lack of communication amongst providers, inconsistent care providers in the community, and lack of training and knowledge of pressure injury and EST. The opportunities to implementing EST included the multitude of funding models accessible to clients, the ability to facilitate interdisciplinary care, and the transition into self-management in the community.

4.3.2 EST-Specific Task and Responsibilities
The adaptation team was also asked to review the various steps associated with applying EST and delineate which regulated and/or unregulated care provider could perform specific tasks. Throughout this discussion, there was considerable debate over whether
implementation should be guided by designating specific disciplines as the key providers of EST, or whether by designating any healthcare provider with the requisite skill set and experience. Consensus was eventually reached to delineate roles and responsibilities of EST-specific tasks (Table 6).

4.3.3  Process Map

A process map for providing pressure injury best practices, specifically EST, to individuals with SCI (Figure 5) may not be feasible or useful for all environments; however, sections can be taken or adapted to fit another local context.

There are 4 main organizations in South West Ontario that frequently interact with one another: the PIC team, CCAC care coordinator including the contracted agencies, the vendor of EST equipment, and the EST consultant who has the expertise in overseeing the treatment with EST. As this is also a research initiative, the process map includes the research team to assist with screening, recruiting, and supporting the patient throughout the process. The subsequent sections briefly summarize the key components to this process map.

4.3.3.1 PICS

From intake assessment to debrief – Once a patient is referred to the PIC team, the team will meet to review the patient’s pre-assessment documents, including medical history, medications, nutrition, wound assessment and blood work, if available, and the triage form which includes data regarding patient’s home environment, equipment and transfers. This will allow the team to determine what team members and assessments are valuable to complete when the client attends the clinic days. In addition, a lead from the PIC team will be identified for the patient. Following the clinic days, the PICS team will have a debrief meeting where they will review their clinic findings, and develop a treatment recommendation suitable for the patient. This treatment recommendation may or may not include EST depending on the client’s eligibility for this therapy.

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4.3.3.2 Initial Joint Care Conference
A teleconference will be scheduled to review and negotiate the treatment plan with the
CCAC care coordinator, the patient and their caregivers, and the PIC team patient lead.
The patient must agree to the treatment recommendations in order for the services to be
provided.

4.3.3.3 Treatment
Each treatment recommendation including EST will be conducted in the community
using CCAC-contracted service providers or the client’s existing care team. If EST is
recommended, a member of the research team with significant EST experience will
perform bedside training with the community provider so they have hands-on experience
with EST and are able to provide the therapy using the recommended protocol.

4.3.3.4 Follow-up Joint Care Conference
After a few months of service, a follow up joint care conference including the PIC team,
CCAC care coordinator, the client and their caregivers, and the providers delivering
community-based services will be scheduled. During this meeting, the group will review
the client’s progress, address any issues that arose with any of the recommendations,
identify wound status, and revise the treatment recommendations as required.

4.3.4 Reflection
In addition to the components summarized above, we asked the team to take some time
and reflect independently and record things they learned or were feeling at the end of
each workshop day. Many members of the adaptation team appreciated the collaborative
nature of the meeting and valued the unique views of different providers across
organizations and setting. Furthermore, the adaptation team understood the importance of
improving pressure injury care and were motivated to develop a process that establishes
best practices, specifically EST, in treating pressure injury in community dwelling
persons with SCI. Although there were positive reactions to the initiative after the first

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day, many felt frustrated at the complexity of the current system and trying to develop a quality process that is efficient, cost effective and realistic within the local health care system. However, following the second day, the perceptions shifted to a state of relaxation and excitement as the process map became clearer through discussion and illustration.

4.4 Discussion

Using a modified ADAPTE process, a group of local stakeholders developed a guide for the adaptation of EST for treating pressure injuries in individuals with SCI living in Southwest Ontario. A sequential process map illustrating the flow of activities to initiate this therapy was developed while taking into account the challenges and opportunities to implementing EST.

Throughout the 3 stages of the ADAPTE process – set-up, adaptation, and finalization, we faced a multitude of challenges and learned some lessons that may be useful to others interested in using the ADAPTE process during implementation planning.

The composition of the adaptation team is critical, as they are the dominant factor in the adaptation of guidelines and will ensure its relevancy and applicability to the local organizations. Our multidisciplinary group, composed of local providers from the community and a tertiary rehabilitation facility, and a SCI consumer representative, exposed us to diverse areas of expertise and perspectives. Although we had great success working with the adaptation team, there were some key lessons learned.

First, consider reducing the number of members on the adaptation team. Given the size of the adaptation team and their distinct views, a great number of challenges to EST implementation were brought to the table and unfortunately could not all be resolved in the course of 2 days. Reaching consensus took considerable amount of time given the various perspectives. A group of 9 or 11 relevant and informative stakeholders has been shown to be an optimal size for guideline adaptation, and so perhaps it would be advisable to convene 2 separate groups with some time in between – one to raise the

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issues, and the second to negotiate the solutions. We also found that it was imperative that all adaptation team members attend the entire workshop. Although the adaptation team included a client services manager from South West CCAC, the representative was only able to attend for a few hours on the second day, and was more heavily involved as an external reviewer. Receiving community care in Southwest Ontario is highly dependent on CCAC as they coordinate community-based services using contracted agencies. In retrospect, their involvement during the ADAPTE workshop would have been critical to assist in sorting out many of the issues that arose during the external review phase with the process map, and therefore would have limited the negotiation time period.

During the adaptation phase including the ADAPTE workshop and the drafting of the document for local adaptation of EST, we were faced with 3 main challenges. One perceived challenge was the lack of initial understanding of the purpose of the workshop by the adaptation team. When asked to reflect upon the workshop at the end of the first day, many felt uncertain or confused and didn't completely understand the objective the ADAPTE workshop. Supplementary material (i.e. agenda and background data) was provided to the adaptation team in advance, and due to time constraints only a brief introduction was provided on the first day of the ADAPTE workshop. Interestingly, when each member had a chance to do their own personal reflection that night, many had a better understanding of the initiative on the following workshop day. It seemed as though a ‘light-switch’ had turned on in their minds, which allowed them to contribute in a more productive manner on the second day. Many realized the complexity of the current issues and the difficulties of implementation.

The adaptation phase requires sustained dedication, time and commitment by the organizing committee and adaptation team. We allocated two full workshop days and subsequent SCIPUT meetings to create a guide for EST adaptation that encompasses detailed information and a process map to EST implementation. In Canada, there are 2 different streams or models in which patients can receive care. The public care model involves the client receiving provider services through CCAC, and the private care model...
involves the client hiring their own provider services through personal income or private insurance. Due to lack of time and resources, the team was unable to create a process map for the private stream. Therefore, based on our experience, we would consider increasing the number of workshop/meeting days; however, there are repercussions for doing so. While our adaptation team was invested and very motivated in participating in this initiative, most of them had full-time caseloads making it difficult for them to take time away. Therefore, increasing the number of days will most likely lead to less involvement or the need for greater financial compensation to team members.

During the external review process in the finalization phase, we were faced with the most significant challenge. Representatives from CCAC viewed the process map and reported significant policy and procedural barriers. Multiple meetings over a 4-month period were held to resolve these issues and create a practical process map. Within the first couple of meetings, we realized the importance of hiring professional facilitators with no stake in any outcome to mediate these meetings. Although hiring professionals can be costly, it can result in significant benefits. The meetings were more productive, resulting in fewer and shorter meetings, and improved the relationship between the research team and the stakeholders from CCAC. As stated previously, these meetings may have also been less challenging if full participation by a CCAC representative was available during the 2-day workshop; however, the creation of the process map did provoke discussion and without it, the issues may have not been obvious at the beginning.

4.4.1 Conclusion

We developed a document for adapting EST locally using a modified ADAPTE process. A detailed process map outlining the flow of activities for providing EST to community-dwelling individuals with SCI was developed based on the opportunities and challenges to implementing EST into practice expressed by local representatives. The team also delineated roles and responsibilities for tasks associated with performing EST.

A number of challenges were faced throughout the ADAPTE process; however, we were able manage the issues as they came and provide some lessons learned to those who wish

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to pursue a similar approach of using the ADAPTE process during the planning phase of implementation.

4.4.2 Future Research
We will be field-testing this locally adapted EST plan using iterative Plan, Do, Study, Act (PDSA) cycles\textsuperscript{24} with a sample of community dwelling individuals with SCI experiencing pressure injuries. The field-tests will not only examine clinical outcomes such as healing but more importantly outcomes related to practice change such satisfaction with the program/model, frequency of consultations, cost-effectiveness, and EST utilization. By testing this model locally, we will be able to determine the feasibility of implementing best practices such as EST in the community in individuals with SCI and pressure injuries at a provincial or national level.

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Table 5: Challenges and opportunities with implementing electrical stimulation therapy in the local environment

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
</table>
| Communication       | • There is a lack of communication between providers across settings (i.e. acute care, rehab and community)  
                     | • There is a lack of communication between community providers from different agencies                                             | • Community providers rarely receive discharge or summary notes from acute care or rehab  
                     |                                                                                                                             | • No means for community providers from different agencies involved in the clients' circle of care to communicate with one another |
| Provider Consistency| • There is a lack of continuity of care providers in the community           | • High turnover rate of providers, lower ratio of providers to clients, and geographical dispersion of clients makes it difficult to for clients to receive continuous care by the same community provider |
| Training            | • There is a lack of training around pressure ulcers and EST amongst care coordinators and community providers | • Community care providers have different levels of knowledge and skills around wound and therapies resulting in inconsistent care amongst clients |

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding</td>
<td>• There are many funding models in Ontario that can be used to support community services</td>
<td>• It is important to tap into different funding models including public, private, and direct, and use what is most appropriate for the client</td>
</tr>
<tr>
<td>Interdisciplinary/ Integrated Care</td>
<td>• There is access to a variety of regulated and unregulated providers in the community</td>
<td>• Advantageous to facilitate joint visits between community providers so that integrated care can be provided to the client</td>
</tr>
<tr>
<td>Client-Centered Practice</td>
<td>• Self-management is increasingly becoming an important care model</td>
<td>• Providers' role should include supporting and educating their clients' to manage their own care, and advocating for clients' right to make decisions related to their care</td>
</tr>
</tbody>
</table>
Table 6: Roles and responsibilities involved in providing EST for treating pressure injuries in community-dwelling individuals with SCI

<table>
<thead>
<tr>
<th>Responsibility (EST-Specific Tasks)</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programming the EST device</td>
<td>Any regulated HCP or delegated individual with EST training and ability to work below the level of the dermis.</td>
</tr>
<tr>
<td>Assessing “moisture balance”, packing and dressing the wound, and applying electrode in the wound (monopolar EST application)</td>
<td>Any regulated HCP with knowledge in wound care, EST training and ability to work below the level for the dermis.</td>
</tr>
<tr>
<td>Connecting leads and application of electrodes to intact skin (dispersive electrode and bipolar EST application)</td>
<td>Any regulated HCP or delegated individual (i.e. patient, caregiver, family member, PSW) with EST training.</td>
</tr>
<tr>
<td>Operating EST device (i.e. turning device on/off)</td>
<td>Any regulated HCP or delegated individuals (i.e. patient, caregiver, family member, PSW) with EST training.</td>
</tr>
<tr>
<td>Observing, monitoring, and reporting adverse events or irregularities to healing</td>
<td>The patient and all individuals involved in the patient’s circle of care.</td>
</tr>
<tr>
<td>Reassessing the wound</td>
<td>Any regulated HCP with advanced wound care training, skills to detect changes in wound status, and ability to work below the level of the dermis</td>
</tr>
</tbody>
</table>

**Delegation:** process in which a healthcare professional (HCP) authorized to perform a controlled act gives that authority to someone who is not authorized to perform the act.
- Does the population described for eligibility match the population to which the recommendation is targeted in the local setting (acceptable)?
- Does the intervention meet patient views and preferences in the context of use (acceptable)?
- Are the intervention and/or equipment available in the context of use (applicable)?
- Is the necessary expertise (knowledge and skills) available in the context of use (applicable)?
- Are there any constraints, organisational barriers, legislation, policies, and/or resources in the health care setting of use that would impede the implementation of the recommendation (applicable)?
- Is the recommendation compatible with the culture and values in the setting where it is to be used (acceptable and applicable)?
- Does the benefit to be gained from implementing this recommendation make it worth implementing (acceptable)?

**Figure 4: Step 15 of the ADAPTE process: assess acceptability and applicability of the recommendations**
Figure 5: Initial process map for initiation of EST in community-dwelling persons with SCI with pressure injuries that will be tested in cycle 1. EST indicates electrical stimulation therapy; SCI, spinal cord injury

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Chapter 5


5.1 Introduction

The Canadian healthcare system prides itself on accessible care for its citizens; however, when it comes to delivering services across different clinical settings, care often becomes very fragmented and lacks coordination. With fragmented care, resources are inefficiently allocated impacting quality, costs, and outcomes. Individuals with disabilities or chronic conditions living in the community are commonly affected by this fragmentation of care. There may be multiple providers for a single patient across different organizations that do not effectively integrate services, which can be inconvenient to the patients and possibly harmful.

Pressure injuries (previously known as pressure ulcers) are a serious and common complication among those with limited or no mobility including individuals with spinal cord injury (SCI). With limited movement, constant pressure, friction or shearing breaks the skin. The presence of pressure injuries results in substantial pain and poor quality of life, predisposing this population to increased morbidity and possibly mortality. In Canada, the prevalence of pressure injuries in community dwelling individuals with SCI has been reported to be 33.5% with significant impact on the ability to participate in meaningful activities (see Chapter 2). Pressure injuries not only occur in acute and long-term care, but also among those living in the community or home care settings.

Electrical stimulation therapy (EST) has been routinely cited by national and international pressure injury guidelines as having the highest level of evidence to effectively treat pressure injuries. EST has greatest effect when implemented within a coordinated inter-disciplinary care strategy across and within organizations that address the
multifactorial causes of pressure injuries. Unfortunately, it is often avoided or disregarded as a first-line treatment due to issues such as lack of awareness about the benefits of EST, knowledge and skills about how to use EST, funding, time and staff, and buy-in and support from leaders and administrators.\textsuperscript{18}

The purpose of this initiative was to apply the Active Implementation Frameworks (AIFs) of the National Implementation Research Network (NIRN) to develop and implement a coordinated pressure injury service including the use of EST to manage pressure injuries in community dwelling individuals with SCI.\textsuperscript{19–21}

This paper describes how the AIFs of the NIRN were actualized, and then describes four key issues that subsisted across the entire implementation timeline along with the different strategies that were utilized to resolve these issues.

5.2 Methods

5.2.1 Implementation Strategy
The AIFs together constitute a strategy to use when putting evidence into practice. Successful implementation may be enabled by the desire to achieve the intended health outcomes by optimizing what needs to be done (effective intervention), how it will be done (effective implementation), and where the intervention and implementation will thrive (enabling contexts). If any of these components are not considered then implementation is unlikely to be achieved to the fullest extent possible. There are 5 components to the AIFs: (1) Usable Innovations, (2) Implementation Teams, (3) Implementation Drivers, (4) Implementation Stages, and (5) Improvement Cycles.\textsuperscript{20}

Usable Innovations is a relatively new concept, introduced after the commencement of this project, and therefore this component was not considered prior to implementation. However, some of the processes conducted within the initiative were consistent with the overall aim of this framework, which involves defining the intervention.

Overall, key implementation processes employed in this initiative are described below somewhat chronologically, using the AIF Implementation Stages. Within this framework,
there are four functional stages including (1) Exploration, (2) Installation, (3) Initial Implementation, and (4) Full Implementation.\textsuperscript{19,20} This paper focuses on the Initial Implementation Stage. An important aspect of the Initial Implementation are plan-do-study-act (PDSA) cycles. These are often used to accelerate quality improvement in the healthcare system.\textsuperscript{22–24} PDSA cycles involve planning an innovation, testing it, observing the findings, and acting on what is learned.

### 5.2.2 Implementation Context

The EST Collaboration Project was a 4-year initiative carried out to implement EST for treating pressure injuries in community dwelling individuals with SCI in the health region of the South West Local Health Integrated Network (SW LHIN), Ontario, Canada. The overarching aim of this initiative was to develop and sustain a comprehensive approach to delivering EST that might be replicated in different healthcare and community settings across Canada.

This initiative was a collaborative effort by a group of researchers in Ontario at Western University, Parkwood Institute, Saint Elizabeth Research Centre, managers from South West home care services (Community Care Access Centre, CCAC), leaders and clinicians from the regional rehabilitation program (St. Joseph’s Health Care London-Parkwood Institute), and local care providers who expressed an interest in improving coordinated care for pressure injury management and acknowledged the benefits of EST.

In Ontario, CCAC coordinates in-home healthcare services that are provided through contracted agencies that employ healthcare providers. CCAC employs care coordinators to liaise between patients and healthcare providers to facilitate necessary community and home services for the patient. In South West Ontario, there are seven contracted agencies which provide a range of services including nursing, in-home therapies, personal support, and medical supplies to urban and rural areas spread over more than 21,000 square kilometres.\textsuperscript{25} During the later stages of this initiative, home care services were transferred from CCAC to the South West Local Health Integration Network (LHIN).
5.2.3 Exploration Stage
Prior to Initial Implementation, multiple steps were undertaken to define the innovation. During the exploration stage, a group of individuals across community and hospital settings including patients, managers and frontline providers were interviewed to identify barriers and facilitators to the implementation of EST. The barriers and facilitators were organized into implementation drivers to determine the components that would contribute to the success and sustainability of EST for managing pressure injuries in community dwelling individuals with SCI (see Chapter 3).\cite{18} These barriers and facilitators were later presented to a group of local champions in a 2-day workshop to assist in adapting the current practices to incorporate EST in managing pressure injuries. A detailed process map outlining the flow of activities of different healthcare providers in providing pressure injury best practices was developed during this workshop and it has been described previously (see Chapter 4).\cite{26} This map was used to guide the implementation process in the first PDSA cycle (refer to Figure 5).

5.2.4 Installation Stage
During the Installation Stage, a teaming structure was developed to provide a framework to guide the principal investigator and research team in decision-making around the implementation initiative. The teaming structure involved four committees – the research committee, the implementation committee, the executive committee, and the advisory committee. The defined purpose, roles and responsibilities of these committees are summarized in Table 7. All committees were formed at the beginning of the initiative, except the Advisory Council, which was constituted in PDSA cycle 4.

In addition, the necessary resources such as training and coaching material, accessing material and equipment, and creating referral mechanisms were developed and integrated across four key aspects of the initiative that supported the Initial Implementation of EST. These included: (1) An electronic platform; (2) Establishing a specialized interdisciplinary pressure injury team; (3) Engaging healthcare professionals; and (4) Facilitating administration of EST.
5.2.4.1 Electronic Communication Platform

The struggle to communicate easily and collaborate within a patient’s care team have been previously identified as a key barrier to successfully implementing EST best practices.\textsuperscript{18,26} During the Exploration Stage,\textsuperscript{18} several stakeholders identified the need to pilot the use of a computer- or electronic-based support system as a means of facilitating communication amongst providers involved in each patient’s care and to better link hospital-based clinicians with community providers. The research team reviewed several existing electronic platforms used to facilitate communication, but found no current system that details a patient’s treatment plan or facilitates interaction between a patient’s care team. Therefore, the research team ultimately decided to explore a new platform called CHAYA™ due its user-friendly interface, and its ability to be customized to meet the needs of this implementation initiative. More importantly, CHAYA™ was customized to enable patients to be at the center of their own healthcare by allowing them to connect directly with their care team for access to health information and services. CHAYA™ also had the functionality to allow patients and caregivers to share and access real-time pressure injury related information in a secure manner along with educational materials related to pressure injury and EST.

Each participating patient and members of their care team were given a unique username and password. Users were also given the opportunity to receive hands-on training by a research team member and an accompanying user-guide to assist in using the electronic platform. The research team and Information Technologist of CHAYA™ supported the resolution of any technical problems. Laptops and wi-fi sticks were provided to patients to facilitate easy access to CHAYA™ by the patient and their care team at the patient’s home.

5.2.4.2 Specialized Interdisciplinary Team

A specialized interdisciplinary team was conceived as part of the model of care during the Exploration Stage and developed in the Installation Stage after it was identified to be a vital aspect to successfully manage pressure injuries in community dwelling individuals with SCI (see Chapter 3 and 4).\textsuperscript{16,18} The team consisted of specialized SCI rehab
clinicians including a physician, two physiotherapists and occupational therapists, a social worker, registered nurse, and registered dietitian.

Initially called the Spinal Cord Injury Pressure Ulcer Team (SCIPUT), the specialized interdisciplinary team was later renamed the Pressure Injury Consulting Service (PIC) to better reflect their role in the pressure injury care. At the outset, the team was responsible for completing a comprehensive pressure injury assessment and developing a care plan that included EST recommendations, but their role evolved throughout the process to focus on sharing their knowledge and expertise of pressure injury care with community providers to facilitate building capacity in the community. The team was situated in the outpatient department in the regional rehabilitation hospital.

5.2.4.3 Provider Engagement
During the Exploration Stage, local champions were identified at each site to engage frontline workers and assist in the implementation process. An implementation committee was also developed with the primary intention of identifying strategies to improve subsequent PDSA cycles based on findings obtained during the ongoing PDSA cycle. In addition, they were required to address any concerns local sites may have, and identify tools that can improve the delivery of EST into practice. The committee consisted of wound care champions in the community, leaders at Parkwood Institute and managers from CCAC. The implementation committee were required to meet monthly on a voluntary basis. Furthermore, during initial implementation, bedside training and coaching were provided by an expert research clinician to assist frontline providers in providing EST during the PDSA cycles.

5.2.4.4 Facilitative Administration of EST
Facilitative administration is a concept within the AIFs which focuses on creating an environment which supports innovation and reduces implementation barriers with special attention to policies and procedures. First, a process map outlining the steps to acquire EST in the community during the Exploration Stage was developed. Funding was secured to reimburse visits by home care professionals to assess and monitor EST treatments, and
provide EST equipment and related supplies. Additional EST equipment was purchased by the research team to aid in training and education of community providers. Additionally, educational modules were developed, local champions were identified to support the innovation and solve ongoing problems within their organization during implementation, and current forms were modified to include EST as a therapy option in the community. A clinician with the knowledge and training in EST was available on-call to coach front line providers in the administration of the therapy.

5.2.5 Initial Implementation

Five PDSA cycles were executed over a two-year period; each cycle lasting approximately 3-4 months with an additional 1-2 months for evaluation and improvement planning for the subsequent cycle. Figure 6 outlines the principal procedures employed during this initiative from the Exploration Stage to Initial Implementation. PDSA cycle 1 trialed the initial model of care and process map that was previously developed in the Exploration Stage (see Chapter 4).26 Initially, men and women 18 years or older living in London, Ontario with SCI and stage II, III, or IV pressure injury who were medically stable, willing to complete study related activities, and eligible to receive EST, were invited to participate in this initiative.

Learnings from the PDSA cycles were captured through surveys seeking feedback from patients and members of their care team regarding their experience with the EST assessment and treatment process in each cycle. The surveys included both open-ended and closed-ended questions. Patient perspectives were also obtained by examining responses to close-ended questions with 5-point Likert scales. This data was compiled and analyzed in Excel and presented as frequency graphs. Data were also captured through the research team’s own observations of the operation of the process in each cycle recorded in journals and emails to and from others involved in the study. The research team also logged issues and recorded process changes throughout the cycles and called patients and providers who were unable or unwilling to complete surveys.
Qualitative data from the survey, recorded observations, and the process documentation for the cycles were analyzed thematically by the same researcher (DL). The issues and some of the underlying data (where necessary to revisit the issues) were reviewed and discussed by the research team until a consensus was reached on the interpretation of the data in each cycle. The challenges in each cycle were organized into tables with corresponding strategies that were successful or not successful to address the challenges. At the end of the 5 PDSA cycles, the data were merged and key issues associated with the resources developed during the installation phases stood out as having needed continual improvement strategies across the cycles of initial implementation.

5.3 Results

Fifty-five individuals were pre-screened over 5 PDSA cycles, 31 were enrolled and underwent a screening assessment to determine eligibility (Table 8). Only 16 of 30 patients received EST. The other 15 individuals were not eligible to receive EST because they had suspected or diagnosed osteomyelitis, they were medically unstable, their pressure injury had healed by the time of EST initiation, their wound was found not to be a pressure injury, or they no longer wanted to participate in the study (see reasons for exclusion in Table 8).

5.3.1 Electronic Platform

In the first two PDSA cycles, CHAYA was not available for use as it underwent a rigorous 12-month review process with the Privacy and Risk Office at St. Joseph’s Health Care London. Therefore, communication amongst healthcare providers and with the patient were conducted by traditional means including telephone, faxes, and care conferences. (Table 9). Community providers and members of the hospital-based PIC team frequently identified communication as an area of concern. Many expressed frustrations in connecting with one another when using traditional methods.

“[I was not satisfied with]...the care plan changing for a patient, and this not being communicated clearly to all those involved in the care plan” (PIC team, PDSA cycle 1).
It was anticipated that implementing the electronic platform would resolve the communication barriers between the patient’s healthcare team and the patient. Unfortunately, CHAYA™ was not easily embedded in the care processes. Despite suggesting the use of CHAYA™ during the Exploration Stage, CCAC did not allow the use of any electronic platform outside of their current system. Since the CCAC care coordinators were an integral part in organizing, coordinating and delivering home care services to the patients, this was a significant limitation. Furthermore, while CHAYA™ was provided to community providers, many did not use the electronic platform, invest the time to learn to use the system or participate in training. Multiple strategies were put in place to encourage the use of CHAYA™ including ongoing IT support from the research team and CHAYA™ developers, step-by-step learning guides and in-person training sessions. Providers also felt they were duplicating documentation, particularly when other members of the care team were not accessing the information (Table 9).

“I have yet to have a patient communicate with me via CHAYA™. I had one phone call with the one participant this PDSA cycle, and this was to review the recommendations. Other than that, I’ve had no communication. I’m not sure if they feel SCIPUT [PIC] is accessible to them or if they want more communication” (PIC team, PDSA cycle 4).

“Since CCAC isn’t on CHAYA™, it seems like CHAYA™ is used for some players but there is redundancy to have to duplicate all the communication to CCAC in fax or telephone” (PIC team, PDSA cycle 3).

Although all patients did not utilize the system as anticipated, many did appreciate the features that supported communication amongst their care team and how easy it was to access educational tools on EST and pressure injuries (Figure 7a).

5.3.2 Specialized Interdisciplinary Service
The PIC team had difficulties transitioning from a typical inpatient and/or outpatient service mindset to a more consultative role. This issue was addressed in several ways including facilitated meetings between PIC and CCAC representatives, role clarity
documents and step-by-step guides that were created to clarify individual roles and responsibilities to assist with the transition (Table 10). The PIC team sometimes provided recommendations that were not feasible or attainable in the community. Appreciating the nature of community-based care was also a challenge for some of the hospital based specialized team members who were accustomed to providing direct patient care. As such, some members felt they needed to directly educate the patient without involving the community providers. In addition, many were surprised to find significant barriers to healing that had not been addressed as part of the patient’s current wound care program.

“Community partners did not always have ‘comprehensive and holistic’ resources available to implement recommendations” (PIC, PDSA cycle 4).

PIC team members’ lack of time to manage their regular caseload in addition to attending to the study patients was a recurring issue throughout the five cycles. At least 1-2 members of the team were missing during pre-scheduled clinic visits. This barrier persisted despite providing research funds for a biweekly half-day for dedicated PIC teamwork. The change in role in conjunction with the time pressures likely explained the high turnover rate of the PIC team. Only one of the 9 PIC team members who started the implementation was still in place at the end of the study.

Given that CHAYA was unavailable during PDSA cycles 1 and 2, care conferences between the PIC team, community providers and CCAC care coordinator were essential. Unfortunately, trying to schedule a time when several healthcare providers were available to attend a conference call was rarely achieved. Despite scheduling conferences several weeks in advance, many absences occurred and seldom did community providers attend. Furthermore, the use of teleconferences and faxes as the principal lines of communication between care providers seeing the same patient was both inefficient and ineffective. This significant communication barrier made it difficult for the PIC team to link with community providers and recommendations of the care plan were often not realized as a result.
“[I would recommend improving the] initial communication at start of treatment with all members involved using teleconference to initiate first contract and agree to care plan (Community Provider, PDSA cycle 1)

“[We] need to improve communication of [any] changes [to the patient’s care plan] during [the] care conference” (PIC, PDSA cycle 2)

Several strategies were employed to resolve these issues including developing documents that clarify the PIC consultative role, organizing facilitated discussions between the PIC team and CCAC to help clarify the community care system, and streamlining the conference call. Initial conversations in the conference call were between PIC and community care providers to determine the feasibility of the recommended treatment plan and what would be funded by the public system. The patient was then included into the call to ensure the patient was in full agreement of the treatment plan. In general, creating a conference call guideline and allowing clinicians to talk prior to inviting the patient into the conference call were successful. Despite these challenges, patients appreciated the communication that was occurring amongst their care team members throughout the initiative and were quite satisfied with the overall care they received (Figure 7b).

5.3.3 Provider Engagement

Engaging the members of the implementation committee was also a significant issue as many members of the committee had competing demands on their time and therefore had difficulties prioritizing the responsibilities of their involvement. Often, there was passive engagement and meeting attendance was quite sparse. Community-based providers with advanced and specialized training in wound care (i.e. Enterostomal nurses, ET), for example, were scarce making it difficult to participate in the implementation committee leading to high turnover rates. In addition, contracted CCAC providers are not compensated financially to attend meetings or non-patient activities. To improve meeting attendance, meetings were scheduled months in advanced, meeting agendas were created by the committee and emailed in conjunction with the meeting reminders, and meeting notes were drafted to be actionable. Unfortunately, this did very little to improve
attendance and participation. As a result, the research committee began to assume much of the implementation responsibilities after PDSA cycle 3.

The lack of awareness and inadequate knowledge and skill related to EST was identified as another issue both in the Exploration Stage and during Initial Implementation. This barrier significantly affected the appropriateness of referrals of patients for EST (Table 11). Many community providers lacked sufficient training in wound care and were ill prepared to deal with the complexities and severity of illness of individuals with SCI and pressure injuries. Strategies to resolve knowledge deficits were extensive and included providing bed-side coaching to developing online educational courses and providing several hands-on workshops.

5.3.4 Facilitative Administration of EST

The process involved in initiating EST was lengthy (Table 12). Due to the difficulties of booking clinic times for a PIC assessment, and the numerous steps involved in ordering and initiating EST in the community, patients had to wait several weeks after being enrolled in the study.

“[It was a] long process and a lot to cover [from screening to PIC assessment] before EST was initiated fully” (Patient, PDSA cycle 1).

To reduce wait times after the first PDSA cycle, processes to initiate EST were started at the same time as the PIC team assessment. The complex nature of ordering the equipment and supplies, though designed carefully in the Exploration Stage, was changed after each PDSA cycle, and was found to be cumbersome by both community providers and patients.

“[There was] confusion and frustration about returning the EST machine back to [vendor] and who the EST machine belongs to” (Patient PDSA cycle 2).
There were several successful strategies to resolve the processes. These included regular training and support for care coordinators by the CCAC client service manager about processing EST requests; continuous revisions and improvements to the model of care for delivering EST; and moving forms within the CCAC internal electronic portal for easier access.

In PDSA cycle 4, one of the EST machine stopped working and an alternate device had to be sourced by the vendor. Introduction of a new device resulted in delays to the patient’s treatment and confusion on the part of the family members and providers in terms of how to use the new machine. Alterations to equipment and the EST protocol resource documents supplemented by individualized bedside coaching of patients and providers about the operation of the new machine were strategies used to resolve this issue.

Despite numerous process changes throughout the 5 PDSA cycles, patients and caregivers strongly agreed that their care plan including EST and other pressure management strategies were delivered as promised, and would highly recommend this program to other individuals with pressure injuries (Figure 7c).

5.4 Discussion

This paper identifies issues that can arise when introducing a new intervention (i.e. EST) for managing pressure injuries in community dwelling individuals with SCI in a very complex healthcare system. The key difficulties in the PDSA cycles were related to the interrupted introduction of a customized electronic platform resulting in poor communication across the provider teams; integrating a new specialized interdisciplinary team; limited engagement of local champions and community providers, and cumbersome process to facilitate the administration of EST. Several implementation strategies to resolve the issues encountered during the PDSA cycles had positive effects on the process; however, there were also strategies that were not as successful. Despite the challenges, the implementation process increased patient’s access to EST and improved the patient’s care satisfaction.
Typical implementation initiatives are generally more effective when PDSA cycles are brief and target one or a few changes to the improvement processes or activities, especially at the outset. While focusing on a single intervention or small change may be easier to implement, this is somewhat artificial when considered within a multi-faceted and complex health system. If executed well, enhanced coordination of care has been demonstrated to improve quality, efficiency and costs of care.\textsuperscript{28–31} To enable successful implementation, the chosen practice changes must be a priority to those involved, and active participation and continued commitment is required from local managers and healthcare teams. Successful implementation also requires the involvement and engagement of communities that are committed to the process.\textsuperscript{32} Significant effort was made to facilitate these processes; however, introducing multiple adaptations at once within a model of care that crosses both hospital and community settings resulted in substantial challenges during the improvement cycles.

5.4.1 Electronic Platform

Delayed communication and inaccuracy of information exchange between care providers, coordinators and patients may have significant implications for quality of care provided to patients.\textsuperscript{33,34} Kripalani et al\textsuperscript{35} highlighted this finding by reporting direct communication between hospital and primary care physicians only occurs 3\%-20\% of the time, resulting in suboptimal delivery of patient care. Therefore, it is not surprising that there has been growing support for the use of electronic systems to improve communication amongst patient care teams,\textsuperscript{36–38} and to decrease in-person patient care visits.\textsuperscript{39} During the development of the model of care in the exploration phase, it was assumed communication difficulties would be addressed with a customized electronic system, like CHAYA\textsuperscript{TM}, that provided direct and secured links between members of the patient’s healthcare team via care conferencing or messaging features. Unfortunately, integrating a new system like CHAYA\textsuperscript{TM} is not easy. It requires a lot of time and effort, and agreement for use from all intended parties.

In hindsight, specific strategies could have been undertaken to improve care provider engagement such as more involvement of end-users in the development of the electronic
If the providers provided feedback on their experience with the system and had a hand in the development process, it could have improved the uptake of CHAYA during implementation. Furthermore, we should have also conducted a more extensive investigation of existing channels of communication and better understood different ways whereby members of a care team could provide integrated care. Given that the model of care crossed different healthcare settings, it might have been better to examine policies and their implications that may have enabled more effective communication.

5.4.2 Specialized Interdisciplinary Service
Managing wounds with an interdisciplinary team has been suggested to be the best way to deliver quality wound care services. An evidence-based review demonstrated that providing an interdisciplinary wound care team can improve healing rates, number of home visits and number of supplies used. However, developing a team to go beyond traditional settings (e.g., inpatient and outpatient hospital services) to non-traditional roles (e.g., moving from a hands-on service to a consultative service) has its challenges. A consulting or “shared care” model should promote a collaborative practice by allowing clinicians to share knowledge regarding patients, and gain information and experience that can be transferred to future patients. Members of the PIC team worked hard to commit to the initiative and understand their new consultative role, but had difficulties fully understanding the consultative concept. They had difficulties appreciating that the primary care was being delivered by healthcare providers outside of their setting and they had a larger role in coaching and educating frontline regarding wound prevention and management in this specialized population, which is a departure from their traditional role.

5.4.3 Provider Engagement
A lack of community engagement was a significant barrier associated with the ease of implementation. Stakeholders play an essential role in changes made to the process and need to be included throughout implementation to strategize and provide their expertise. However, providers are often pushed beyond their limit making it difficult to deliver services in collaboration and coordination with their colleagues or participate in other
initiatives. Unfortunately, without feedback from frontline providers and active participation from the implementation committee, it was difficult to gather findings from each PDSA cycle, study the findings, and create a plan to improve the implementation process for the subsequent cycle. In Ontario, community providers are paid based on patient visits and are not compensated for participating in non-patient related activities. Therefore, future initiatives should consider compensating members of the implementation committee for their participation and efforts in best practice initiatives, or perform a stakeholder analysis to ensure stakeholder interests align with the goals of the implementation process, and to minimize the risks associated with stakeholder non-support\textsuperscript{46}.

Further, even with pre-implementation planning, we did not predict an overhaul of the administrative structure of CCAC in Ontario\textsuperscript{47}. In 2016, the provincial government enacted the Patient First Act to ensure that patient-centered care is provided\textsuperscript{48}. The Act involved abandoning the CCAC system and putting the LHIN in charge of supervising, managing, and funding the home care providers. Such a substantial change to a key decision-making organization (i.e. SW-CCAC), undoubtedly affected the engagement of their representatives. Integrating a new practice into an existing system is more successful when implemented in a strong structurally sound organization with limited issues\textsuperscript{49}. In hindsight, it would have been beneficial to develop an alternative model of care that did not including CCAC or the LHIN to facilitate pressure injury management. One example would be an outreach program in which a specialized team in pressure injury care manages these complex pressure injury cases in the community.

Another issue encountered early in the implementation project was the difficulty in identifying people who were appropriate for EST therapy, resulting in few patients being involved in the study. While referrals increased slightly after expanding the inclusion criteria to patients with limited mobility (i.e. with or without SCI) living in SW-LHIN and introducing an extensive EST awareness campaign, it continued to be difficult to identify appropriate patients who were receiving wound care from local CCAC and could benefit from EST. This was complicated by the lack of CCAC-based coding system that
could easily identify people with SCI with or without pressure injuries. Through discussions with managers, it became apparent that care coordinators had large caseloads and were unable to identify patients with pressure injuries. As a result, many patients who were referred had long-term chronic and severe wounds that were complicated with osteomyelitis. A very concerning observation was that some patients screened by the research team required an immediate emergency department visit or hospital admission because of the seriousness of their condition. Managing osteomyelitis requires costly surgical intervention and a course of antibiotics. This points to the need for greater effort in identifying these patients earlier and putting in place the types of services established within the present initiative. The lack of awareness of the seriousness of the pressure injuries in the community uncovered during the exploration stage represents a wake-up call to health planners and policy-makers for more attention to the impacts of current methods of community care provision, especially in persons with complex needs and co-morbidities.

5.4.4 Facilitator Administration of EST
A common issue that was identified following each PDSA cycle was the complexity of the process needed to order and authorize EST equipment. Although, we undertook an extensive adaptation phase where step by step processes were outlined and newly designed forms were created to help providers order the correct equipment and supplies, providers continued to encounter difficulties.

There are examples of other devices (i.e. negative pressure wound therapy) used in wound care that have been successfully embedded into practice. However, this was facilitated by huge investments by a large wound care company that provided a single patented device. No similar company exists for EST equipment and supplies.

5.4.5 Limitations
A limitation during the improvement cycles was the paucity of feedback that was received from community providers. Low completion rates by community providers continued through the 5 PDSA cycles despite multiple strategies to gain their input.
Strategies included providing consent forms and surveys at initial identification of patient’s care teams, mailing the survey or the research team offering to complete it over the phone, completing the survey electronically through CHAYA™, and changing the consent form so that completing the survey implied consent to participate. The lack of engagement may be symptomatic of the severe challenges that exist within the wound care community.

Another important limitation was that the research team identified the key issues summarized in this paper, which has the potential for research bias. Research bias potentially could have been reduced by performing member checking such that the participants involved in the implementation process, including patients and providers in the hospital or community, review and validate the findings. There may be other issues that were more important and applicable to their setting.

5.4.6 Conclusions
This is the first implementation initiative that attempted to coordinate cross-setting providers and improve pressure injury care using EST for community dwelling individuals with SCI. This chapter illustrates key issues that can arise with initial implementation initiatives. Implementing an electronic platform to improve communication between care settings can be challenging, while creating a new specialized interdisciplinary team in a consultative role requires purposeful training. Furthermore, engaging local providers and champions is essential to obtain feedback to facilitate ongoing PDSA cycles, and the process of ordering EST equipment and supplies should be simple for ease of providers and patients.

Multiple strategies were undertaken to improve and facilitate the implementation and foster the sustainability of pressure injury best practice. Specifically, support and buy-in was obtained from upper management stakeholders from CCAC and the local regional rehabilitation center, and the change in practice was embedded directly in the current healthcare system such that financial support by the research funds was not provided to CCAC. CCAC delivered the necessary home care providers to the patient and provided
EST through a local EST vendor using their existing care procedures resulting in a simpler transition following this initiative. Alternatively, research funds were used to support the PIC team, which negatively impacted its ongoing service. Therefore, successful sustainability is associated with using existed procedures and requires financial support by organizations and not by research funds.

Despite the significant amount of preparation and strategies to facilitate the uptake of EST, changing practice is not an easy task. Introducing multiple adaptations in a model of care that crosses both hospital and community settings at a time when substantial changes to the Ontario healthcare system may have limited the impact of this implementation project. However, the lessons learned from this very realistic initiative are invaluable and should shape other knowledge mobilization projects in the future.
5.5. References


36. Bishop TF, Press MJ, Mendelsohn JL, Casalino LP. Electronic communication improves access, but barriers to its widespread adoption remain. Health Aff.


### Table 7: Teaming structure summarizing roles and responsibilities

<table>
<thead>
<tr>
<th>Committee</th>
<th>Purpose</th>
<th>Members</th>
</tr>
</thead>
</table>
| Research    | Provide support and guidance to the principal investigator and research team on research-related components of the initiative including ethics, funding, agreements, data collection and analysis, study deliverables, and issues or challenges that are encountered. | • Principal investigator  
• Co-investigators  
• Research team                                                                                                                               |
| Implementation | Provide operational level advice and support to the principal investigator and research team to implement and improve the delivery of E-Stim in the local community.                                      | • Principal Investigator  
• A research team member  
• Local community and hospital providers (nurses, enterostomal therapy nurses, physical therapists, occupational therapists)  
• Clinical lead of the South West Regional Wound Care Program  
• SCI consumer  
• SCI-Ontario social worker                                                                                                                     |
| Executive   | Provide project oversight, ensuring that the principal investigator has the advice and input needed to move the project forward, and meet the deliverables in support of knowledge translation to successfully implement E-Stim locally and nationally. | • Principal Investigator  
• Co-Investigators  
• A research team member  
• Program coordinators from Parkwood Institute  
• SW-CCAC client service manager                                                                                                                 |
| Advisory Council  | Provide guidance to the Principal Investigator and Executive Committee to promote broader stakeholder awareness, and recommend and support knowledge mobilization activities to facilitate local sustainability and implementation of E-Stim at a national level. | • 15 researchers and clinicians across Canada                                                                                                    |
Table 8: Number of patients screened for E-Stim

<table>
<thead>
<tr>
<th>Reasons for Ineligibility</th>
<th>PDSA cycle</th>
<th>Total patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone Screen</td>
<td>1 2 3 4 5</td>
<td>6 8 19 16 6 55</td>
</tr>
<tr>
<td>Wound already healed/healing well</td>
<td>1 2 0 3 0</td>
<td>6</td>
</tr>
<tr>
<td>No longer wanted to participate</td>
<td>0 0 5 1 0</td>
<td>6</td>
</tr>
<tr>
<td>Did not have a pressure injury</td>
<td>0 0 3 2 0</td>
<td>5</td>
</tr>
<tr>
<td>Under physician care/other treatment</td>
<td>0 0 1 3 0</td>
<td>4</td>
</tr>
<tr>
<td>Osteomyelitis (suspected/diagnosed)</td>
<td>0 0 0 0 1</td>
<td>1</td>
</tr>
<tr>
<td>Does not speak English</td>
<td>1 0 0 0 0</td>
<td>1</td>
</tr>
<tr>
<td>Palliative</td>
<td>0 0 1 0 0</td>
<td>1</td>
</tr>
<tr>
<td>In-Home Assessment by Research Clinician</td>
<td>4 6 9 7 5</td>
<td>31</td>
</tr>
<tr>
<td>Patient deemed not eligible</td>
<td>1 2 6 3 0</td>
<td>12</td>
</tr>
<tr>
<td>Enrolled: Assessed by PICS only</td>
<td>2 0 0 0 1</td>
<td>3</td>
</tr>
<tr>
<td>Enrolled: Received EST</td>
<td>1 4 3 4 4</td>
<td>16</td>
</tr>
<tr>
<td>Reasons why EST was not appropriate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteomyelitis (suspected/diagnosed)</td>
<td>1 1 2 3 0</td>
<td>7</td>
</tr>
<tr>
<td>Patient medically unstable/ill</td>
<td>1 1 0 0 0</td>
<td>2</td>
</tr>
<tr>
<td>Pressure injury healed</td>
<td>1 0 1 0 1</td>
<td>3</td>
</tr>
<tr>
<td>Not a pressure injury</td>
<td>0 0 2 0 0</td>
<td>2</td>
</tr>
<tr>
<td>No longer wants to participate</td>
<td>0 0 1 0 0</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 9: Implementation efforts associated with electronic platform

<table>
<thead>
<tr>
<th>ELECTRONIC PLATFORM</th>
<th>Attempted Solution</th>
<th>Successful?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Issue</td>
<td>Solution</td>
</tr>
<tr>
<td>1</td>
<td>CHAYA not available</td>
<td>Telephone communication, Faxing of forms, Paper-based health record</td>
</tr>
<tr>
<td>2</td>
<td>CHAYA not available</td>
<td></td>
</tr>
<tr>
<td>3, 4 &amp; 5 (CHAYA initiated)</td>
<td>CCAC policy restricted care coordinator from using CHAYA</td>
<td>No solution – outside sphere of influence, Needed to use existing system (i.e. teleconference, faxes, forms)</td>
</tr>
<tr>
<td></td>
<td>Patients and health care providers not using CHAYA</td>
<td>No solution – outside sphere of influence</td>
</tr>
<tr>
<td></td>
<td>Glitches in the system</td>
<td>Research team and CHAYA IT support, Step-by-step guides, In-person training</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Table 10: Implementation efforts associated with a specialized interdisciplinary service

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Issue</th>
<th>Attempted Solution</th>
<th>Successful?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lack of time</td>
<td>• Dedicated time provided for the initiative</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• Team members were dealing with their regular work schedule as well study patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Understanding consultative role</td>
<td>• Document that clarified role</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• Difficulties transitioning from outpatient/inpatient service</td>
<td>• Facilitated several discussions with PICS to clarify team objectives</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Understanding role of patient lead</td>
<td>• Document that clarified role</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• Increased responsibility for the patient lead</td>
<td>• Step-by-step guide outlining the process and responsibilities of patient lead</td>
<td>X</td>
</tr>
<tr>
<td>2</td>
<td>Communication with community counterparts</td>
<td>• Patient lead responsible for connecting with CCAC to identify community care providers</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• Traditional means of communication (i.e. faxing and teleconferences) were not inefficient and ineffective</td>
<td>• Rule of engagement document created – what can and cannot be said in front of the patient</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Initial 15 minutes of the care conference without the patient to discuss treatment plan</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Treatment form revised to be more community friendly</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• CHAYA implemented</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sent out contact sheet with recommendations</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Long Travel Time</td>
<td>• Assessment performed over the phone with community provider available in patient’s home</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• Prevented in person assessment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 3, 4 & 5 | Team Turnover  
• Due to lack of time and alternative job opportunities | Program coordinator explored different team configurations | X |
<table>
<thead>
<tr>
<th>Cycle</th>
<th>Issue</th>
<th>Solution</th>
<th>Successful?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lack of appropriate referrals</td>
<td>• Expanded geographical area to included all SW-CCAC region (not just London) and sitting acquired pressure injury</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Limited wound care knowledge and expertise</td>
<td>• Bed side training</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• Generalist lack experience in wound care (i.e. identifying wound deterioration after infection, awareness of expected healing time, recognizing common wound etiologies)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Generalist have difficulty addressing complexity and severity of illness</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inappropriate patients identified screening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Lack of appropriate referrals</td>
<td>• Created newsletter to update community on study</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• In-person educational workshops</td>
<td>• Online educational course and 1-day hands on training session</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Limited EST knowledge and education</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Many providers unaware of EST or use EST as last resort</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low attendance rate at Implementation Committee</td>
<td>• Scheduled meetings months in advance</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• Unable to engage some community service providers</td>
<td>• Weekly reminders</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>• Passive participation of committee members</td>
<td>• Had the committee involved in creating the agenda</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Meetings notes were created to be actionable</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Not all community agencies represented</td>
<td>Focus on 4-5 members who were keen to participate</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------</td>
<td>-------------------------------------------------</td>
<td>---</td>
</tr>
</tbody>
</table>
| 3 | Limited community based wound care experts  
• There is a lack of providers with wound care expertise working in the community | No solution – outside of sphere of influence |   |
|   | Lack of appropriate referrals | Online educational resources | X |
|   | High turnover rate of ETs | Created EST Consultant List on CCAC website | X |
| 4 | Lack of appropriate referrals | Online educational resources | X |
Table 12: Implementation efforts associated with administration of EST

<table>
<thead>
<tr>
<th>FACILITATIVE ADMINISTRATION OF EST</th>
<th>Solution</th>
<th>Successful?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cycle</strong></td>
<td><strong>Issue</strong></td>
<td><strong>Solution</strong></td>
</tr>
<tr>
<td>1</td>
<td>Long Process</td>
<td>· Initiate EST earlier (before appointment with specialized interdisciplinary service could be scheduled)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Process of ordering and returning EST equipment</td>
<td>· Emailing form to community nurse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>· Regular training and support for care coordinators by CCAC care manager</td>
</tr>
<tr>
<td></td>
<td></td>
<td>· Regular meetings between research team and CCAC care manager</td>
</tr>
<tr>
<td></td>
<td></td>
<td>· Continued revision of model of care</td>
</tr>
<tr>
<td></td>
<td></td>
<td>· Created standardized order forms</td>
</tr>
<tr>
<td></td>
<td>Process of ordering and returning EST equipment</td>
<td>· End of study letter to patients that states how to return the equipment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>· Research team provided EST equipment until order was filled</td>
</tr>
<tr>
<td></td>
<td></td>
<td>· CCAC moved form for easier access under their portal</td>
</tr>
<tr>
<td>4</td>
<td>EST Equipment Change</td>
<td>· Form changed to include new equipment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>· New machine was supplied by vendor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>· Patient, family, and providers were retrained in new machine</td>
</tr>
</tbody>
</table>
Figure 6: Diagram of procedures from exploration to initial implementation process
I am satisfied with the clinical care I received.
I am satisfied with how the care team communicated with me and with one another.
Communication across team members occurred in a timely and efficient manner.

My care plan was delivered in a timely and efficient manner.
EST and other treatments were delivered as promised.
I would recommend this program to other people with ulcers.
EST and other treatments were delivered as promised.

Figure 7: Patient’s perspective on a) electronic platform; b) communication amongst their care team; and c) the facilitative administration of EST
Chapter 6

6 Discussion

The overall purpose of this thesis was to develop and field test an intervention that incorporates the application of best practices including electrical stimulation therapy (EST) for community dwelling individuals with spinal cord injury (SCI). In Chapter 2, the impact of pressure injuries on the SCI population was evaluated. Chapters 3 and 4 outlines the preparation that was undertaken to support the implementation process, while Chapter 5 evaluates the initial implementation of pressure injury best practices and EST in the local community.

In Chapter 2, pressure injuries were found to have a profound influence on the ability to participate in ADLs and recreational activities, QOL, and health care utilization. Given these findings, its concerning that appropriate skin and wound management services are not consistent across Canada. According to the Environmental Scan Atlas\(^1\), which provides an overview of the current Canadian SCI rehabilitation landscape, the extent of pressure injury care services provided across Canada ranges considerably from the wide spectrum of treatments to the diverse multidisciplinary team make-up. There seems to be a disconnect between the published guidelines\(^2\) and current pressure injury management approaches. Therefore, it became evident that an adaptable program using evidence-based practice needed to be created to improve the quality of care for this population. Due to strong EST evidence\(^3\) and the significant impact that pressure injuries have on community dwelling individuals living in Canada, there was a need to develop a pressure injury management plan involving EST to implement into practice.

In Chapter 3 and 4, a model of care and process map were developed based on the barriers and facilitators identified by key stakeholders. The success of the model of care and process map was contingent on continued communication between hospital and community providers. The Ontario health care system is extremely fragmented; acute care hospitals, rehabilitation hospitals, home and community care, and primary care are disconnected and work in their individual silos. There is little to no interorganizational
communication making it difficult for health services to be planned and delivered as intended. The fragmented system affects patient health outcomes and experiences, and waste a significant amount of resources.\(^4\)

In study 4 (Chapter 5), multiple attempts were made to improve the coordinated care and communication between organizations, but the issues were too great for us to make an immediate impact. Changes that scan across hospital and community care need to be administered at the provincial level. Now knowing the significant communication barriers that exist between hospital and community settings and providers, the model of care developed in 2014 and 2015 (Chapter 3 and 4) now seems complex and unrealistic. Upon reflection, alternative models could have been studied including a possible outreach program or a specialized team developed within the community rather than a regional rehabilitation hospital.

In Chapter 5, the delivery of community based care, including pressure injury management, was and still is currently being overhauled in Ontario. Under the new community service structure lead by the LHIN, change in how community care is coordinated is inevitable. The experiences and lessons learned from this knowledge translation initiative could be extremely informative as new leaders and decision makers formulate alternative policies and procedures over the next few years.

### 6.1 Future Directions

In summary, the four studies in this dissertation provide a comprehensive representation of the importance of promoting best practices, like EST, to manage pressure injury in community dwelling individuals with SCI, and the significant effort required not only by the research team but also the involving organizations to implement the therapy and promote its use. Although additional work is still warranted to establish EST in the local environment, the findings from this study provide valuable insight for future initiatives. The research team organized a meeting in conjunction with the National SCI Conference in November 2017 with key researchers and clinicians across Canada interested in pressure injury management and EST. The findings and lessons learned through this local
implementation initiative were shared, and strategies to overcome challenges to implementing pressure injury best practices across the country were discussed. Currently 10 new sites located across Canada are actively implementing EST. By continuing the discussions on the impact of pressure injuries on the Canadian population, we hope that it encourages the Ministry of Health to enforce changes to its policy in managing wounds.
6.2 References


Chapter 7

7 Appendix

7.1 Appendix A: Reprint approval from Archives of Physical Medicine and Rehabilitation

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Best of luck with your thesis and best regards,

Laura

Laura Stingelin
7.2 Appendix B: Reprint Approval from Topics in Spinal Cord Injury

Re: Permission to Use Copyrighted Material in a Doctoral Thesis

To: Derua Lala

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Thank you for your inquiry. You have permission to reproduce TSCIR 22(4):277-287 in your thesis. Please include the url, scijournal.com, in the attribution and provide us a link to the final posting.

Regards,

Mary

Mary Killion
7.3 Appendix C: Reprint Approval from Rehabilitation Process and Outcomes

Dear Deena Lala,

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If you have any questions, or if we may be of further assistance, please let us know.

Best regards,

Craig Myles
on behalf of SAGE Ltd. Permissions Team
7.4 Appendix D: University of Western Ethics Approval Notice

Western University Health Science Research Ethics Board
HSREB Annual Continuing Ethics Approval Notice

Date: February 03, 2017
Principal Investigator: Dr. Pamela Houghton
Department & Institution: Health Sciences/Health & Rehabilitation Sciences, Western University

Review Type: Full Board
HSREB File Number: 106157
Study Title: Best Practice Implementation of Electrical Stimulation Therapy for Healing Pressure Ulcers in Community Dwelling Persons with Spinal Cord Injury
Sponsor: Rick Hansen Foundation

HSREB Renewal Due Date & HSREB Expiry Date:
Renewal Due -2018/02/28
Expiry Date -2018/03/27

The Western University Health Science Research Ethics Board (HSREB) has reviewed the Continuing Ethics Review (CER) Form and is re-issuing approval for the above noted study.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH E6 R1), the Ontario Freedom of Information and Protection of Privacy Act (FIPPA, 1990), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Ethics Officer, on behalf of Dr. Joseph Gilbert, HSREB Chair
EO: Erika Basile, Nicole Kaniki, Grace Kelly, Katelyn Harris, Nicola Morphet, Karen Gopaul
PARTICIPANT
LETTER OF INFORMATION

Title of the study: Best Practice Implementation of Electrical Stimulation Therapy for Healing Pressure Ulcers in Community Dwelling Individuals with Spinal Cord Injury
Primary Investigator: Pamela Houghton, PT, PhD
Co-Investigators: Dalton Wolfe, PhD; Deena Lala, MSc; Anna Kras-Dupuis, CNS; Patrick Potter, MD; Eldon Loh, MD; Lyndsay Orr, PT, MCiSc; Jacqueline Marsh, PhD; Melissa MacKay, BSc

Sponsors: Rick Hansen Institute

You are being invited to participate in a research study because you have a condition that limits your mobility and/or requires you to use a wheelchair, and you are currently experiencing a pressure ulcer. To decide whether or not you want to take part in this research study, you should understand what is involved. This form will provide you detailed information about the research study, which will also be discussed with you in person. Once you understand the study, you will be asked to sign the form at the end of this information letter if you wish to participate.

PURPOSE OF THIS STUDY
Pressure ulcers are one of the most common secondary health complications among individuals who have a condition that makes it difficult to walk. When skin breakdown occurs, it limits people’s ability to participate in activities and increases the time they spend in bed, leading to decreases in quality of life.

Many guidelines recommend the use of electrical stimulation therapy (EST) to promote the closure of pressures ulcers. EST is a therapy used alongside standard wound care that mimics the natural electrical current of the skin to stimulate the wound healing process. However, due to limited knowledge and experience with EST, very few care providers in the community provide this therapy.

The purpose of this study is to determine whether we can successfully develop a program that includes EST to improve the healing of pressure ulcers in individuals who have a condition that makes it difficult to walk.

WHAT WILL BE ASKED OF YOU IF YOU PARTICIPATE
If you agree to participate in this study, you will participate in the following:

1. Pre-assessment: A preliminary screening assessment will be conducted in order to determine if you are eligible for this study. To gather this information, you will be provided a unique user name and password for a private and secure website to
complete the pre-assessment form related to your current and past medical history. If you are unable/unwilling to complete the pre-assessment online, this information can be gathered using a short phone interview with the project coordinator.

2. A researcher and/or qualified clinician will arrange a visit in your home where he/she will review the medical history form that you completed and perform a wound assessment. Alternatively, an assessment can be performed in Dr. Houghton’s research facilities at Western, London, Ontario. We will take a photo of the wound and surrounding skin. This image will assist in documenting changes in the wound status and lends important information about how well the wound treatment is working. When taking these visual images of the wound, a measuring ruler with your patient ID number and the date will be included and the image will focus only on the area of the skin affected by the ulcer. Neither your name nor any information that might reveal your identity will be contained in the wound photograph. You may request at any time to have the photographs destroyed.

3. Assessment: You may also undergo a comprehensive assessment by other health care professionals such as a physician, registered nurse, physical therapist, occupational therapists, social worker, and registered dietician. The assessment will include reviewing any existing medical concerns, whether EST treatment for your wound is right for you, and identifying factors that may be contributing to delayed wound healing.

4. Care plan: A conference call will be set up between health care providers who were involved with your assessment, the study participant, and any other members of the participants care team in the community (including family members, attendant services, and community care providers), and any relevant researchers. The care team will work with you to develop a personal care plan that addresses factors that are preventing wound healing such as pressure produced by activities or equipment used throughout the day, your diet, or any unresolved medical conditions.

5. EST treatment: Your wound care plan may include EST. EST is a therapy used to deliver electrical current at low levels directly to the wound using specialized electrodes and equipment, which will be provided to you at no cost. A trained person, which may be yourself and/or chosen caregiver, will apply EST to the wound for 30-90 minutes at least 5 times a week. There is a possibility that EST may not be suitable for you; in this case, you will still be provided a customized pressure ulcer treatment plan and educational resources that are based on Canadian best practice guidelines.

6. Community follow-up: You will be followed for at least 3 months by members of the research team and associated care providers which may include personal support workers, care attendants, family members, nurses, physical and occupational therapists, dietician, and psychologist or social workers.

7. Over the course of this study, you will be able to access educational resources and learn as much as you want about pressure ulcer care and electrical stimulation therapy.

8. An evaluation of costs associated with your health care will occur by tracking your equipment and health care services over the study period. This will be compared to costs associated with your pressure ulcer care prior to study enrolment. This will involve completing a cost diary and quality of life questionnaire (called EQ-5D-5L) at the beginning of the study, monthly until the ulcer heals, or 1 year, or until study completion, whichever comes first. We may also need to check your health records to accurately estimate costs associated with your health care.

9. You will be asked to complete a survey by phone or on the electronic platform to describe your experiences with the program. You may elect to complete this survey and
questionnaire on hardcopy. If this is the case, the researchers will mail you a copy with a stamped envelope included so you can mail the survey back to us.

If you feel uncomfortable using an electronic system to store your medical information, you can choose to complete the pre-assessment forms and research surveys using hardcopy.

**STUDY TECHNOLOGY**

Multiple electronic systems are commonly used by health care professionals and community agencies to store patient information and order medical tests. Unfortunately, not all of these systems are linked or allow all users access. CHAYA is a web-based platform that allows for patients and care providers at Parkwood Institute and in the community to share medical information and communicate using a single system. CHAYA will also provide you access to current resources that provide information and helpful hints about recommended best practices in the area of pressure ulcer care. There is also information about why, when and how to apply electrical stimulation therapy. For this study, you will have access to this educational site using your existing home computer and Internet connection. If you do not have a computer, you will be provided a tablet or laptop. CHAYA can be launched directly from an Internet browser and you may login to your profile using a secure username and password.

All electronic personal health information (ePHI) such as name, address and email are encrypted according to the Advanced Encryption Standard. CHAYA uses a secure socket layer (SSL), which means that all the data sent through the system is encrypted to protect the privacy and confidentiality of your information. Users who attempt to access data, for which they do not have approved access, will be denied and their attempts will be logged and flagged.

Individuals who will have access to your ePHI include members of your care team including providers at Parkwood Institute and in the community, and relevant members of the research team. The feedback you provide in surveys and questionnaires will be shared with members of the implementation committee, the investigators and their research team. However, this information will not be linked to your personal information (i.e. name). You will be assigned a unique ID when you login to the password protected site and answers to the surveys and questions will be summarized and collated to reduce the chances that your comments will be identified.

There will be many times in this study where the researchers will need to contact you. If you prefer, we ask that you provide us your email address. Researchers will only email you to schedule appointments and send reminders to complete study forms. Sensitive personal or health information will be not be communicated through e-mail.

**POSSIBLE RISKS**

There are potential discomforts associated with wound care (e.g. pain associated with dressing changes and debridement). However, these are standard clinical practices in wound care. There are also risks associated with the use of EST, but they are minimal. Potential risks include skin irritation (i.e. redness, and itchiness) under the electrodes, pain, infection or further breakdown of the wound, and electric shock or surge if the EST device fails. You may also be asked to get a blood test to assess your nutrition. Possible side effects include pain and bruising at the site of the needle hole. Bleeding and infection may also occur, but these complications are very rare.
There is also the potential to encounter technical difficulties when using CHAYA. In such case, technical support will be available.

If you agree to e-mail communication, you need to understand the risks of using e-mail. The security of e-mail is not guaranteed. Messages sent to, or from, researchers may be seen by others using the Internet and e-mail can be accidently forwarded.

**BENEFITS**
There are possible benefits for participating in this study. You will receive a full work up of your wound and a specific care plan by an interdisciplinary team who have advanced training in wound care and EST treatment. You will also receive timely access to care providers in the community, equipment and supplies (e.g. EST). During this study, you will have access to resources that may contribute to your understanding of pressure ulcers and EST. In addition, the information collected will help identify the barriers and facilitators of this program. This information will be essential for the development of future programs that incorporate EST for managing pressure ulcers, and improve access to health care services for individuals with SCI.

**CONFIDENTIALITY**
All information that is obtained during this study and that can be used to identify you will remain confidential. Electronic data (including name, email, and survey data) stored in CHAYA will be encrypted and stored on a secure server at Lawson. Your information will be sent to Lawson directly from your home computer or tablet through a secure network. To ensure privacy of your data, do not share your username and password with anyone that should not have this information. The network is managed by an outside company who may occasionally need to perform maintenance and troubleshoot problems with the online network; however, your personal health information is completely encrypted and will not disclose any information to them.

Written data will be securely stored in a locked cabinet in a secure office and personal information will be saved on a password-protected computer in the research lab.

If the results are published, your name will not be used, and no information that discloses your identity will be released or published without your specific consent to the disclosure.

Representatives of the Western University Health Sciences Research Ethics Board may contact you or require access to your study related records to monitor the conduct of the study.

**WILL I BE PAID TO PARTICIPATE IN THIS STUDY?**
You will not be compensated for your participation in this study. However, any travel or other expense you incur as a result of participating in this study will be reimbursed.

**VOLUNTARY PARTICIPATION**
Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. If you choose to not participate in this study, you will continue to receive usual care or your current care regimen. At the time of withdrawing from the study, we will ask you to briefly provide your reasons for leaving the program. You do not have to provide this feedback. In addition, you will
have the decision to remove or allow your data to continue to be used for research purposes. If you allow the researchers to use your data, that data will remain with the research team.

**QUESTIONS OR CONCERNS?**
If you have questions about the research now or later, please feel free to contact the following:

Melissa MacKay  
Project Coordinator

Pamela Houghton  
Principal Investigator

This study has been reviewed and received ethics clearance from the Research Ethics Board at the Western University and from Lawson Clinical Research Impact Committee at Parkwood Institute. If you have any questions regarding your rights as a participant of this study, you may contact one of the following.

The Office of Research Ethics  
Western University  
519-661-3036
Title of the study: Best Practice Implementation of Electrical Stimulation Therapy for Healing Pressure Ulcers in Community Dwelling Individuals with Spinal Cord Injury

Primary Investigator: Pamela Houghton, PT, PhD

Co-Investigators: Dalton Wolfe, PhD; Deena Lala, MSc; Anna Kras-Dupuis, CNS; Patrick Potter, MD; Eldon Loh, MD; Lyndsay Orr, PT, MCISc; Jacqueline Marsh, PhD; Melissa MacKay, BSc

Sponsors: Rick Hansen Institute

☐ I have read the letter of information thoroughly. I have had the opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study.

☐ I agree to allow wound photographs to be obtained by my wound care team and used for the purpose of documenting changes in my wound.

☐ I prefer the researchers contact me through email to schedule appointments and send reminders. My email address is: ________________________________

Participant Name (Print)

___________________________                         _____________________________

Participant Signature                     Date (MM/DD/YYYY)

If verbal consent is obtained in lieu of a signature, the person obtaining consent will initial here:

_____ 

I confirm that I have explained the nature and purpose of this study to the participant named above.
I have answered all questions.

_______________________________

Person Obtaining Consent Name (Print)

_______________________________                     _____________________________

Person Obtaining Consent                     Date (MM/DD/YYYY)

Copy of Study Results
I would like a copy of the study results: ☐ Yes ☐ No
If yes, please write your mailing address below.

____________________________________________________________________________
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You are being invited to complete a survey because you are a healthcare provider or caregiver that has been involved in the implementation of electrical stimulation therapy (EST) for managing pressure ulcers in individuals who have limited mobility. To decide whether or not you want to take part in the survey, it is important that you understand what is involved. This letter of information will provide you with detailed information about the research study and what your involvement would entail.

If you decide to participate, please complete the survey attached. Your completion of this survey indicates your consent to participate in this research study.

WHAT WILL BE ASKED OF YOU IF YOU PARTICIPATE
You will be invited to provide feedback about your experiences providing best practices to people living with spinal cord injury and pressure ulcers, including the use of EST. You will be asked to share your experiences including barriers that were encountered and possible solutions.

POSSIBLE RISK AND HARMs
There are no anticipated risks or potential discomfort related to your completion of the survey.

POSSIBLE BENEFITS
There are no direct benefits related to your completion of the survey. However, your thoughts and feedback are essential to improving the care we provide to persons with spinal cord injuries and pressure ulcers.

VOLUNTARY PARTICIPATION
Your participation in this survey is completely voluntary. Your decision about whether or not to participate has no effect on your relationship with your employer, any of the researchers, or any
organization associated with the research. You can decline to participate in the survey without penalty.

**WILL I BE PAID TO PARTICIPATE?**
You will be offered a small an honorarium for the time you spend providing this feedback.

**CONFIDENTIALITY**
All surveys will be anonymous – your name or contact information will not be collected or recorded on the survey. Paper-based survey data will be securely stored in a locked cabinet in a secure office and electronic data will be saved on a password-protected laptop. Only the research team will have access to this data. If we want to use a specific quote made by you in a publication, your name or any information that discloses your identity will not be released or published. The recordings and any transcriptions that are created will be destroyed 5 years after the final publication. The tapes will be erased and any transcriptions will be shredded and given to a confidential waste management company for disposal.

Representatives of the Western University Health Sciences Research Ethics Board may contact you or require access to your study related records to monitor the conduct of the study.

**QUESTIONS OR CONCERNS?**
If you have questions about the research in general or about your role in the study, please feel free to contact:

Melissa MacKay  
Project Coordinator

Pamela Houghton  
Principal Investigator

This study has been reviewed and received ethics clearance from the Research Ethics Board at the Western University and from Lawson Clinical Research Impact Committee at Parkwood Hospital. If you have any questions regarding your rights as a participant of this study, you may contact one of the following.

The Office of Research Ethics  
Western University  
519-661-3036  
ethics@uwo.ca
7.7 Appendix G: Curriculum Vitae

**EDUCATION:**

2013 to Present  
Masters of Physical Therapy/Doctoral of Philosophy (MPT/PhD)  
University of Western Ontario, London, ON

2009 to 2011  
Masters of Science (M.Sc.)  
University of Waterloo, Waterloo, ON

2005 to 2009  
Bachelor of Science in Kinesiology, Honours  
McMaster University, Hamilton, ON

**RESEARCH EXPERIENCE:**

Research Associate  
*Toronto Rehabilitation Institute, Lyndhurst Centre, Toronto, ON*

**GUEST LECTURER:**

1. **Bone Physiology and Osteoporosis**  
Health/Gerontology 400  
*Class Professor: Nancy Pearce*  
Feb. 11 2010

2. **Bone Physiology and Osteoporosis**  
Health/Kinesiology 210  
*Class Professor: John Mielke*  
Mar. 24 2010

**TEACHING ASSISTANT**

Jan. 2014 to Apr. 2014  
Practice in Context II, OT9642X, Western University.

**PEER REVIEWED PUBLICATIONS:**

1. Lala D, Houghton PE, Holyoke P, Wolfe DL. *Using a modified ADAPTE process to enable effective implementation of electrical stimulation therapy for treating pressure ulcers in persons with spinal cord injury.* Rehabilitation Process and Outcome 2017;6: https://doi.org/10.1177/1179572717745836


3. Lala D, Spaulding SJ, Burke SM, Houghton PE. *Electrical stimulation for the treatment of pressure ulcers among individuals with spinal cord injury: a*


OTHER PUBLICATIONS


BOOK CHAPTERS


PUBLISHED ABSTRACTS


CONFERENCE PRESENTATIONS:


3. **Lala D, Dumont FS, LeBlond J, Houghton PE, Noreau L. The impact of pressure ulcers on individuals living with a spinal cord injury.** Canadian Association of Wound Care, Toronto, ON, Oct 30-Nov 2, 2014 (*Poster and Oral Presentation*).

4. **Lala D. Spaulding SJ, Burke SM, Houghton PE. Electrical stimulation for the treatment of pressure ulcers among individuals with spinal cord injury: a systematic review and meta-analysis.** Canadian Association of Wound Care, Toronto, ON, Oct 30-Nov 2, 2014 (*Poster and Oral Presentation*).


6. **Lala D, Dumont FS, LeBlond J, Houghton PE, Noreau L. The impact of pressure ulcers on individuals living with a spinal cord injury.** Aging, Rehabilitation and Geriatric Care (ARGC) of the Lawson Health Research Institute, Western University, London, ON February 7th, 2014 (*Poster Presentation*)


Research Day. Toronto Rehabilitation Institute, November 26th 2010. *(Poster Presentation and One-Minute Madness)*


**GRANTS**

2015-2017  **Best practice implementation of electrical stimulation for healing pressure ulcers in community dwelling persons with spinal cord injury**
Rick Hansen Institute, Co-Investigator (Grant# G2015-34, $300,000)

2014-2015  **Implementing best practices for pressure ulcer treatment in community dwelling adults with spinal cord injury**
St. Joseph’s Healthcare London Foundation, Principal Investigator (Grant# 078-1314, $10,451)

**SCHOLARSHIPS**

2017-2018  Ontario Graduate Scholarship ($15,000), Western University
2016-2017  Ontario Graduate Scholarship ($15,000), Western University
2015-2016  The Siskinds Studentship in Spinal Cord Injury ($10,700)
2015-2016  Ontario Graduate Scholarship ($15,000), Western University
2014-2015  Ontario Graduate Scholarship ($15,000), Western University
2009-2011  Ontario Neurotrauma Foundation Grant #2009-SCI-MA-684 ($46,000)
2005    Entrance Scholarship ($1000), McMaster University
2005    Queen Elizabeth II: Aiming for the Top Scholarship ($3500)

**HONOURS AND AWARDS:**

2016    HRS Graduate Student Conference Award, Western University ($400)
2016    FHS Graduate Student Conference Award, Western University ($300)
2015    Ontario Spinal Cord Injury Research Network Travel Stipend ($100)
2014    Society of Graduate Students (SOGS) Travel Subsidy ($500)
2014    FHS Graduate Student Conference Award, Western University ($400)
2011    Toronto Rehab Team Excellence Award ($500)
2010    Research Travel Assistantship from University of Waterloo ($600)
2007-2009  Dean’s Honours List
2007    Golden Key International Honour Society Member: McMaster Chapter