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Electrical Stimulation for Treating Pressure Injuries: Evaluation of a Knowledge Mobilization Project

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Abstract

Pressure ulcers (PrU) are a secondary health complication that cause increased morbidity, mortality and decreased quality of life. PrUs have also been shown to have a significant financial burden on the healthcare system. Current best practice guidelines strongly recommend the use of electrical stimulation (E-Stim) to increase healing rates of PrUs. Unfortunately, there has been lack of uptake for the use of E-Stim in clinical practice. To address this gap in practice, a knowledge mobilization project called the E-Stim Collaboration Project was developed. The aim of this dissertation was to 1) determine if an education program can change knowledge, attitudes and practice (KAP) in a variety of health care providers providing care to people with PrUs, 2) the cost effectiveness of E-Stim, and 3) estimate the cost of PrU treatment in community dwelling individuals. Chapter 2 outlines an education program that was developed for health care providers (n=83) to determine whether KAP can be improved for the use of E-Stim in individuals with chronic wounds. Knowledge and attitudes were found to be significantly increased after the education program, certain attitudes changed after a hands-on workshop, however practice change only occurred in 39% of participants. Chapter 3 evaluates the cost effectiveness of E-Stim using decision analytic modelling to determine the cost per quality-adjusted life year (QALY). The model results showed that E-Stim is a cost-effective treatment for this patient population especially when compared to a more commonly used advanced wound therapy called negative pressure wound therapy. In Chapters 4 and 5, the cost of living in the community with a PrU is estimated from a health care and societal perspective using current PrU treatment methods and showed an average cost of $8247.48 per month which can be as high as $37,873.65 per month when a person develops osteomyelitis in the bone underlying their PrU. Health care costs spent to date on the 22 study participants who had their PrU for an average of 21.2 months was approximately $3,846,624.50. Using advanced wound therapies such as E-Stim are known to speed healing and avoid complications is warranted and cost effective.

Keywords

Pressure Ulcers, Electrical Stimulation, Education, Cost, Cost Analysis

Co-Authorship Statement

This thesis work was performed under the supervision of Dr. Pamela E. Houghton and advisory committee members Dr. Jacquelyn Marsh and Dr. Eldon Loh. This thesis was part of a large, multi-disciplinary and multi-sector knowledge mobilization project called the E-Stim Collaboration Project which took place in the South West LHIN. The role of the 1st author in the E-Stim Collaboration Project included clinical lead, educational lead and evaluation of cost effectiveness.

The clinical lead role included meeting at the participants home for an initial assessment which included a comprehensive wound assessment and a cost diary. Re-assessment would occur on a monthly basis or sooner if required. The educational lead role included the development of an educational framework which is described in chapter 2, as well as providing bedside education for nurses and physiotherapists in the community providing E-Stim to participants in the E-Stim collaboration project. The evaluation of cost-effectiveness was completed utilizing modeling and evaluation of the cost diary which are outlined in chapters 3, 4, and 5.

Chapter 2

Co-authors for this chapter include Dr. Pamela E. Houghton, Dr. P. Holyoke and Deena Lala PhD(c). The role of the 1st author for this chapter included assisting in the development of the educational online modules and testing materials, submission to ethics, delivery of the hands-on education, analysis of participant data and writing of the manuscript.

Chapter 3

Co-author for this chapter is Dr. Pamela E. Houghton. The role of 1st author was to complete the cost evaluation utilizing data collected in chapter 4 and to write the manuscript.

Chapter 4

Co-author for this chapter is Dr. Pamela E. Houghton. The role of 1st author was collection of participant cost data for the E-Stim Collaboration Project, synthesis and evaluation of the data as well as writing the manuscript.

Chapter 5

Co-author for this chapter is Dr. Pamela E. Houghton. The role of 1st author was collection of participant cost data for the E-Stim Collaboration Project, synthesis and evaluation of the data as well as writing the manuscript.

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Dedication

Thank you to my parents; Mom and Dad, Gwen and Bill, for all your help to make this happen. To my children, Billy and Lauryn, for their patience over the past 4 years.

I dedicate this work to my best friend and husband, Nathan Orr. None of this would be possible without you.

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List of Abbreviations

ADL	Activities of Daily Living
APuP	Attitude towards Pressure Ulcer Prevention
CDN	Canadian
CIHI	Canadian Institute for Health Information
DAM	Decision Analytic Model
DSA	Deterministic Sensitivity Analysis
DAD	Discharge Abstract Database
E-Stim	Electrical Stimulation
ET	Enterostomal Therapist
EAS	E-Stim Attitude Survey
FP	Family Physician
HCP	Health Care Provider
HRQoL	Health Related Quality of Life
HCC	Home and Community Care
HK	Housekeeping
ICER	Incremental Cost Effectiveness Ratio
ICU	Intensive Care Unit
KAP	Knowledge, Attitude, and Practice
LPN	Licensed Practical Nurse
LHIN	Local Health Integration Network
MRI	Magnetic Resonance Imaging
MOHLTC	Ministry of Health and Long-Term Care
NPUAP	National Pressure Ulcer Advisory Panel

NPWT	Negative Pressure Wound Therapy
NA	Nursing Assistant
OT	Occupational Therapist
OCCI	Ontario Case Costing Initiative
OHTAC	Ontario Health Technology Advisory Committee
OSM	Osteomyelitis
PICC	Peripherally Inserted Central Catheter
PrU	Pressure Ulcer
PT	Physiotherapist
PSW	Personal Support Worker
PUKAT	Pressure Ulcer Knowledge Assessment Tool
PSA	Probabilistic Sensitivity Analysis
QALY	Quality Adjusted Life Year
RD	Registered Dietitian
RN	Registered Nurse
RNAO	Registered Nurses Association of Ontario
SCI	Spinal Cord Injury
SWC	Standard Wound Care
US	United States
WTP	Willingness to Pay

1 Thesis Introduction

The aim of this doctoral research is to improve wound care treatment for patients living in the community with mobility impairment and pressure ulcers (PrU). A PrU is a localized injury to the skin and/or underlying tissue usually over a bony prominence due to pressure, or pressure in combination with shear. The severity and depth of PrUs has been characterized by the National Pressure Ulcer Advisory Panel (NPUAP) using a staging system of I-IV.[1] Stage III and IV PrUs indicate a deeper wound. PrUs are a prevalent secondary health complication for individuals with mobility impairment. In a 2004 Canadian prevalence study, it was reported that 26% of institutionalized patients suffer with a PrU.[2] In a Canadian Institute for Health Information (CIHI) report using the discharge abstract database (DAD), a database which captures clinical information based on physician hospital discharge summaries, the prevalence of PrUs in the community was estimated to be 2.4%. This was assumed to be an underestimate due to lack of reporting.[3] The cost of treating PrUs is also significant. A conservative estimate of annual costs for wound care treatment in Ontario is $1.5 billion with PrUs and surgical wound infections costing each Canadian hospital more than $1 million per year.[4,5] Research has also shown that hospital costs can range from $11,000 to as high as $90 000 for a single PrU.[6] However, these costs are based on administrative databases which are known to be flawed.

Multiple best practice guidelines have been developed to guide clinicians in the management of PrUs. Best practice guidelines utilize a systematic approach to evaluate treatment evidence and assist health care providers in making treatment decisions. International, national, and local best practice guidelines for the treatment of PrUs have made recommendations for the use of advanced therapies to speed the closure of PrUs.[7–9] Advanced therapies is the term used for modalities that are utilized when standard practices may not be adequate for wound healing.[10] The advanced therapy which has the highest level of evidence for the treatment of PrUs is electrical stimulation (E-Stim).[11] E-Stim involves the placement of electrodes in or around a wound to deliver a small current to the wound bed. By delivering this current to the wound, several wound healing

processes are stimulated and optimized. Despite the vast amounts of evidence in the literature supporting the use of E-Stim for PrU healing in multiple best practice guidelines[7-9] there has been lack of uptake for its use in hospitals, long term care or the community.

To address the need for the implementation of E-Stim from "bench to bedside", a knowledge mobilization project called the E-Stim Collaboration Project was initiated. Researchers collaborated with stakeholders from the hospital, long term care, and community sectors to develop resources and pathways to increase the use of E-Stim as an evidence-based intervention for PrU treatment. The aim of the E-Stim Collaboration Project was to develop and sustain a comprehensive approach to delivering E-Stim that could be replicated in different healthcare and community settings across Canada. As part of this multi-year project, several facilitators and barriers were identified during the first phase of the project.[12] Two of the main themes identified as barriers for the uptake of E-Stim included lack of knowledge and education, and concerns about expense (i.e. cost of treatment). The focus of this thesis was to develop and evaluate an educational framework for the implementation of E-Stim, and to analyze the costs associated with living in the community with a PrU as part of the E-Stim Collaboration Project.

The E-Stim Collaboration Project used a model of care that was based on Knowledge to Action (KTA) and National Implementation Research Network (NIRN) frameworks to ensure the facilitation of knowledge translation into practice.[12] This was completed using plan, do, study act (PDSA) cycles to have an informed process for E-Stim implementation. A total of five cycles were completed over a two year and nine month time period. A detailed account of the E-Stim Collaboration Project and its use of knowledge frameworks has been documented in the literature by Lala et al (2018).[13]

1.1 Educational Programs: Pressure Ulcer Prevention

A literature review was conducted to explore educational programs that have been developed and evaluated for PrUs. Gunningberg in 2004 investigated the effect of a PrU prevention program with 20- registered nurses (RNs) from hospital and community settings in Uppsala, Sweden.[14] Knowledge, as well as documentation and prevention

strategies, were assessed immediately before and after an educational program, as well as eight months after attending the educational program. Knowledge was measured using a questionnaire and documentation was evaluated by conducting chart reviews. PrU prevention strategies used by nurses were assessed by interviewing the head nurse before and eight months after the education program to determine nursing change in practice. The educational program delivered by Gunningberg consisted of a multidisciplinary team approach and included 40 hours of lecture and 40 hours of practice. The authors found a significant increase in knowledge about PrU prevention after the educational program. At eight-month follow-up, 55% of the RNs had implemented new routines based on the education they received. Documentation on patient risks and treatment interventions for the prevention of PrUs was still lacking after the program.

Sinclair et al, 2004 assessed the difference in knowledge between RNs and licensed practical nurses (LPNs) immediately after and three months following a PrU prevention workshop.[15] Five hundred, ninety-five RNs and 59LPNs who worked at one of three hospitals in Calgary, Alberta, Canada participated in the study. The researchers assessed change in knowledge using a modified version of the Pressure Ulcer Knowledge Assessment Tool (PUKAT) which included 53items on PrU staging, wound description and risk assessment and prevention.[16] Knowledge was significantly higher after attending the 3.5hr workshop compared to pre-workshop scores. There was a decrease in knowledge in the three months follow up scores in relation to the scores immediately after the workshop. The authors concluded that the education for evidence-based practice in PrU prevention is effective and suggested that ongoing staff education for PrU prevention and treatment is both necessary and important.

Results from prior studies support the need for educational programs to increase knowledge for PrU prevention, however, an increase in knowledge does not always lead to a change in practice.[14,15] In order to further evaluate comprehension of PrU prevention, knowledge, attitude, and practice (KAP) surveys have been utilized to assess individual's behaviour. KAP surveys identify what people know (knowledge), how they feel (attitude) and what they do (practice).[17] Kallman and Suserud (2009) used a questionnaire consisting of 47 items designed to assess RNs and nursing assistants (NAs)

knowledge, attitudes and practices as well as perceived possibilities and barriers regarding PrU prevention.[18] Two hundred and thirty questionnaires were distributed in both community and hospital care settings in the western part of Sweden. Sixty-seven percent of participants responded, and the authors found that nursing staff had a positive attitude regarding PrU prevention. They reported that nurses had a generally good knowledge about prevention and the treatment of pressure injuries, although in terms of practice only 37% (n=55) of the participants said that they have a strategy in place for PrU prevention at their place of work. The authors concluded that given the low number of reported PrU prevention strategies, this may adversely affect the quality of care provided to the patients and lead to PrU development.

Strand and Lindgren in 2010, distributed a questionnaire to assess nurses knowledge, attitudes and perceived barriers and opportunities towards PrU prevention in an intensive care unit (ICU) setting in a Swedish hospital.[19] A total of 315 questionnaires were distributed and 146(46%) were completed and returned for evaluation. PrU staging was correctly made by only 47% of respondents and the authors noted that several respondents did not answer some of the knowledge questions. Perceived barriers to PrU prevention included lack of time for interventions such as turning schedules, and severely ill patients in the ICU setting. Opportunities for knowledge and access to pressure relieving equipment were most commonly reported as facilitators for best practices. The authors concluded that raising knowledge among nursing staff as well as making PrU prevention a priority in daily care is an important organizational challenge in the ICU.

Demarre et al(2011) completed a cross-sectional multi-centre study to evaluate the association between knowledge and attitudes of nurses and nursing assistants, and compliance with PrU prevention guidelines in residents at long term care homes in Belgium.[20] PrU prevention was defined as fully compliant if all preventative measures in bed and when seated were applied, partly compliant if some measures were applied in bed and/or while seated, and no prevention compliance if there was a total absence of any adequate preventative measure. Knowledge and attitude was assessed using a random sample of at least five nurses from 18 participating long-term care wards. The PUKAT and Attitude towards Pressure Ulcers (APuP) instrument were used, both of which have

been validated in the literature.[16,21] One hundred and forty-five nurses and nursing assistants were included, and compliance with the guidelines was evaluated in 615residents. The mean knowledge scores were 29% for nurses and 29% for nursing assistants. The overall attitude score was 75%. The authors concluded that attitudes of nurses and nursing assistants towards pressure injuries were strongly associated with the application of fully compliant PrU prevention guidelines, while knowledge was not.

Cullen-Gill et al in 2013 also used the PUKAT and APuP instruments to evaluate the knowledge and attitudes of fourth-year undergraduate nurses towards PrU prevention.[22] A quantitative cross-sectional survey design of 60 undergraduate nurses revealed that nursing students had an overall positive attitude towards PrU prevention, but a poor knowledge of PrU prevention methods. Simonetti et al(2015) assessed a total of 742 nursing student's knowledge and attitudes on PrU prevention using the PUKAT and APuP in seven Italian nursing schools.[23] The overall knowledge scores were 51% and attitude scores were 77%. The authors found a weak correlation between total knowledge scores and total attitude scores and concluded that their results suggested that positive attitudes toward PrU prevention may contribute to the compliance with clinical practice guidelines in PrU prevention.

Review of the existing literature revealed that PrU prevention educational programs have been well studied; however, there are gaps in terms of PrU treatment educational programs. Research also suggests there may be a disconnect between having the knowledge about what to do and implementing that new knowledge into practice. Based on the findings of the literature review, an educational framework was developed and delivered as part of the E-Stim Collaboration Project and knowledge, attitudes, and practice were measured before and after completing the educational program (see Chapter 2).

1.2 Cost of Pressure Ulcers

To be successful in the implementation of an advanced therapy in the current healthcare climate, knowledge of its use and effectiveness is not enough to influence a change in practice. Costs associated with treatments and how one advanced therapy may be more

cost effective than a comparator is an important factor to influence change. Treatment effectiveness as well as cost benefit through cost analysis is required to engage health care providers, stakeholders and decision makers.

To address the question of costs associated with interventions for the treatment of PrUs, a literature search was conducted for economic analysis evaluations that have been completed on interventions to speed the healing of PrUs. Three systematic reviews were found that have synthesized information on the cost-effectiveness for the treatment of PrUs.[24–26] Tricco et al(2015) sought to elucidate cost-effective treatment strategies for all types of complex wounds.[24] Fifty-nine cost-effectiveness studies were included in the systematic review, with 14 of the included studies evaluating interventions for the treatment of PrUs.[27-40] Of the 14 included studies, 10 evaluated the cost effectiveness of PrU dressings [28-30,32,34-38,41], one evaluated the cost effectiveness of growth factors in PrU healing[31], one evaluated the cost-effectiveness of a specialized nursing intervention program on the healing of PrUs[39], and two evaluated the cost effectiveness of pressure management surfaces on the treatment of PrUs.[27,33] Of these included studies, three interventions were found to be dominant (more effective and less costly)for the treatment of PrUs. The dominant treatments included moisture vapor permeable dressing vs. gauze, advanced dressings vs. gauze, and hydrocolloid vs. gauze.

In 2014 Carter conducted a systematic review of literature that addressed the economic evaluation of guideline-based or strategic interventions for the prevention or treatment of chronic wounds and identified two studies that assessed the cost effectiveness of PrU management.[26] The first study evaluated the cost effectiveness of a PrU dressing[41] and the second evaluated the cost effectiveness of an incentive strategy for the treatment of PrUs.[43] Palfreyman and Stone(2014) completed a systematic review of economic evaluations assessing interventions aimed at preventing or treating PrUs. They found 23 studies for inclusion in the analysis, 11 of which were specific for PrU treatment.[33,35,36,38,41,42,44-48] Eight studies evaluated the cost effectiveness of dressings on PrU management[35,36,38,42,45,46,48], two evaluated the cost effectiveness of pressure managing surfaces for the treatment of PrUs[33,44], and one study evaluated the cost effectiveness of E-Stim for the treatment of PrUs.[47] The majority of the studies had ulcer

healing as the primary outcome measure but one used rate of healing.[36] Conclusions from both systematic reviews were similar reporting that there is a plethora of evidence based best practice guidelines for the treatment of PrUs, however evidence of cost-effectiveness for various interventions is lacking.

In review of the literature, only one cost-effectiveness study for the evaluation of E-Stim for the treatment of PrUs was identified. The study by Mittmann et al, 2011 evaluated the incremental cost-effectiveness of E-Stim plus standard wound care (SWC) versus SWC alone in a spinal cord ulcer population with stage III/IV PrUs in Ontario, Canada from the public payer perspective.[47] A decision analytic model was constructed for a one-year time horizon. Model inputs for the clinical probabilities and direct health system and medical resources were based on a randomized controlled trial of E-Stim plus SWC versus SWC alone.[49] They found that E-Stim plus SWC were associated with better outcomes and lower costs than SWC alone. There was a 16.4% increase in the PrUs healed and a cost saving of $224 at one year. Therefore, E-Stim plus SWC was considered a dominant strategy. Despite this evaluation, E-Stim continues to be underutilized as an advanced therapy for PrU treatment.

This thesis will focus on the education and cost aspects of the E-Stim Collaboration Project, a large, multi-sector knowledge mobilization project conducted in the South West Local Health Integration Network (LHIN). Chapter 2 reports on the evaluation of the educational program developed for health care providers to address the gap of knowledge and awareness for the use of E-Stim for PrU treatment. Chapter 3 is a cost analysis using modelling to compare the advanced therapy of E-Stim to another commonly used advanced therapy; negative pressure wound therapy (NPWT). Chapter 4 estimates the costs of living in the community with a mobility impairment and PrU to establish baseline data prior to intervention. Chapter 5 is a case study estimating the cost of an individual with an SCI and PrU with underlying osteomyelitis.

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2 Evaluation of an Education Program for the use of Electrical Stimulation Therapy to Heal Pressure Ulcers

2.1 Introduction

Pressure ulcers (PrU) are a common complication occurring across all sectors of health care including hospitals, long term care, and home and community care.[1,2] PrUs result in a decreased quality of life[3–5] and increased mortality rates.[6–8] PrUs also cause a large financial burden to the health care system. It has been estimated that PrU care can have a monthly cost of $4,750 CDN for individuals with a spinal cord injury who live in the community, and the hospital cost of a single PrU can range from $11,000 to $90,000 CAN.[9–11] Given the high cost to patients and the health care system, it is imperative that evidence-based interventions are utilized to maximize healing rates in patients with a PrU.

Electrical stimulation (E-Stim) involves applying low levels of electrical current in or around a wound for the purpose of promoting wound closure.[12–15] E-Stim is strongly recommended for the treatment of PrUs and had the highest level of evidence (level 1a)[16] in several national and international best practice guidelines.[17–20] Despite having the highest level of evidence, there has been little uptake for the use of E-Stim in clinical practice. One of the perceived barriers to the implementation of E-Stim is the lack of competency in providing the treatment in the community which is associated with the lack of awareness of E-Stim, lack of knowledge, and lack of training and skill.[21]

Educational programs about PrU prevention have been well studied; however, there is limited information about implementation of treatment programs for PrUs. To date, the impact of educational programs on knowledge, attitudes and practices (KAP) of practitioners have focused on the nursing profession and implementing practices that address pressure ulcer prevention. Additionally, previous studies have evaluated change in knowledge over time, but none of the studies measuring KAP reassessed the effect that an educational intervention had on these attributes.[22–28]

Gunningberg (2004) and Sinclair et al (2004) investigated the effects of a PrU prevention educational program with nurses. Both studies found a significant increase in nurse's knowledge immediately after the educational programs, however the knowledge gained was not sustained when re-evaluated several months later.[22,23] These findings suggest that education on PrU prevention is effective but requires ongoing staff education to ensure continued knowledge. Research has also shown that an increase in knowledge does not always lead to a change in practice. To further evaluate comprehension of PrU prevention, KAP surveys have been developed. KAP surveys identify what people know (knowledge), how they feel (attitude) and what they do (practice).[29] Kallman and Suserud(2009) used a KAP survey and found that nursing staff as a whole had a positive attitude and good knowledge about prevention and the treatment of PrUs; however, results relating to practice were poorer.[24] They concluded that without a change in practice, the quality of care provided to patients may be adversely affected and lead to PrU development.

Strand and Lindgren in 2010 used a questionnaire to assess nurses knowledge, attitudes and perceived barriers and opportunities towards PrU prevention. They found educational opportunities and access to pressure relieving equipment were most commonly reported as ways to improve PrU prevention.[27] Demarre et al(2011) examined the correlation between the knowledge and attitudes of a random sample of RNs and nursing assistants (NAs) working in long term care homes.[30] Knowledge and attitudes were measured using the previously validated Pressure Ulcer Knowledge Assessment Tool (PUKAT) and the Attitude towards Pressure Ulcers (APuP) instruments.[31,32] The mean knowledge scores for RNs and NAs were relatively low (less than 30%) while attitude scores were high (74.5%). The authors concluded that attitudes of RNs and NAs towards PrUs were significantly correlated with the application of PrU prevention guidelines, while knowledge was not. Collectively these studies suggest that positive attitudes toward PrU prevention may contribute to compliance with clinical practice guidelines in PrU prevention more than knowledge scores.

The purpose of this study was to determine if an educational program can change KAP in a variety of health care providers providing care to people with PrUs living at home. Specifically, we set out to identify:

a) Negative attitudes for the use of E-Stim which may impact its clinical use;
b) The outcome of an online educational program on knowledge and attitudes;
c) The outcome of a hands-on workshop on knowledge and attitudes; and
d) If participation in an educational program can translate to a change in practice.

2.2 Setting

The educational program described in this article was developed as part of a multi-year knowledge mobilization project aimed to implement E-Stim for treating pressure injuries in community dwelling individuals with spinal cord injury (SCI) living in one region of Ontario, Canada. Within this region, health care is coordinated by the South West Local Health Integrated Network (South West LHIN) which is funded by the Ministry of Health and Long-Term Care. The South West LHIN provides home care services by contracting several provider agencies that employ nurses, allied health professionals, as well as unregulated support workers. The overall aim of the E-Stim Collaboration Project was to support home care services of the South West LHIN in a way that promoted uptake and use of E-Stim therapy in a sustainable way. This portion of the project will focus on how we addressed the lack of information and training about E-Stim that was identified as a barrier during a pre-implementation environmental scan.[21]

2.3 Methods

The quasi experimental design involved healthcare providers from different disciplines who volunteered to participate in the educational program. Participants' knowledge and attitude was measured at three points: 1) Pre-Education, 2) Post-Online and 3) Post-Workshop. Participants' change in practice was assessed six months after receiving the hands-on education.

2.3.1 Subjects

As part of the E-Stim Collaboration Project, an awareness campaign was conducted to engage providers in all healthcare sectors including the community, homecare, long term care, hospitals and private clinics in the South West LHIN. Multiple agencies with a variety of healthcare providers were visited by a research team member who provided information about the E-Stim Collaboration Project and invited them to participate in the E-Stim Education Program. Participation in the education program was not limited to healthcare providers within the South West LHIN. The South West LHIN home and community care (HCC) providers had access to E-Stim equipment and supplies through previously established vendor contracts.

All the participants who took part in the educational program signed written consent after reading a letter of information. The study was approved by the ethics review committee of Western University Health Science Research Ethics Board of London, Ontario, Canada (HSREB File Number 107778, Appendix 1). Informed written consent was obtained from all participants to share pooled results of completed tests and surveys (Appendix 2). Before beginning the education, demographic information was collected about the participants professional background, education and experience in providing wound care (see Table 1).

Table 1: Participant Demographic Data (n=74)

Profession	**N**	**%**	**Province**	**N**	**%**
Registered Nurse	32	43	Ontario	70	95
Physiotherapist	20	27	Alberta	2	3
Enterostomal Therapist	8	11	Newfoundland	1	1
Occupational Therapist	6	8	Nova Scotia	1	1
Registered Nurse Practitioner	5	7	**Percent of role in wound care**		
Other	2	3	< 25	33	45
Physician	1	1	25-49	22	30
Experience, year			50-74	9	12
0-5	21	28	75-99	8	11
5-10	16	22	100	1	1
10-15	6	8	**Work Hours**		
More than 15	30	41	Full time	58	78
Sector			Part time	14	19
Hospital	41	55	Casual	1	1
Home Care	16	22	Other	1	1
Clinic	5	7	**Level of Wound Education**		
Long Term Care	4	5	In-services	19	26
More than one of above	8	11	1-2-day workshops	23	31
Role in Wound Care			Enterostomal Therapy Certificate	9	12
Direct	50	70	Certificate Program	7	9
Indirect	15	20	Master's level	7	9
Organizational Support	4	5	Other	9	12
None of the above	4	5			

2.3.2 Education Program

An education program for the use of E-Stim on PrUs was developed to address key competencies for skilled application. The education program was delivered in two phases: online modules and a hands-on workshop. The educational program was developed based on prior consultation with key stakeholders who identified perceived facilitators and barriers of implementing E-Stim for PrU healing.[21] Many stakeholders stated that there was lack of awareness, knowledge, training, and skills surrounding the use of E-Stim. The stakeholders expressed a preference for open educational resources that would be freely accessible online and available in print, in addition to hands-on demonstrations on how to use E-Stim.[21]

2.3.3 Online Modules

The modules were completed using a secure online learning platform associated with Western University and were developed to allow participants to review material at their own pace and on their own schedule. Online learning allowed for increased access for participants, and modules could be reviewed as needed. The online modules consisted of background theory and knowledge using narrated PowerPoint presentations that were organized into eight recorded lectures totaling approximately four hours. See Table 2 for a description of the content contained in the eight modules.

Table 2: Online Module Descriptions

Module Number	Summary
1.	Overview of the course content and pre-requisite information including wound healing principles, best practice guidelines, wound bed preparation, wound assessment and aseptic technique.
2.	The history of E-Stim, basic overview of what E-Stim is, and different types of equipment for E-Stim delivery.
3.	Review of the biological mechanisms and physiological processes that speed the healing process with the use of E-Stim.
4.	Clinical research evidence and clinical practice guidelines for the use of E-Stim.
5.	Indications, precautions and contraindications for the use of E-Stim in pressure injuries.
6.	Overview of dressings that are compatible for use with E-Stim in pressure injuries.
7.	Electrical Principles and stimulus parameters
8.	A detailed review of application techniques. Including three 5-7minute videos that showed different ways to deliver electrical currents to the wound and peri-ulcer skin. These demonstrations allowed participants to see how to apply E-Stim during the workshop as well as later when they needed reminders.

2.3.4 Hands-on Workshop

Once participants completed the online modules, they were invited to participate in one of seven hands-on workshops that were offered over a one-year period in different

locations. The hands-on workshop began with a brief overview of the content from the online modules. The main objective for the hands-on workshop was to develop the clinical skills required to apply E-Stim to patients with PrUs and included interactive case discussions to promote critical thinking and the clinical decision-making judgements necessary to use E-Stim in a safe and effective manner.

The specialized equipment and supplies (electrodes, leads) required for the delivery of E-Stim to wounds was available during the hands-on workshop. The first component of the workshop was initiated with a demonstration of E-Stim application techniques. Wound healing fundamentals including wound bed preparation, wound etiology, and aseptic techniques were embedded throughout the hands-on session.[17-20] Participants were able to actively set up the E-Stim equipment on realistic latex wound models. They also were encouraged to experience the sensation of E-Stim to diminish fears and describe expected sensations to their patients. This was followed by a peer evaluation that was supervised by two of the study researchers to confirm participants completed all the application steps in a safe and effective manner.

The second component of the workshop included a review of wound dressings that are compatible with E-Stim. Participants were exposed to samples of different types of wound dressings and products. Selection and rationale of the most appropriate dressing for each case was developed via interactive case discussions with the class. Patient scenarios were developed and reviewed during the hands-on workshop to test participant's understanding of electrical principles and how changing the E-Stim set up or wound environment can affect electrical current flow.

At the end of the workshop, the clinicians were invited to participate in a Community of Practice which continued to meet monthly to share experiences and discuss challenges regarding E-Stim implementation via a secure web-based online video/audio link. The community of practice was developed as part of the E-Stim Collaboration Project and provided an online forum to link over 300 clinicians across Canada who are working in this field.

2.4 Instruments

2.4.1 Knowledge Test

Knowledge about principles of electricity, mechanism of action, and research evidence was measured using a multiple-choice test. The knowledge test was either administered online where 10 questions were randomly selected from a pool of 25 multiple choice questions, or on paper where all 25 questions were included in an in-class quiz (Post-Workshop). Knowledge questions were developed by the research team and pilot tested during a pre-study education session.

2.4.2 E-Stim Attitude Survey (EAS)

An attitude survey was developed by the research team to understand the attitudes participants had towards the use of E-Stim on pressure injuries and their willingness to incorporate an advanced therapy into practice (Table 3). The survey was based on the APuP test developed by Beeckman et al, 2010.[30]

Questions were grouped into three subscales to define participant's attitude including:

1. Education: Attitude towards the importance of knowledge and skills for the use of E-Stim in practice.
2. Evidence based practice: Attitude towards research evidence and effectiveness of E-Stim to stimulate/accelerate the healing of pressure injuries
3. Resources: Attitude towards efficiency and equipment needs when using E-Stim in clinical practice

The EAS consisted of 14 items measured on a 5-point Likert scale including Strongly Agree, Agree, Neutral, Disagree and Strongly Disagree. The education subscale consisted of 5 items, the evidence-based practice subscale consisted of 4 items, and the resources subscale consisted of 5 items. Internal consistency measured using Cronbach's alpha was calculated for each subscale and found to be acceptable for education (α=0.74), evidence-based practice (α=0.76), and resources (α=0.74).

Table 3: E-Stim Attitude Survey (EAS)

EDUCATION SUBSCALE
1. Based on my current knowledge, I am willing to incorporate E-Stim into my current practice.
2. I am reluctant to use E-Stim because of the high risk of harm to my patients.
3. I cannot use E-Stim because it is not within my scope of practice.
4. I do not feel I have the advanced knowledge and skills that are required to apply E-Stim to wounds.
5. I need more hands-on practice and clinical experience with E-Stim before I could use it in my clinical practice.
EVIDENCE BASED PRACTICE SUBSCALE
6. Providing E-Stim to patients with delayed wound healing is important.
7. The individuals I see with open wounds are more appropriate for negative pressure wound therapy rather than E-Stim.
8. The individuals I see with open wounds could benefit from E-Stim.
9. There is little evidence to support the use of E-Stim for individuals with pressure injuries.
RESOURCES SUBSCALE
10. I currently use E-Stim when appropriate for individuals with stalled or non-healing wounds.
11. I don't have time to provide E-Stim treatment to my clients.
12. I have good support from supervisors and managers to use E-Stim in my clinical practice.
13. The cost to provide E-Stim to patients is too high.
14. The equipment required to use E-Stim is not available to me.

2.4.3 Practice Change

To assess change in practice, participants were followed up via email six months Post-Workshop session and asked the following question:

Since attending the E-Stim Consultant Education, I have used E-Stim for chronic would healing on: a) 1-5 patients; b) 6 or more patients; or c) I have not used E-Stim since attending the workshop.

2.5 Time Course of Evaluations

Knowledge tests and the EAS survey were evaluated at three time points throughout this study; prior to commencing the education (Pre-Education), after completing the online modules (Post-Online), and after completing the hands-on workshop (Post-Workshop). Tests and surveys were administered electronically via the online education system Pre-education and Post-Online. A paper tool was used to evaluate the participant's knowledge and attitudes Post-Workshop.

2.6 Data Analysis

Eighty-seven individuals completed both the online modules and the hands-on workshop. Of the 87 who completed the education program, 83 individuals were included for data analysis. Four participants were excluded due to missing baseline data. Demographic information describing the type and amount of clinical experience were collated and analyzed using descriptive statistics. See Table 1.

Knowledge was assessed using the percentage of correct answers on the knowledge test. EAS results were converted to numeric scores to analyze the data. Attitudes were assessed using the subscales of education, evidence-based practice, and resources. To evaluate the impact of the education program on knowledge, and on the three subscales of the attitude questionnaire, a separate linear mixed effects model was fit to each of the four dependent variables. Time of measurement (Pre-Education, Post-Online, Post-Workshop) was included in the model as a fixed effect, and participants were included as

a random effect. Utilizing a linear mixed effects model allowed us to use all available data without the need for list-wise deletion of participants with missing data, or interpolation of these missing data points.[32] The statistical significance of the fixed effect was identified by comparing this model to a 'null' model in which the dependent variable was predicted only by random error. In the event of a statistically significant fixed effect, post-hoc testing was done by testing all possible pairwise comparisons using t-tests with degrees of freedom estimates that were calculated using a Satterthwaite approximation. All statistical analyses were performed in R[33], with linear mixed effects analyses conducted using the lme4[34] and lmerTest[35] packages. Post-hoc pairwise comparisons were completed using the lsmeans package.[36]

2.7 Results

2.7.1 Demographics

The majority of the participants were registered nurses (43.2%) followed by physiotherapists (27.0%), enterostomal therapists (10.8%), occupational therapists (8.1%), registered practical nurses (6.8%), other (2.7%) and one physician (1.4%). Most participants worked in a hospital environment (55.4%) and in a full-time capacity (78.4%). Participants had a variety of background knowledge in wound management but the majority (56.8%) had taken either in-services or 1-2-day workshops as their highest level of wound care knowledge.

2.7.2 Change in Knowledge Scores

Mean scores for the knowledge tests for the three time points are presented in Figure 1. Total scores ranged from 20-100% Pre-Education, 50-100% Post-Online and 52-96% Post-Workshop. Using the mixed effects model, the effect of time was statistically significant ($p < .001$). Post-hoc evaluation showed that there was a statistically significant increase in knowledge from Pre-Education to Post-Online, $t(145) = 9.18$, $p < .0001$. Knowledge scores were higher Post-Workshop compared to Pre-Education, $t(141) = 9.81$, $p < .0001$. Participants were most challenged by E-Stim knowledge questions pertaining to biological mechanisms and the physiological effects of E-Stim.

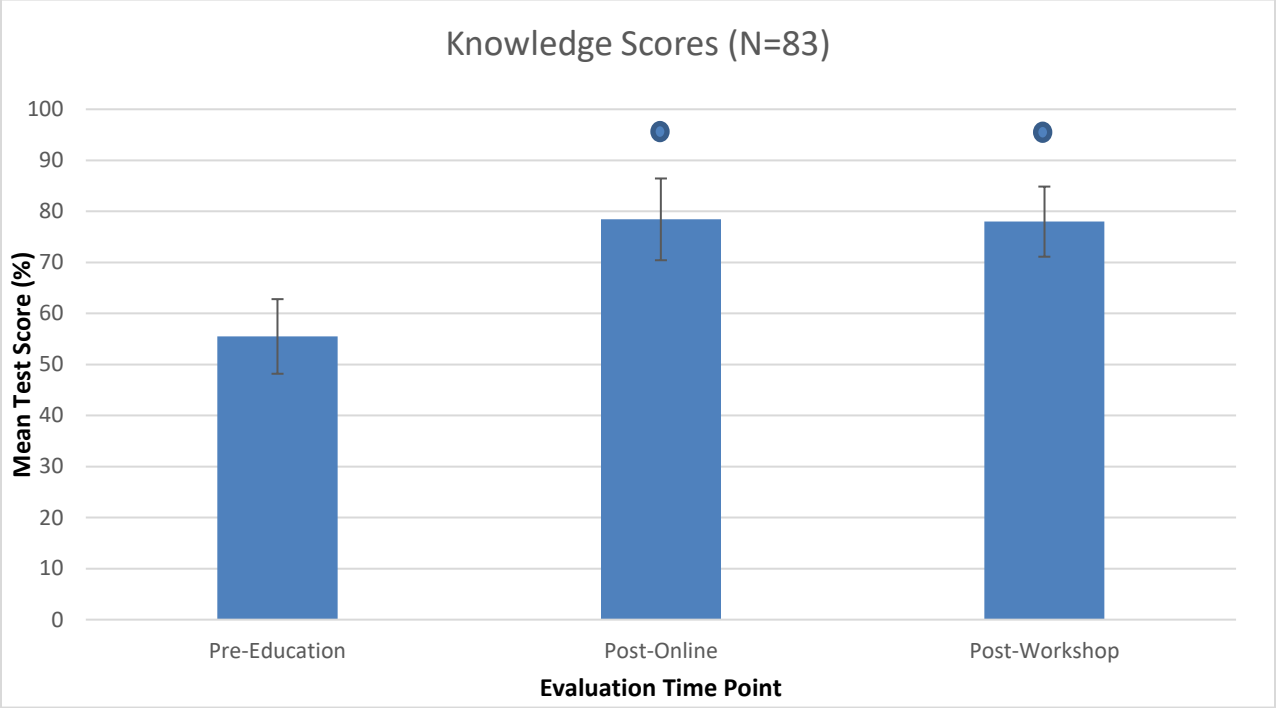

Figure 1: Knowledge Test Scores; ● = significant difference

2.7.3 Change in Attitude Scores

Baseline attitude scores for the EAS are shown in Figure 2. Mean scores for the EAS subscales of education, evidence-based practice, and resources over time are shown in Figure 3. Post-hoc analysis revealed that there was a significant increase in attitudes related to the education subscale over all three time points: Pre-Education and Post-Online, $t(140)=7.08$, $p < .05$; Pre-education and Post-Workshop, $t(136) = 10.98$, $p < .05$; and between Post-Online and Post-Workshop surveys, $t(140) = 3.13$, $p < .05$.

For the evidence-based practice subscale, attitudes were significantly increased between Pre-Education and Post-Online groups, $t(127) = 6.03$, $p < .05$, as well as between Pre-

Education and Post-Workshop, $t(122) = 4.86$, $p < .05$, but not between Post-Online and Post-Workshop.

For the resources subscale, there was also a significant increase in attitudes between Pre-Education and Post-Workshop, $t(113) = 5.22$, $p < .05$, Post-Online and Post-Workshop, $t(115) = 4.07$, $p < .05$, but not between Pre-Education and Post-Online time points.

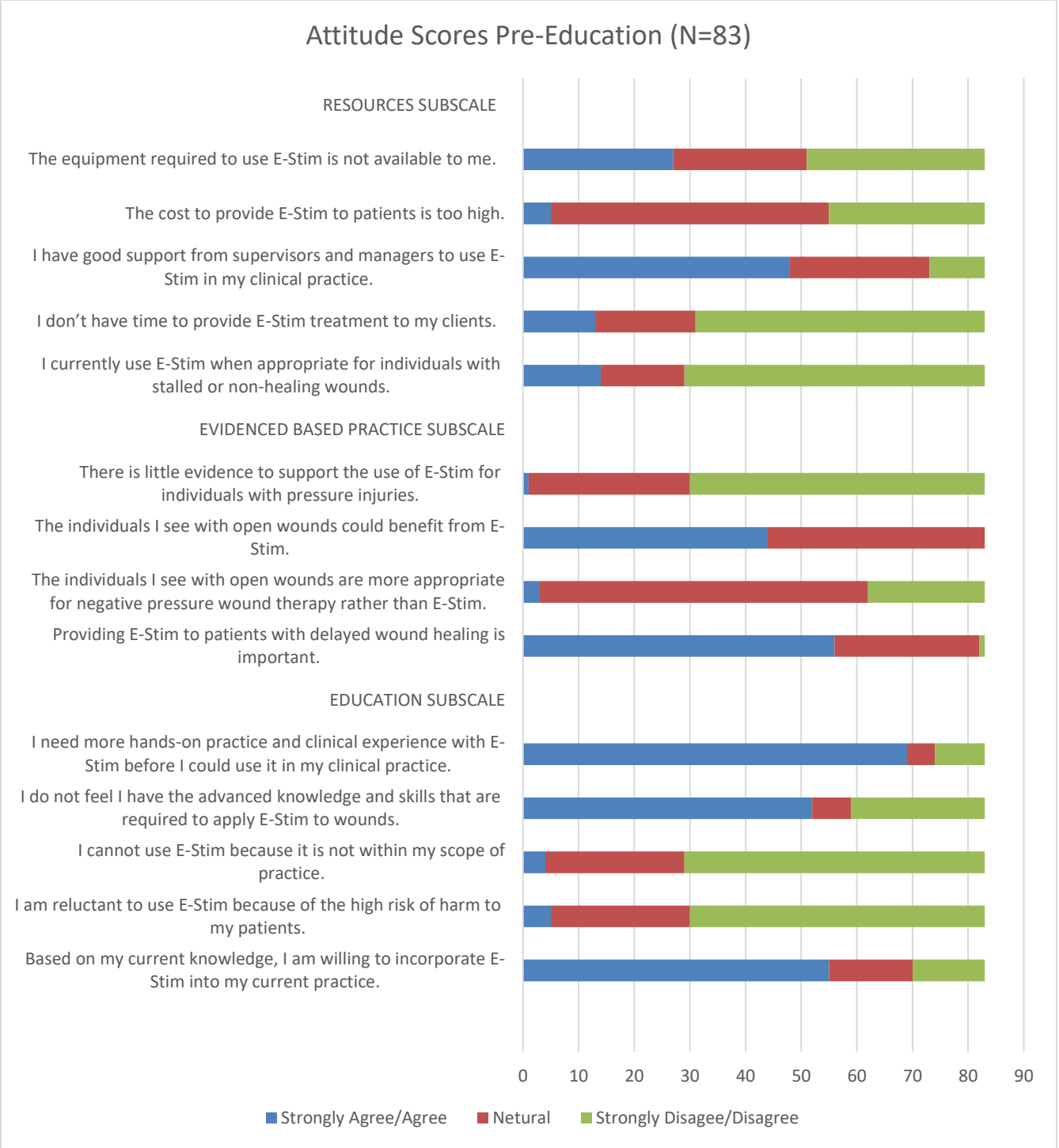

Figure 2: E-Stim Attitude Survey Pre-Education Program

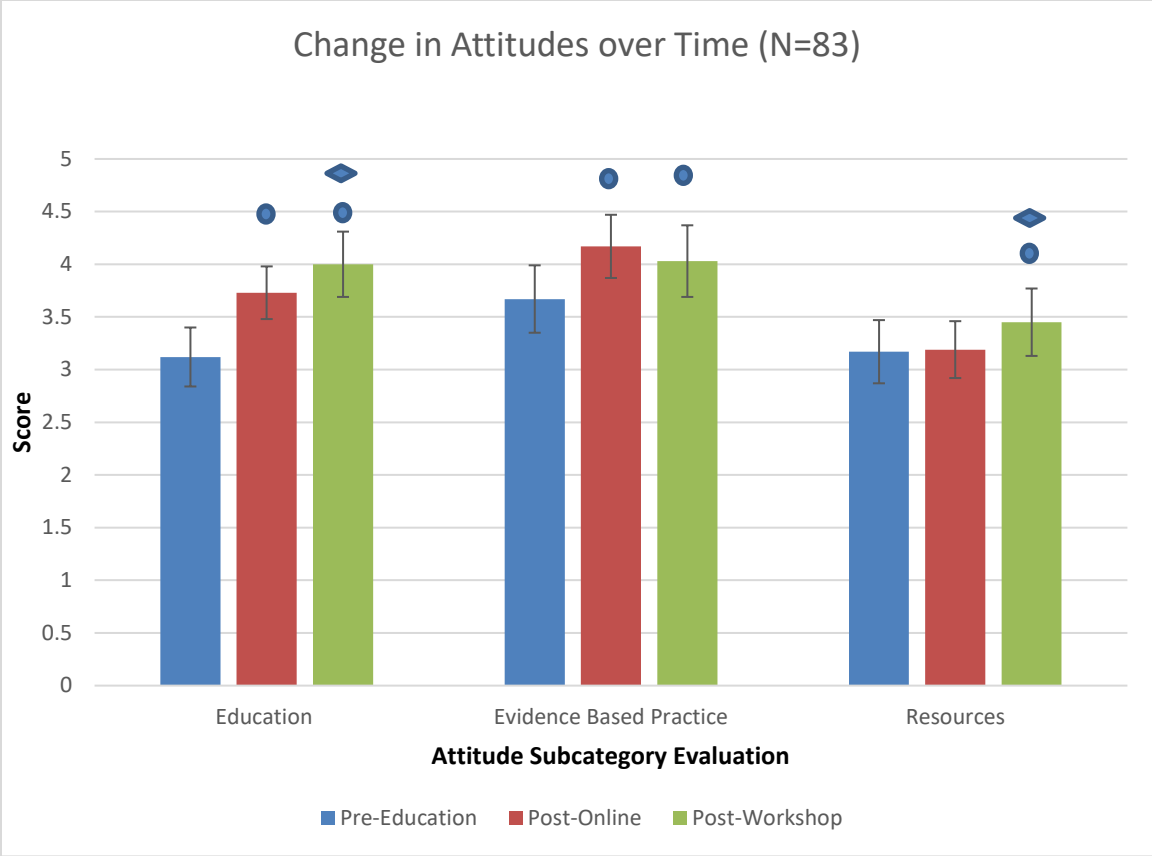

Figure 3: E-Stim Attitude Survey Scores; ● = significant difference from Pre-Education Scores, ◆ = significant difference from Post-Online

2.7.4 Practice Change

Thirty-three of a potential 83 participants who had completed the hands-on session six months prior responded to the practice change question (40% response rate). Of the group that responded, 33% had used E-Stim on 1-5 patients, 6% had used E-Stim on 6 or more patients, and 61% had not used E-Stim since attending the workshop.

2.8 Discussion

The results of this study have demonstrated that a customized online education program increased knowledge about E-Stim in a group of multidisciplinary health care providers. Subsequent completion of a hands-on workshop was required to change certain attitudes

about E-Stim. Despite being able to increase knowledge and improve attitudes toward E-Stim, less than half of the responding participants changed their practice six months after attending the education program.

To our knowledge, this is the first research study to evaluate the knowledge, attitudes and practices regarding the use of E-Stim by health care providers involved in the treatment of PrUs. Assessment of knowledge and attitudes for the use of an evidence-based intervention such as E-Stim is important given the many barriers associated with the implementation of evidence-based guidelines.[21] Our study showed that a 4-hour online education program could significantly improve clinician's knowledge about E-Stim. Clinicians could independently complete this online program when it was convenient, and this background information could be referenced in the future when required by the clinician.

Interestingly, there was no further increase in knowledge detected after completion of a hands-on session. This was expected given the theoretical knowledge component of the educational program was delivered via online modules and we did not repeat any of the background knowledge during the hands-on workshop. It is also possible that we were unable to detect changes in knowledge scores after the hands-on workshop because the test was administered differently pre and post workshop. The paper-based test with all 25 multiple choice questions that was administered after the workshop may have been more difficult than previous tests where only 10 questions were selected randomly.

The EAS was used to assess whether clinicians would be more willing to incorporate E-Stim as PrU treatment. The education subscale, which measured attitudes about the importance of E-Stim knowledge, increased after the online education and continued to improve after the hands-on workshop. This demonstrates that attitudes towards the importance of E-Stim knowledge can be optimized when a combination of online and face to face skills workshop are provided. In evaluating the attitude pre-education scores, 69 (83%) participants agreed with the statement "I need more hands-on practice and clinical experience with E-Stim before I could use it in my clinical practice." Fifty-two participants (63%) also agreed with the statement "I do not feel I have the advanced

knowledge and skills that are required to apply E-Stim to wounds". We were able to demonstrate a significant increase in attitudes towards the use of E-Stim after our education program, however a hands-on workshop was not sufficient to change clinician's practices. Further mentorship and education in a clinical setting may be required to increase use of E-Stim for PrU treatment.

The evidence-based practice subscale, which measured attitudes towards research evidence and E-Stim effectiveness, increased after completing the online modules but did not change after the hands-on workshop. The lack of change in this portion of the attitude survey is likely because information about clinical research and best practice recommendations was only included in the online modules, and not part of the hands-on workshop. The resources subscale measured attitudes towards E-Stim efficiency and equipment needs and showed that improvements in this attitude did not occur until after completing the hands-on workshop. This is because we provided in the hands-on workshop an opportunity for participants to observe and use the specialized equipment and supplies that were available to them for E-Stim treatments.

Previous studies have shown an increase in nurse's knowledge after educational workshops, but did not evaluate attitudes.[22,23] The studies that evaluated attitudes, did not assess if an educational program could change nurses attitudes.[24,25,27,28,35] Our findings demonstrate the importance of providing a combination of knowledge and skills, and having a hands-on workshop. We were able to overcome these negative attitudes and barriers to E-Stim implementation by having the equipment available for participants to use during the workshop and have a better understanding of the time and steps required for E-Stim set up. We also required all course participants to demonstrate they were able to manipulate the equipment and set up all the supplies appropriately during the hands-on workshop.

Although we found that knowledge and attitudes towards E-Stim improved significantly after this education program, only 39% of respondents had used E-Stim in their wound care practice six months Post-Workshop. This relatively low rate of practice change is consistent with other reports that showed improved knowledge does not subsequently

impact behavior.[36] Of the 83 participants, only 33 responded. With this response rate (40.8%) it is unclear whether this relatively low level of E-Stim use is representative of the larger group of clinicians who completed the education. It is possible this rate of practice change may be falsely elevated given that participants who used the intervention may be more willing to respond to the question. We did not investigate the reasons why participants did not use E-Stim in their practice. It is possible that they did not receive referrals or encounter appropriate patients for E-Stim treatment.

A lack of translation of knowledge into practice is not uncommon.[37–39] Beeckman et al in 2011 evaluated the relationship between knowledge, attitudes and the application of evidence-informed PrU prevention strategies for nurses working at 14 Belgian hospitals. They concluded that nurse's knowledge about PrU prevention was inadequate and that knowledge of prevention methods was not associated with the application of prevention methods. Attitude scores were higher than the knowledge scores and did have a significant correlation with evidence-based practices being utilized for patients.

Previous studies that recorded nurse's attitudes toward evidence-based practices in PrU prevention showed nurses were negatively affected by a lack of resources; more specifically lack of time[40], lack of nursing staff[40,41] and insufficient equipment.[41] In our study, we know that the equipment and processes needed to provide this E-Stim to patients living in this region were in place over this time period.

The challenge with producing practice change and encouraging clinicians to adopt new approaches into clinical care is well documented in the literature.[36, 42–45] This has fueled the emergence of a new area of research called implementation science. Despite numerous frameworks and established processes to identify and address barriers and involve end users, sustained practice change remains elusive. Our experience suggests that filling knowledge gaps and addressing concerns about competency using an innovative and very accessible education program is only part of the underlying problem with getting new treatments into wound care practice.

2.9 Conclusions

Training is perceived as a barrier for the implementation of evidence-based practice in wound healing, specifically for the use of E-Stim in the treatment of pressure injuries. Education delivered using online modules that includes theoretical background and a critical review of clinical research evidence can increase health care providers knowledge about E-Stim and other best practices used in the treatment of PrUs. A one-day face to face session which involved practice with hands-on skills was required to improve certain attitudes towards E-Stim. More clinicians who completed this education used E-Stim in their practice; however, the rate of practice change remained low. These findings suggest that further intervention is required to change practice patterns, such as ongoing coaching and mentorship in the clinical setting.

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3 Evaluation of the Cost-Effectiveness of Electrical Stimulation and Negative Pressure Wound Therapy versus Standard Wound Care for the Treatment of Pressure Ulcers

3.1 Introduction

Pressure ulcers (PrU) are a common and costly complication occurring across all sectors of health care. In 2013, the Canadian Institute for Health Information (CIHI) reported PrU prevalence rates that ranged from 0.4 percent to 14.1 percent in acute care, home care, long term care and complex continuing care.[1] It has been estimated that PrU care can have a monthly cost of $4,750 CDN for individuals with a spinal cord injury who live in the community and the cost of a single PrU can range from $11,000 to 90,000 CAN.[2-4] The severity and depth of PrUs has been characterized by the National Pressure Ulcer Advisory Panel (NPUAP) using a staging system between I-IV.[5] Stage III and IV PrU indicate a deeper wound. Given the high cost to patients and the health care system, it is imperative that evidence-based interventions are utilized to maximize healing rates in patients with a PrU. Multiple best practice guidelines have been developed nationally and internationally to guide clinicians to implement best practices for the treatment of PrU.[6–8] Interventions for the management of PrUs include pressure offloading, appropriate nutrition, pain management, and local wound care which can include the use of advanced therapies such as electrical stimulation (E-Stim) or Negative Pressure Wound Therapy (NPWT).

E-Stim involves the delivery of low-level current via surface electrodes to the area of the wound bed for speeding wound closure. Several randomized controlled trials, systematic reviews and meta-analyses have concluded that E-Stim can speed healing and promote wound closure.[9] Despite having strong recommendations to use E-Stim in several best practice guidelines, there has been little uptake of the use of E-Stim in clinical practice for the treatment of PrUs.[6] This may be due to implementation barriers including: lack of interdisciplinary collaboration and communication amongst providers between and across settings, inadequate training, and lack of resources such as funding, time, and staff.[10] To address these barriers, a multi-year research project was conducted in community dwelling individuals living in one region of Ontario, Canada. Within this region health

care is coordinated by the South West Local Health Integrated Network (South West LHIN) that is funded by the Ministry of Health and Long-Term Care (MOHLTC). The South West LHIN provides home care services by contracting several provider agencies that employ nurses, allied health professionals, as well as unregulated support workers. The E-Stim Collaboration Project was a knowledge mobilization project with the overall aim to support home care services of the LHIN in a way that promoted uptake and use of E-Stim therapy in a sustainable way.

Negative pressure wound therapy (NPWT) is an advanced therapy that has been used for treating chronic wounds since it was introduced in the early 1990's.[11] NPWT consists of a machine which exerts a carefully controlled suction (negative pressure) attached to a wound dressing that covers the PrU. NPWT is a technology that is widely used and is promoted for use on many types of wounds but is not recommended by the Registered Nurses Association of Ontario (RNAO) best practice guidelines for the treatment and management of PrU.[6,12]

Despite widespread use of various advanced therapies in wound care, only a limited amount of data exists on their cost effectiveness. In review of the literature, only one cost-effectiveness study for the evaluation of E-Stim for the treatment of PrUs was identified. In a study by Mittmann et al (2011), the incremental cost-effectiveness of E-Stim plus standard wound care (SWC) versus SWC alone was estimated in a spinal cord injury population with stage III/IV PrUs from the public payer perspective.[13] Cost analysis was conducted using the cost data and healing probabilities from a randomized controlled trial of E-Stim plus SWC versus SWC alone.[14] SWC included using advanced wound dressings for local wound treatment. They found that E-Stim plus SWC were associated with better outcomes and lower costs with a 16.4 % increase in the PrUs healed and a cost saving of $224 at 1 year. E-Stim plus SWC had higher effectiveness and lower costs than SWC alone and was therefore considered a dominant strategy.[15] Despite this evaluation, E-Stim continues to be underutilized as an advanced therapy for PrU treatment. The study by Mittmann et al demonstrated the benefits of E-Stim using a one-year timeline; however, PrUs may be present for many years in clinical practice and a one-year analysis may not capture the true value of using E-Stim.

The cost effectiveness of NPWT in comparison to advanced wound dressings has been investigated. Braakenburg et al conduced a cost comparison study by assessing the clinical efficacy and cost of NPWT versus advanced wound dressings in acute and chronic wounds in a hospital in the Netherlands.[16] They reported no significant difference in healing rates or costs between the two groups. Dowsett et al also evaluated the economic benefits of NPWT in a variety of wound types in the community sector.[17] NPWT use and resources in the community in the United Kingdom was tracked over a 16-month time period. They calculated the mean cost per episode (£818) over the average number of days for NPWT. They concluded that the average cost of treating complex wounds using NPWT could be significantly less than using traditional dressings by saving nursing time to complete the dressing changes.

Soares et al(2013) conducted a cost-effectiveness analysis on NPWT for the treatment of PrUs, recognizing NPWT as a treatment that was widely used for PrUs.[18] They evaluated the use of NPWT for the treatment of PrUs given a range of alternative treatments using a decision analytic model. A literature search was completed for model inputs and given the limited evidence in the literature; the authors also elicited judgments from experts using formal elicitation exercises as well as data derived from a pilot trial.[19] The three sources of evidence were collated and the impact of each on cost-effectiveness was evaluated. They used a model based on three transition states: unhealed, healed and dead. The authors concluded that when all evidence sources were combined, NPWT was expected to be less costly and more effective than advanced dressings alone; however, they recommended that a randomized controlled trial with long term follow up would be beneficial to reduce decision uncertainty in their model.

Economic evaluations for the treatment of PrUs using advanced technologies are scarce and clinical studies that directly compare two different advanced therapies do not exist. Best practice guidelines used clinical research evidence to identify and recommend which advanced therapies should be used in the treatment of PrUs. It is important to not only evaluate their clinical effect on healing, but also consider the economic value of these therapies.[6–8]

The aim of this study was to estimate the cost effectiveness of two advanced therapies using cost utility analysis to calculate outcomes in units that could be compared using cost per quality assisted life years (QALY). There are no known studies comparing the clinical effectiveness of E-Stim versus NPWT, therefore two decision analytic models (DAM) were designed. The cost effectiveness of E-Stim and NPWT versus SWC for the treatment of PrUs from a health care resource perspective was determined.

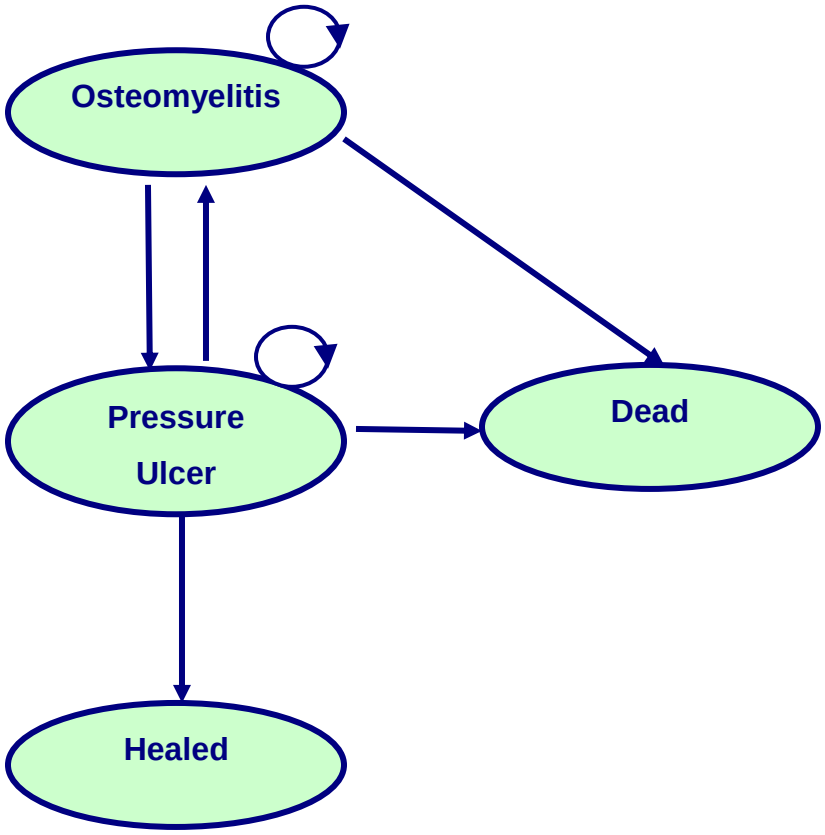
3.2 Methods

The DAMs were constructed using Tree-Age Pro Software Inc, version 2018. A DAM of E-Stim versus SWC was developed based on a previous meta-analysis conducted by Koel and Houghton including both published and unpublished data (see Appendix 5).[20] An extensive literature search did not reveal a meta-analysis on the use of NPWT for the treatment of PrUs. Therefore, the DAM for NPWT versus SWC was based on a randomized controlled trial by Ford et al, 2002.[21] These studies were chosen since they both reported the number of PrU wounds healed. Demographic characteristics of the patient population were not included in the meta-analysis; therefore, the starting mean age of 48 was used in the models which was the mean age of participants in the NPWT study and ran until age 90. Both models were run for a cohort of 1000 patients treated with each of the wound management regimens considered. The models assumed that, except for the treatment regimen, all other characteristics of the patients treated were equal (e.g. wound size, wound duration, and other treatments such as PrU offloading, etc.). The perspective of the study is that of the MOHLTC and no attempt was made to capture any indirect costs associated with PrUs.

In both models, individuals received E-Stim or NPWT versus SWC for six weeks. SWC was defined as the use of basic or advanced wound dressings for local wound management. If the PrU did not heal or patients suffered a recurrence, the patient transitioned through various health states using Markov modeling. Markov models predict how a patient or group of patients with a particular condition progress through a number of defined health states.[15] At the end of a predefined period, individuals can remain in one health state or move from one health state to another, according to transition probabilities. Markov models are particularly useful in modeling conditions

which can be categorized by a number of discrete health states, and for chronic conditions such as PrUs.[15] The structure of the Markov model for this study is illustrated in Figure 4.

Figure 4: Markov Model Diagram



The health states are intended to reflect separate states that an individual with a PrU may experience. The health states selected in this study were osteomyelitis (OSM), PrU, healed or dead.

Dead and healed states were included as absorbing states meaning that once individuals were in the dead or healed states, they could not move out of that state. The duration of each Markov cycle was defined as 3 months which is a suitable length of time for individuals to move between each of the health states based on clinical practice. Data utilized to build the model were converted as required using the following equations:

$$\text{Rate} = -\ln(1-p)/t$$

$$\text{Probability} = 1-\exp^{(-rt)}$$

Where p=probability, t=time, r=rate

In some instances, the progression in between disease states was zero if it is not clinically feasible. For instance, individuals with OSM cannot progress directly to a healed state. The DAM assumes that individuals would first progress to the PrU state before progressing to the healed state. The model structure allows for the recurrence of a pressure injury once healed, and the recurrence of OSM. The model arms were identical for the E-Stim, NPWT and SWC model arms. An example of one model arm is seen in Figure 5.

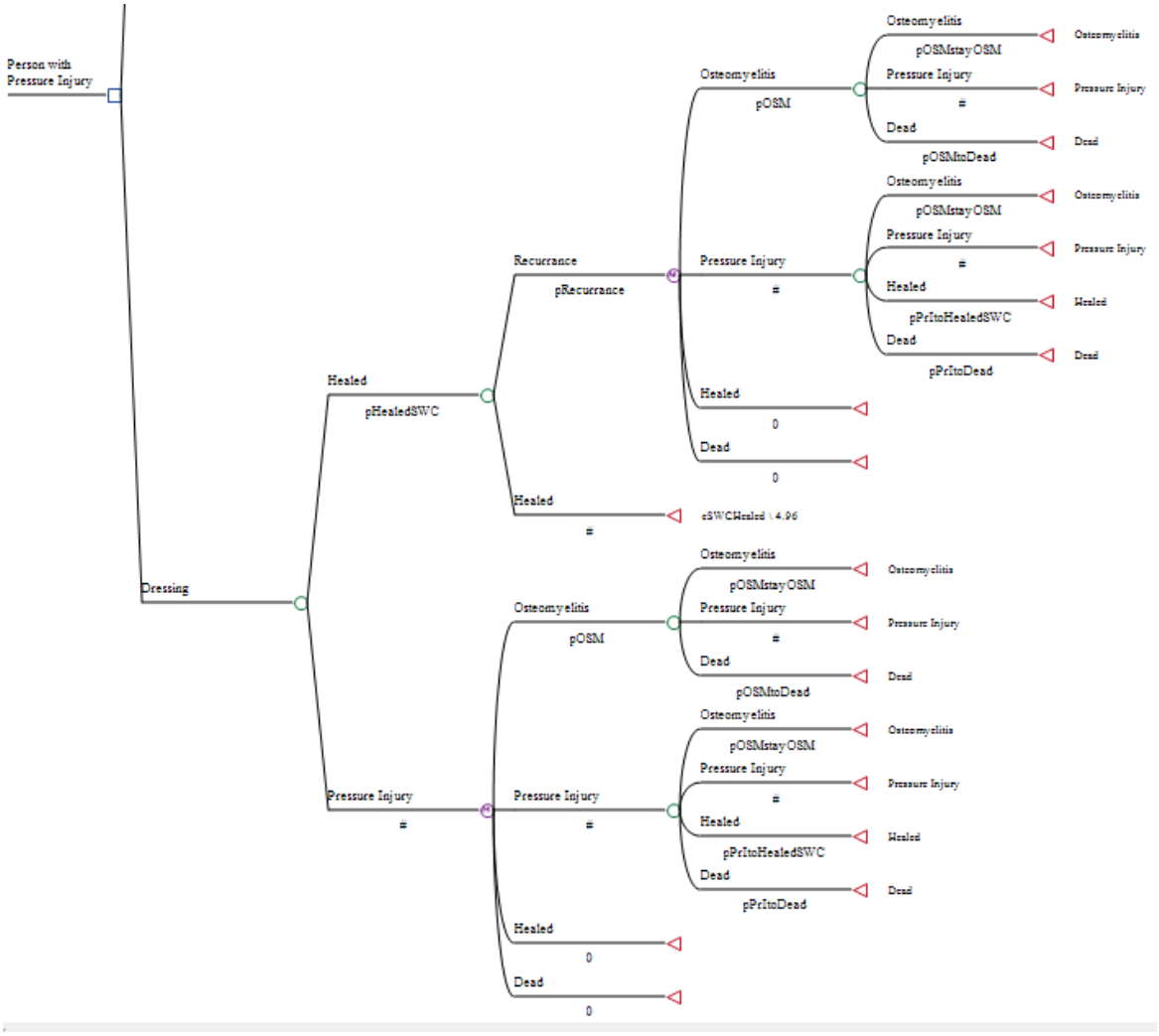


Figure 5: Decision Analytic Model Arm

3.2.1 Costs and Resource Use

Canadian dollars (2017) were used in this analysis and costs were converted using the Bank of Canada and Consumer Price Index as appropriate.[22,23] One and a half percent discounting was applied for the reference model in both analyses and a half cycle correction was applied for the Markov models as recommended by the Guidelines for the Economic Evaluation of Health Technologies, 2017.[24] Only direct medical costs were considered in both analyses. All cost references and data sources are summarized in Table 4.

Table 4: Treatment Costs

Medical Expense	Cost per day	Reference	SD	Reference	Distribution
E-Stim Equipment	**13.35**	**Houghton et al, 2010**	**6.04**	**Houghton et al, 2010**	**Gamma**
NPWT Equipment	**88.41**	**Delhougne et al, 2018**	**42.51**	**Delhougne et al, 2018**	**Gamma**
SWC	**9.58**	**Houghton et al, 2010**	**4.73**	**Houghton et al, 2010**	**Gamma**
Interdisciplinary Team	**38.32**	**Research Data, 2017**	**19.00**	**Research Data, 2017**	**Gamma**
RPN	**26.39**	**www.jobbank.gc.ca**	**2.64**	**Assumption**	**Gamma**
Hospitalization	**1199.60**	**OCCI**	**1911.29**	**OCCI**	**Gamma**

SD-Standard Deviation; E-Stim-Electrical Stimulation; NPWT-Negative Pressure Wound Therapy; SWC-Standard Wound Care; RPN-registered practical nurse; OCCI-Ontario Case Costing Initiative

Patients in the OSM and PrU states were assumed to incur costs related to the treatment of their PrU and the healing of the PrU would be by secondary intention. We did not include surgical closure as part of the models since this option is seldom available to patients with PrU in this region. Costs for E-Stim equipment and SWC were referenced from the study by Mittmann et al(2011) and converted to 2017 dollars.[13] NPWT equipment costs were calculated using the data from the study by Delhoughne et al(2018), a retrospective cost minimization analysis of disposable and traditional NPWT from Medicare claims with costs being converted to 2017 Canadian dollars.[25] Interdisciplinary team costs were derived from data collected as part of the E-Stim Collaboration Project which was described above. These costs are outlined in detail in Chapter 4. Registered practice nurse (RPN) costs were calculated using data from the Government of Canada job bank website.[26] One hour of nursing time costs were assumed to be the same as one patient visit for a dressing change. OSM hospitalization costs were calculated using the Ontario Case Costing Initiative (OCCI) data.[27]

Multiple assumptions were made to build and compare the two models. Costs for PrU healed were calculated for a six-week time period for each intervention and total cost was the cost of the equipment, plus the cost of the interdisciplinary team needed to provide optimal wound care. Markov state costs are reported in Table 5. For the Markov model

OSM state, it was assumed that a patient would be admitted to hospital for 24.8 days over the course of one year which is the average length of stay for patients in Ontario with pelvic osteomyelitis from OCCI data. [27] When patients in the OSM state were not in hospital, they were assumed to receive daily dressing changes from an RPN based on current clinical practice. In the Markov model PrU state, patients were assumed to receive daily dressings by an RPN. In the healed and dead states, costs were assumed to be zero. Initial costs for the OSM and PrU states were calculated for patients receiving E-Stim or NPWT based on clinical practice. Patients who do not heal their PrU after receiving six weeks of E-Stim or NPWT were assumed to continue with the advanced therapy for an additional three months prior to being discharged from the advanced therapy. For NPWT, it was assumed that if a patient entered the OSM or PrU state, they would receive three months of NPWT to manage symptoms of OSM or as a trial period for the treatment of the PrU. If the patient remained in the OSM or PrU state for longer than three months, the PrU was assumed to be a non-healing or non-healable. A non-healing wound is defined as a wound that has healing potential, but causes and co-factors that can interfere with healing have not yet been removed and a non-healable wound is defined as a wound where causes and co-factors that can interfere with healing cannot be removed, e.g., in cases of terminal disease or end-oflife care.[28] Patients with non-healing or non-healable wounds receive SWC and are discharged from advanced wound therapies due to their low probability that their wound will heal. For the E-Stim model, it was assumed that if a patient had a PrU, they would receive three months of E-Stim as a trial period. If the patient remained in the PrU state for longer than three months, the PrU was assumed to be a non-healing or non-healable wound and therefore E-Stim would be discharged.

Table 5: Costs per Three Months Based on a Given State

State	Cost	SD	Distribution
cOSM State	**10496.75**	**11858.95**	**Gamma**
cPrU State	**3282.26**	**431.68**	**Gamma**
ctransition 3mon NPWT	**7426.44**	**3570.84**	**Gamma**
ctransition 3mon E-Stim	**1926.12**	**644.42**	**Gamma**

cOSM-cost osteomyelitis; cPrU-cost pressure ulcer; NPWT-negative pressure wound therapy; E-Stim-electrical stimulation

3.2.2 Effectiveness

The primary outcomes of both analyses were healthcare costs per QALYs gained. A literature review was conducted to select the clinical inputs for the model including recurrence rates, rates for progressing to OSM, rates for progressing to death, and utility rates. Search terms were derived to capture information on the effectiveness of E-Stim and NPWT. References used in this analysis focused on the clinical effectiveness of healing rates for each of the treatment regimens and are summarized in Table 6 and 7.

Table 6: Economic Model Clinical Inputs: E-Stim versus SWC

Variable	Value	Unit	Reference and Year	Distribution
PrU healed with E-Stim	**56.0**	**%**	**Koel and Houghton, 2013**	**Beta**
PrU healed with SWC	**21.3**	**%**	**Koel and Houghton, 2013**	**Beta**
Recurrence	**38.0**	**%**	**Bates-Jensen et al, 2009**	**Beta**
Develop OSM	**24.5**	**%**	**Darouiche et al, 1994 Sugarman et al, 1983**	**Beta**
E-Stim Healed	**5.29**	**QALY**	**Assumption from Model**	**Gamma**
SWC Healed	**5.00**	**QALY**	**Assumption from Model**	**Gamma**

PrU-pressure ulcer; E-Stim-electrical stimulation; SWC-standard wound care; OSM-osteomyelitis; QALY-quality adjusted life year

Table 7: Economic Model Clinical Inputs: NPWT versus SWC

Variable	Value	Unit	Reference and Year	Distribution
PrU healed with NPWT	**10.0**	**%**	**Ford et al, 2002**	**Beta**
PrU healed with SWC	**13.0**	**%**	**Ford et al, 2002**	**Beta**
Relapse	**38.0**	**%**	**Bates-Jensen et al, 2009**	**Beta**
Develop OSM	**24.5**	**%**	**Darouiche et al, 1994 Sugarman et al, 1983**	**Beta**
NPWT Healed	**4.49**	**QALY**	**Assumption from Model**	**Gamma**
SWC Healed	**4.71**	**QALY**	**Assumption from Model**	**Gamma**

PrU-pressure ulcer; NPWT-negative pressure wound therapy; SWC-standard wound care; OSM-osteomyelitis; QALY-quality adjusted life year

Efficacy rates (% of patients with completely healed PrUs) for E-Stim were obtained from unpublished meta-analysis data by Koel and Houghton, 2014 that was calculated for seven studies with a total of 412 stage III/IV PrUs.[20] They found 57.2% of participants completely healed with E-Stim versus 21.3% of participants who received SWC. The average duration of E-Stim treatment at 7.25 weeks. The rate of healing was assumed to be the same for six weeks of E-Stim treatment to keep the treatment time prior to entering the Markov states similar in the two models.

Efficacy rates for NWPT were obtained from Ford et al, 2002 who reported 10% of participants with PrUs completely healed using NPWT versus 13% of participants with PrUs who completed healed using SWC alone over a six-week treatment period. Recurrence was defined in the model as recurrence of a PrU after healing. A value for the probability for a recurrence was estimated based on a study by Bates-Jensen et al, 2009. The authors reported that 24 out of 64 veterans had a recurrence of a stage III/IV pelvic PrU in a nine month follow up period.[29] This study was selected given the lack of published Canadian PrUs recurrence rates, and it was used in previous economic analyses.[13] The recurrence rate was assumed to be identical between all treatment arms. The prevalence of osteomyelitis for patients with PrUs is between 17%[30] to 32%.[31] The

mean of the studies by Darouiche et al, 1994 and Sugarman et al, 1983 was used in the models since these studies continue to be routinely referenced in the current literature as the prevalence of OSM for individuals with chronic PrU.

3.2.3 Transition Rates

Transition probabilities between each health state and the converted Markov model probabilities are shown in Table 8. The transition probability for the OSM state was derived from a study by Bodavula et al, 2015 who performed a retrospective cohort study of adult patients with PrUs and pelvic OSM from 2006 to 2011.[32] In this study, 120 of 220 patients diagnosed and treated with OSM were readmitted with OSM equating to a probability of 54.5% recurrence over six years. The transition probability of PrU to Dead was referenced from the article by Lynder et al, 2012, who completed a retrospective analysis of hospital-acquired PrUs and reported on the risk of mortality with PrUs within 30-days of being discharged from the hospital.[33] OSM to Dead transition probabilities were derived from the study by Huang et al, 2016 who evaluated the risk of mortality in the elderly who have been diagnosed with chronic OSM.[34] The transition probabilities of PrU to healed was obtained from the Koel and Houghton, 2014 and Ford et al, 2002 studies for the applicable DAM.[20,21]

Table 8: Yearly Transition Probabilities in Both Models

Variable	%	Reference	Distribution
pOSM to Death Age 70	**0.7**	**Huang et al, 2016**	**Beta**
80	**1.1**		
>85	**1.4**		
pPrU to Death	**2.0**	**Lynder et al, 2012**	**Beta**
pOSM stay OSM	**4.2**	**Bodavula et al, 2015**	**Beta**
pPrU to Healed E-Stim	**84.0**	**Houghton et al, 2010**	**Beta**
pPrU to Healed SWC	**40.5**	**Houghton et al, 2010**	**Beta**
pPrU to Healed NPWT	**20.3**	**Ford et al, 2002**	**Beta**
pPrU to Healed SWC	**26.1**	**Ford et al, 2002**	**Beta**

pOSM-probability of osteomyelitis ; pPrU-probability of pressure ulcer ; E-Stim-electrical stimulation ; SWC-standard wound care ; NPWT-negative pressure wound therapy ; SWC-standard wound care

3.2.4 Utility Values

Utility values for individuals in the community with PrUs have not been published. However, Thein et al, 2009 evaluated the health status utilities in long-term care residents in Ontario both with and without PrU on health-related quality of life (HRQOL).[35] Essex et al, 2009 studied the impact of pressure ulceration on health-related quality of life for hospital inpatients in the United Kingdom.[36] The mean utility scores of these two studies were used in the models and assumed to be similar to the community PrU population and shown in Table 9. QALYs in the healed terminal mode in the decision tree were assumed to be the same as the QALYs for the healed absorbing state in the Markov model.

Table 9: Utility Values

EQ-5D Index Scores	With PrU	Without PrU	Reference	Distribution
Markov Model	**0.225 (0.35)**	**0.42 (0.36)**	**Thein et al, 2009** **Essex et al, 2009**	**Beta**

3.2.5 Cost-Effectiveness Analysis

The cost-effectiveness of managing patients with an advanced therapy compared with SWC alone was calculated as the difference between the expected costs of the two strategies divided by the difference between the expected outcomes between the two strategies. The relative cost effectiveness of E-Stim and NPWT was defined as the cost per QALY gained. If a treatment resulted in an improved outcome for less cost, it was defined as a "dominant treatment". A treatment is considered dominant when one treatment has a higher effectiveness and lower cost than its comparator.[15] The willingness to pay (WTP) values a health gain in terms of the amount a person is willing to pay to obtain the health gain.[37] The WTP threshold chosen for this analysis was $50,000 per QALY which is frequently referenced in the literature.[38]

3.2.6 Sensitivity Analyses

Deterministic sensitivity analyses (DSA) were performed to identify how the cost per QALY gained with using E-Stim or NPWT would change by varying different individual parameters in the models. For the E-Stim versus SWC model, cost for E-Stim was increased, probability of PrU healing was decreased, and probabilities of recurrence rates were decreased by a rate of 25%. For the NPWT versus SWC model, costs for SWC were increased, probability of healing was decreased, and probabilities of recurrence rates were decreased also by a rate of 25%.

Probabilistic sensitivity analyses (PSA) were undertaken to assess uncertainty in the model inputs using Monte Carlo simulations (1000 iterations of the model) by simultaneously varying the probabilities, unit costs, resource use values and utilities within the model. Probabilities were varied according to a beta distribution using expected values of population size and occurrences, utilities were varied according to a beta distribution using means and standard deviations. Costs were varied randomly, according to a gamma distribution using means and standard deviations.

3.3 Results

3.3.1 E-Stim versus SWC

Patients who receive E-Stim for the treatment of PrUs benefit from an additional 0.2 QALYs at an incremental cost of $3675.82 less than SWC (Table 10). The cost analysis determined that E-Stim is dominant over SWC since E-Stim treatment is less costly but more effective in comparison to SWC. The cost for treating a patient with a PrU using SWC alone was $7976.02 with an effectiveness of 5.14 QALYs. The cost for treating a patient with a PrU using E-Stim was $4300.20 with an effectiveness of 5.34 QALYs (as shown in Figure 6). The Markov model predicted that 96.8% individuals with a PrU receiving E-Stim would be healed compared to 80.9% of individuals receiving SWC alone after one year (Table 11).

Table 10: ICER Value E-Stim versus SWC

	Cost	**Incremental Costs**	**Effectiveness**	**ICER**
SWC	**7976.02**	**3675.82**	**5.14**	**dominated**
E-Stim	**4300.20**		**5.34**	

Table 11: Number of Patients in Each Health State after 1 year in the Markov Model for a Cohort of 1000 Patients (%)

	OSM	**PrU**	**Healed**	**Dead**
E-Stim versus SWC model				
E-Stim	**0**	**0**	**96.8**	**2.5**
SWC	**1.0**	**13.8**	**80.9**	**4.2**
NPWT versus SWC model				
NPWT	**2.2**	**38.5**	**53.8**	**5.5**
SWC	**1.8**	**29.4**	**63.7**	**5.1**

OSM-Osteomyelitis; PrU-Pressure Ulcer; E-Stim-electrical stimulation; SWC-standard wound care; NPWT-negative pressure wound therapy

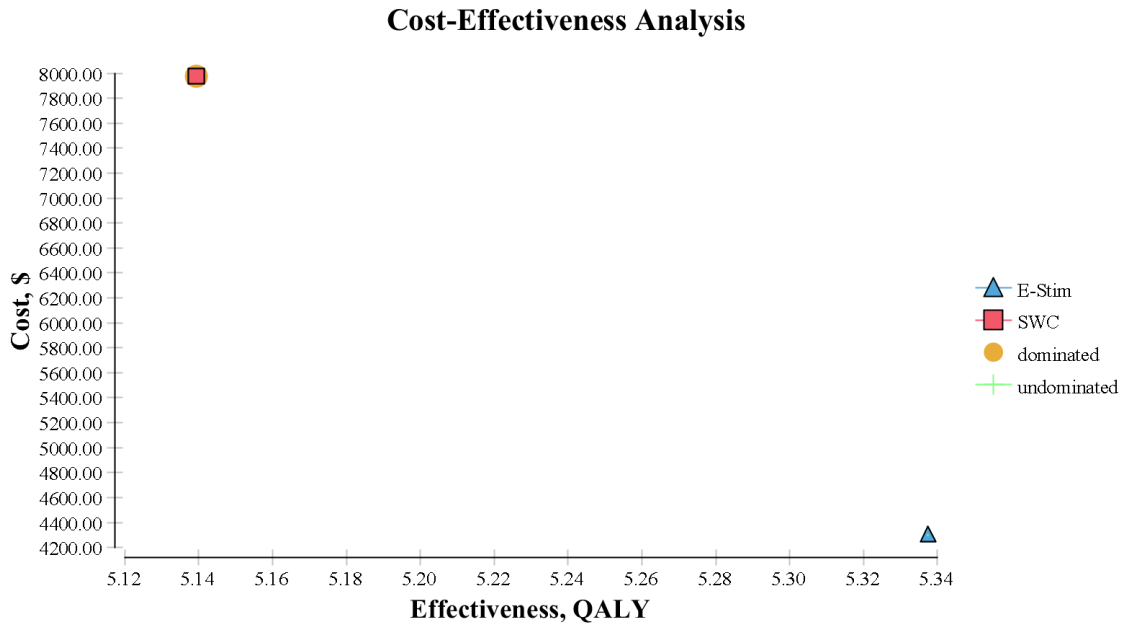


Figure 6: Cost-Effectiveness of E-Stim versus SWC

Using DSA for multiple parameters, E-Stim continued to be dominant versus SWC (Figures 7-9). In the PSA, 65.3% of the total iterations resulted in Incremental Cost Effectiveness Ratios (ICERs) that were economically dominant for E-Stim and an additional 31.0% of iterations were below the WTP threshold which is most commonly set at $50,000. Thirty-eight percent of iterations were greater than the $50,000 per QALY threshold (Table 12). A visual representation of the probabilistic sensitivity analysis is shown using an ICER Scatterplot (Figure 10). Scatterplots are useful to visually demonstrate the amount of uncertainty by plotting the data into quadrants. In the E-Stim versus SWC scatterplot, most data points fall in Quadrant 1 showing that E-Stim is dominant over SWC. All points fall below the $0.00 line showing that E-Stim is always less costly than SWC.

Table 12: ICER Report E-Stim versus SWC

COMPONENT	QUADRANT	ICER	FREQUENCY	PROPORTION
C1	IV	Superior	652	0.652
C2	I	ICER<50000.0	0	0
C3	III	ICER>50000.0	38	0.038
C4	I	ICER>50000.0	0	0
C5	III	ICER<50000.0	310	0.31
C6	II	Inferior	0	0
Indifferent	origin	0/0	0	0

ICER-Incremental Cost Effectiveness Ratio; E-Stim- electrical stimulation; SWC- standard wound care

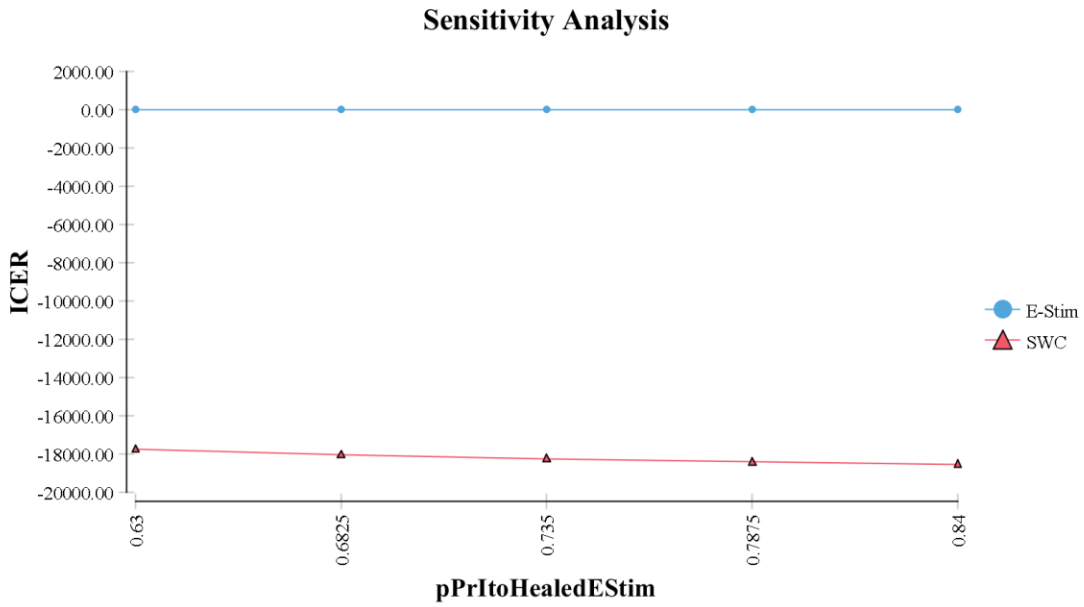


Figure 7: Pressure Ulcers Healed with Electrical Stimulation Treatment Decreased by 25%

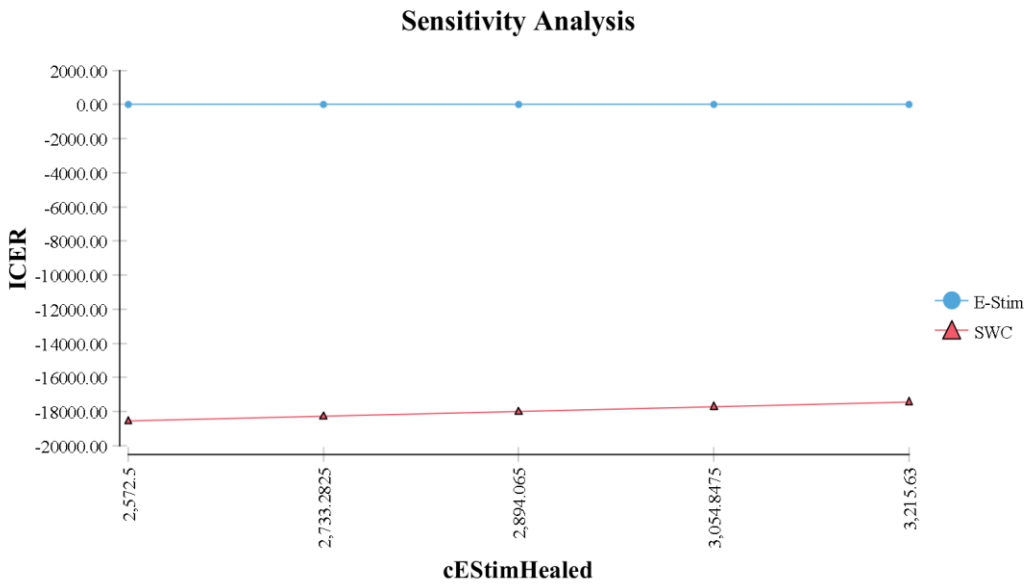


Figure 8: Electrical Stimulation Cost Increased by 25%

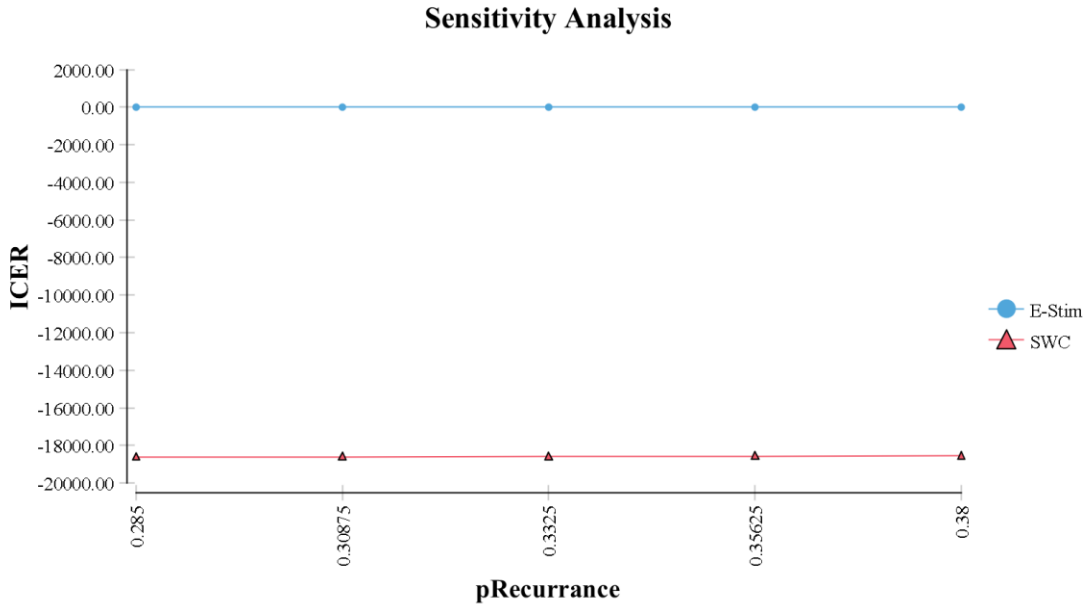


Figure 9: Pressure Ulcer Recurrence Rate Decreased by 25%

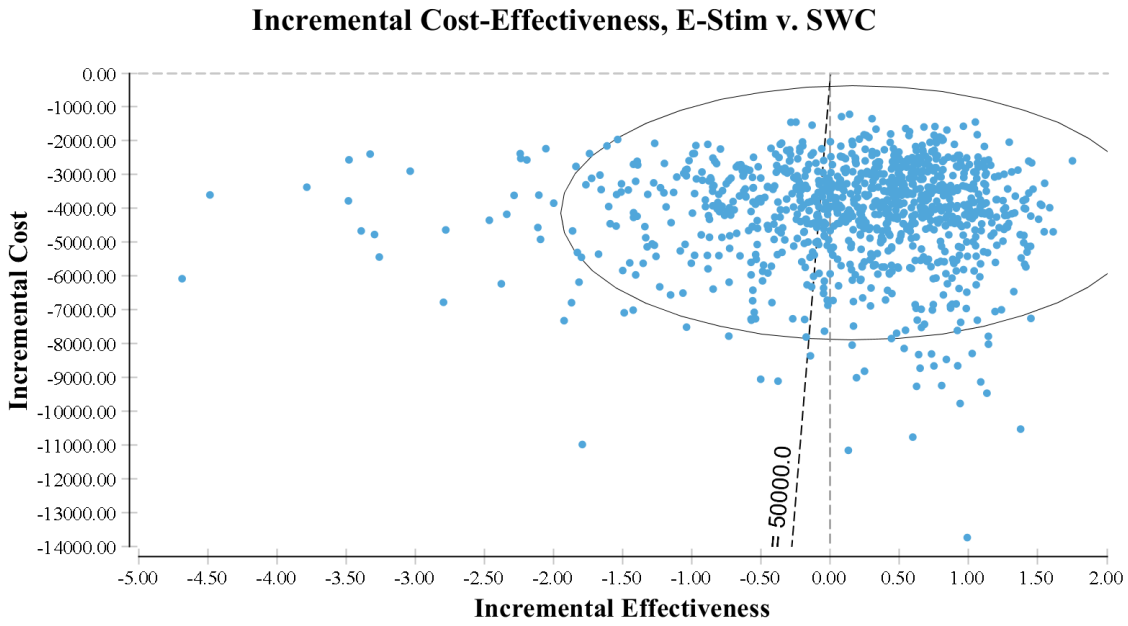


Figure 10: Incremental Cost-Effectiveness Ratio Scatterplot: Electrical Stimulation (E-Stim) versus Standard Wound Care (SWC)

3.3.2 NPWT versus SWC

Patients who receive NPWT for the treatment of PrUs decreased 0.14 QALYs at an incremental cost of $7041.56 for NPWT over SWC resulting in SWC being the dominant intervention for the treatment of PrUs in the second model (Table 13). The cost for treating a patient with a PrU using SWC was $12,379.69 with an effectiveness of 4.94 QALYs. As shown in figure 11, the cost for treating a patient with a PrU using NPWT was higher than SWC ($19,421.25) and the QALYs was lower (4.80). For individuals that did not heal within the six-week period and have a PrU or recurrence, the Markov model predicted that 53.8% of PrUs would be healed using NPWT compared to 63.7% of individuals receiving SWC alone after one year (Table 11).

Table 13: ICER Value NPWT versus SWC

	Cost	Incremental Costs	Effectiveness	ICER
SWC	**12379.69**		**4.94**	

NPWT	**19421.25**	**7041.56**	**4.80**	**dominated**

ICER- Incremental cost effectiveness ratio; NPWT-negative pressure wound therapy; SWC- standard wound care

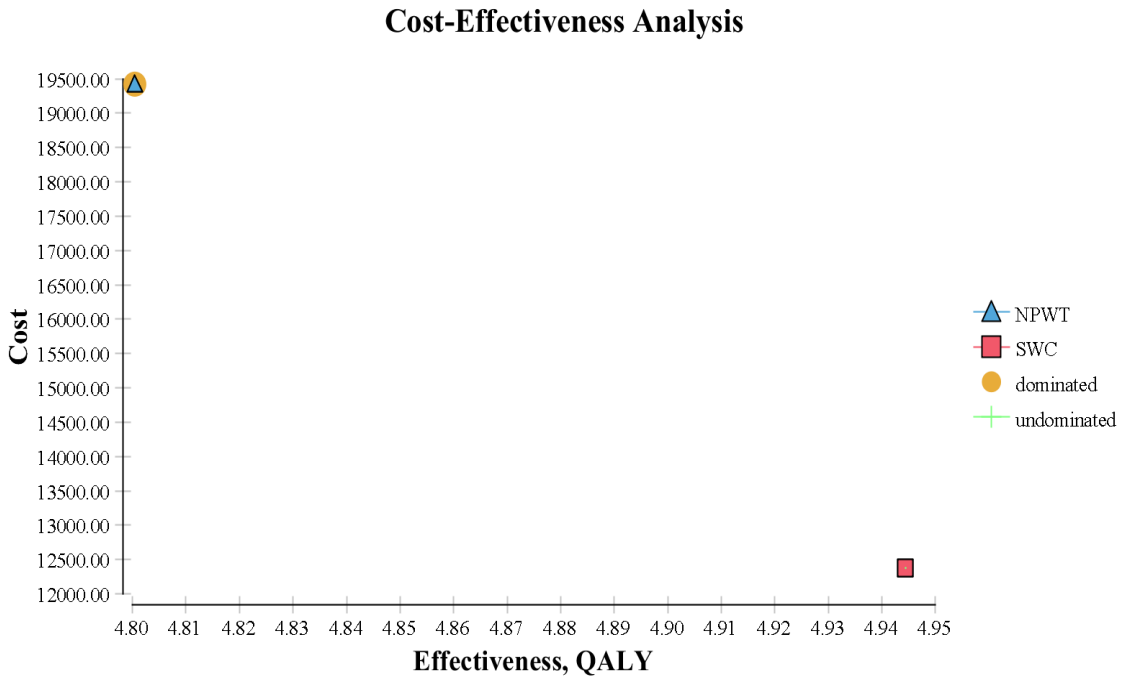


Figure 11: Cost-Effectiveness of NPWT versus SWC

Using the deterministic sensitivity analysis for multiple parameters, SWC continued to be dominant versus NPWT (Figures 12-14). In the probabilistic sensitivity analysis, 44.9% of the total iterations resulted in ICERs where NPWT was costlier than SWC but below the WTP threshold, 5% of the total iterations where NPWT was less costly than SWC but above the WTP threshold, and 24.5% of the total iterations resulted in ICERs that were economically inferior for NPWT (Table 14). The ICER Scatterplot for NPWT versus SWC is shown in Figure 15. Most of the data points fall into quadrants 2, 4, and 6 above the $0 line indicating SWC is less costly than NPWT in most instances.

Table 14: ICER Report NPWT versus SWC

COMPONENT	QUADRANT	ICER	FREQUENCY	PROPORTION
C1	**IV**	**Superior**	**9**	**0.009**

C2	**I**	**ICER<50000.0**	**449**	**0.449**
C3	**III**	**ICER>50000.0**	**1**	**0.001**
C4	**I**	**ICER>50000.0**	**291**	**0.291**
C5	**III**	**ICER<50000.0**	**5**	**0.005**
C6	**II**	**Inferior**	**245**	**0.245**
Indifferent	**origin**	**0/0**	**0**	**0**

ICER-incremental cost effectiveness ratio; NPWT-negative pressure wound therapy; SWC-standard wound care

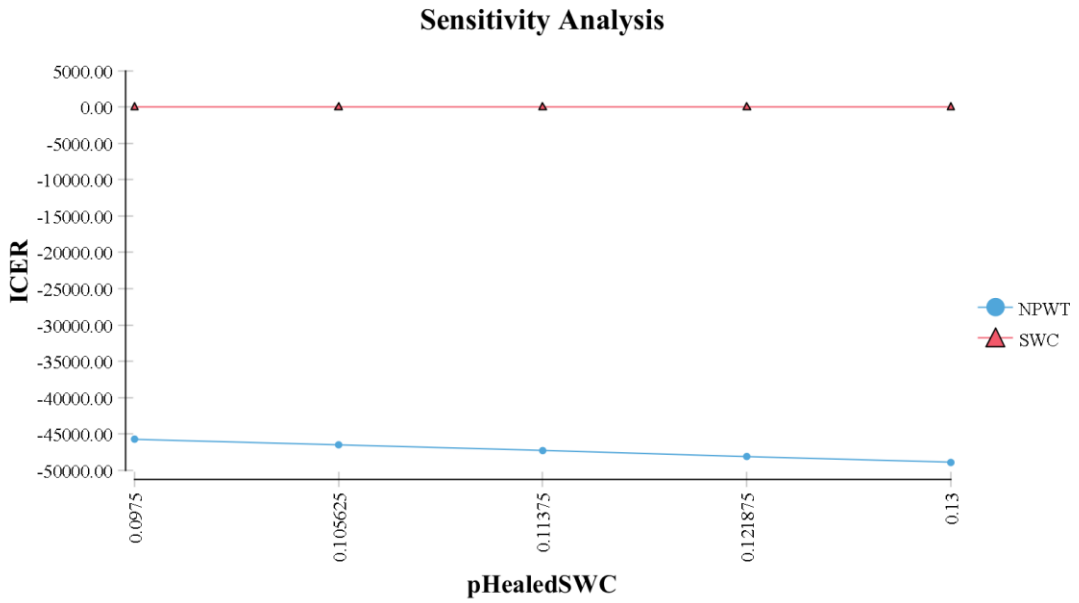


Figure 12: Pressure Ulcers Healed with Standard Wound Care Decreased by 25%

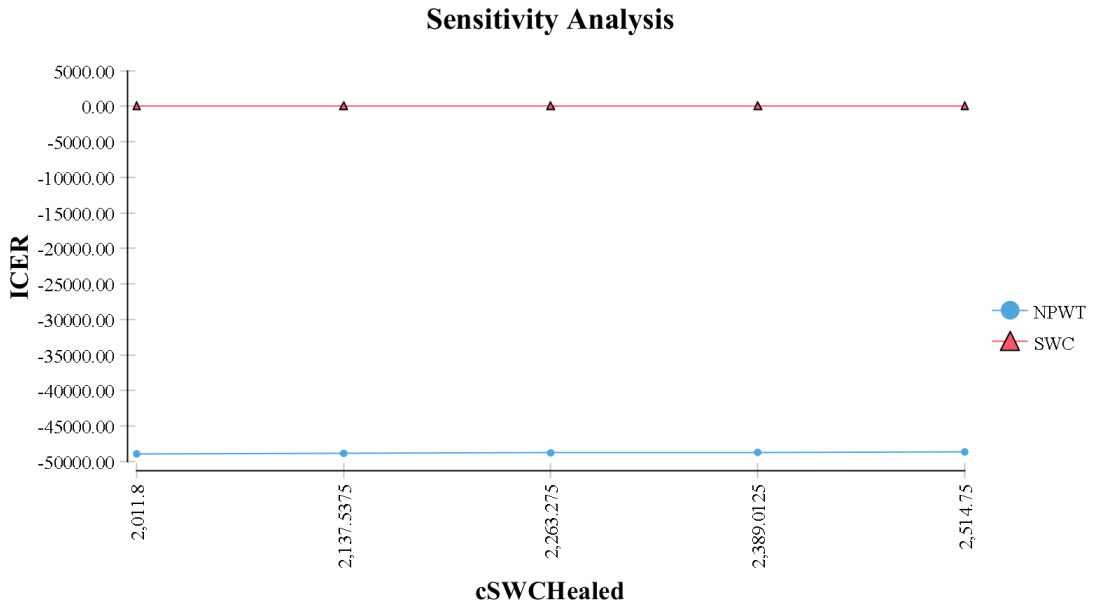


Figure 133: Standard Wound Care Costs Increased by 25%

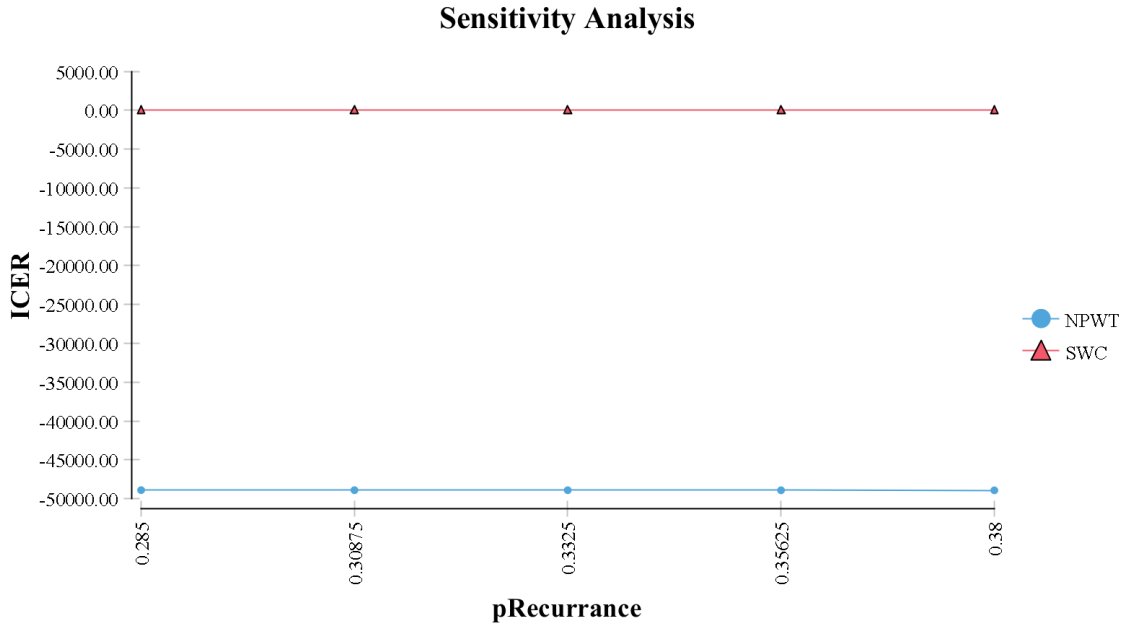


Figure 144: Pressure Ulcer Recurrence Rate Decreased by 25%

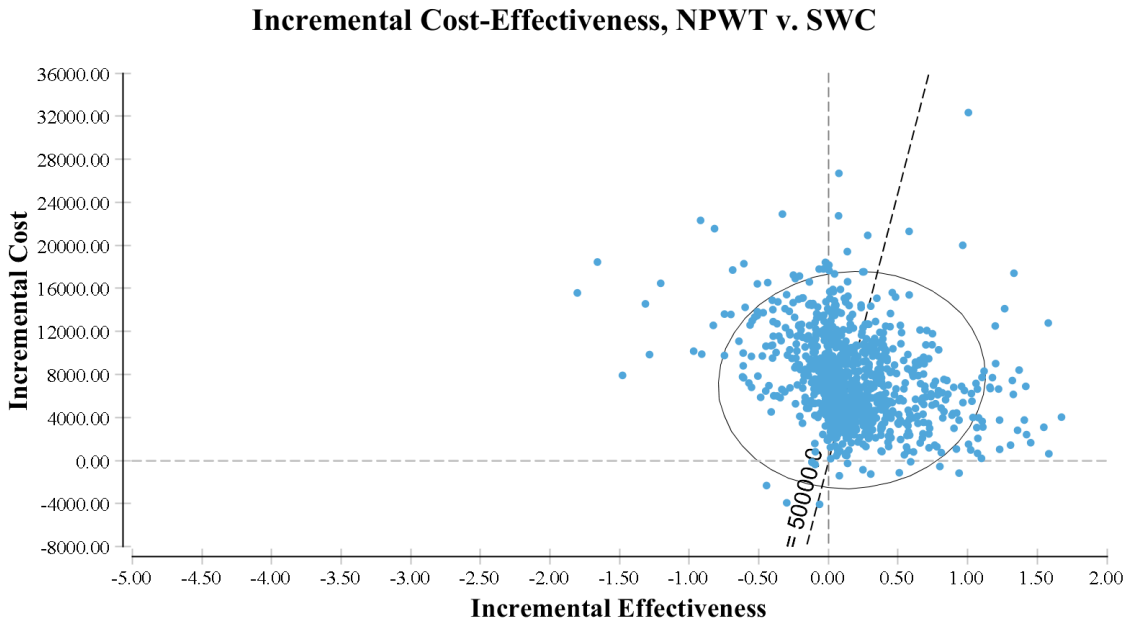


Figure 15: Incremental Cost Effectiveness Ratio: Scatterplot Negative Pressure Wound Therapy (NPWT) versus Standard Wound Care (SWC)

3.4 Discussion

Using the decision analytic framework for E-Stim versus SWC, the use of E-Stim for the treatment of PrUs was dominant over SWC. By contrast, in the decision analysis that compared NPWT to SWC, the use of SWC for the treatment of PrUs was dominant over NPWT. The analysis of the two models demonstrates that from a cost-utility perspective, E-Stim is the most cost-effective treatment for the healing of PrUs. This finding is supported by treatment recommendations made in multiple best practice guidelines.[6–8]

The results from this study are based on a DAM that combines a decision tree with a Markov model, which is a new approach to estimate and compare the cost for two treatment interventions for PrUs. This approach was used since it most closely mimics clinical pathways for individuals with PrUs receiving treatment in home and community care (HCC). Patients who are diagnosed with PrUs are provided SWC and advanced therapies such as E-Stim or NPWT. The decision as to which treatment they receive is determined by the physician or nursing health care provider in the home. Patients that progress to healing utilizing the initial treatment intervention are discharged from HCC

services. Patients who do not heal their PrU or have a recurrence of their PrU, progress to the chronic disease states of OSM or PrU and continue to require HCC. Our model allowed for patients to follow the decision tree arm for six weeks, and if not healed, a Markov model was applied for the chronic states.

This paper was also unique in its use of two models in order have a common parameter of QALYs to compare two PrUs advanced treatments. There are no known research papers that directly compare E-Stim to NPWT and therefore each was analyzed separately using SWC as the comparator. The evidence for the use of E-Stim for the treatment of PrU was taken from a meta-analysis because it is the highest level of evidence and therefore considered to be the most accurate in its ability to determine the number of PrUs healed with use of E-Stim versus SWC.[20] For the NPWT analysis, no meta-analysis that compared NPWT to SWC using number of healed PrU was available. Therefore, a randomized controlled trial (RCT) was used.[21] With both therapies, the highest level of available evidence was chosen.

In order to assess for the variables of number of PrUs healed, length of time to PrU healing, and recurrence rates, sensitivity analysis was conducted for both models using one-way sensitivity analysis of 25%. After sensitivity analysis the results remained similar for the E-Stim versus SWC and NPWT versus SWC. Specifically, E-Stim remained dominant over SWC, and SWC remained dominant over NPWT in all the explored scenarios.

The results from the DAM for E-Stim versus SWC showed that after one year, individuals receiving E-Stim for the treatment of PrU's would be healed in 96.8% of cases versus 80.9% of cases treated with only SWC. These estimates are significantly higher than the estimates found in the study by Mittmann et al, 2011 who reported that after 1 year of treatment with E-Stim, an average of 20.8% of individuals with a PrU would be healed compared to an average of 4.5% of individuals receiving SWC alone. We used healing rate probabilities for E-Stim and SWC which were much higher than the RCT data used to build the model in the study by Mittmann et al.

The cost for the predication of healing with the use of E-Stim over six weeks was found to be $2572.50. The results are similar to a recently published Ontario Health Technology Advisory Committee (OHTAC) analysis which reported that when E-Stim was administered by a health care professional for the treatment of PrU, cost per patient ranged from $712 in long-term care to $2,572 in home care. When administered by a patient or caregiver, cost per patient was $179.00 CDN (2017).[39] OHTAC predicted the need for $0.77 to 3.85 Million yearly costs to implement E-Stim for the treatment of PrUs in Ontario. Contrary to the results in the OHTAC review, we found that the addition of E-Stim for the treatment of PrUs is cost effective given it is dominant over SWC.

The cost for the healing of PrU in six weeks with NPWT was estimated to be $5322.66 which is comparable to the average cost to heal multiple types of wounds using NPWT of $4650.00 US reported by Delhougne et al, 2018.[25] We attempted to use the costing data and QALY data to determine cost per QALYs gained for the use of NPWT as an advance treatment versus SWC since this has not been previously reported in the literature. Due to SWC being a dominant treatment in comparison to NPWT, we were unable to report on cost per QALYs gained. These findings contrast with previous cost studies which showed NPWT was a cost-effective treatment for PrUs.[16–18]

This research uses a novel approach by linking a decision tree and Markov model for cost analysis of two advanced therapies for PrU treatment. Using this decision analytic model, cost analysis was able to closely mimic outcomes that are based on clinical practice. This approach for the costing of wound care treatment also can also allow for the evaluation of healing, non-healing and non-healable wounds in the same model which may be useful in future research.

3.5 Conclusion

From an Ontario health system perspective, the use of E-Stim for the treatment of PrU's is a cost-effective intervention whereas using NPWT to treat PrU's is not cost-effective when compared to standard wound care practices without an advanced therapy. This study supports the need for increased knowledge translation for the use of E-Stim in the

treatment of PrUs as an intervention that supports best practice and cost effectiveness in this patient population.

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4 Cost of Pressure Ulcer Care for Individuals Living in the Community with a Mobility Impairment

4.1 Introduction

Pressure ulcers (PrUs) are a common complication occurring across all sectors of health care including hospitals, long term care, and home and community care.[1–3] A PrU is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.[4] The severity of PrUs has been described by the National Pressure Ulcer Advisory Panel's Staging system, with a Stage IV PrU representing a more severe and deeper wound.[4] PrUs often occur in those with mobility impairment and are a common secondary health complication for individuals with spinal cord injury (SCI).[5,6] PrUs result in a decreased quality of life[7–9] and increased mortality rates.[10–12] PrUs also cause a large financial burden to the health care system.

Bennett et al, 2004 evaluated the cost of patients in a hospital or long term care setting in the United Kingdom and found the mean cost of healing a single stage III PrU was 7,313£ and rose to 10,551£ if the patient had a Stage IV PrU.[13] Brem et al, 2010 also evaluated the cost of PrUs in a hospital setting by conducting a retrospective chart review of 19 patients with PrUs who were admitted over a 29 month period to a university based, tertiary-care hospital in the USA.[14] The total hospital costs for a community-acquired PrU was $124,327US. Chan et al, 2013 conducted a similar study while patients with PrUs were admitted to acute care hospitals in Canada.[15] Specifically, they used an administrative database called the Ontario Case Costing Initiative (OCCI) to evaluate the net cost of PrUs that were either present prior to admission or occurred during admission to acute hospitals. Over a 5-year period (2002-2006), 1351 with hospital acquired PrUs and 2524 people with community acquired PrUs were identified and compared to a similar matched group of elderly patients (>65years of age) without PrUs. The total net adjusted hospitalization cost of treating someone with a stage II – IV PrU ranged between $11,000 and $90,000 CDN with higher costs for people with more severe PrUs (stage IV) and with hospital acquired ulcers. These results provide estimates of the additional costs incurred by hospitals for patients with PrUs, however, this does not provide a value for

the total cost of a PrU to other parts of the Canadian health care system and to society in general.

Costs of living in the community with a PrU have been explored as part of a pragmatic clinical research trial conducted in a small urban center in Ontario, Canada.[16] Health care costs associated with community based PrU care was gathered for 12 community dwelling individuals living with SCI and PrUs who were followed for a 7-month period. Using unit costs from publicly available sources, they estimated an average incremental cost of $4745 +/- 9270 per month in 2011 Canadian dollars. Values per patient were markedly different depending on whether they required emergency room visits (5 patients) or hospital admissions (2 patients). However, these cost estimates did not include any out-of-pocket expenses or costs associated with wound care equipment or supply costs. A case study published by Allen and Houghton in 2004, estimated the cost of treating a stage III PrU in the community was $9000 per month Canadian dollars. This case did include lost wages, wound care supplies and equipment rental costs.[17]

There is very limited information about the cost of treating chronic PrUs occurring in people living in the community. Most cost estimates published to date use administrative databases and aggregate data rather than patient level data that is collected prospectively to identify the number or type of resources used. The objective of this study was to determine the cost of PrU care in a representative sample of individuals living in the community with a mobility impairment. We used cost diaries to follow patients who had been living with a chronic PrU allowing for a cost estimate of "real life" practice. Costs were evaluated from a ministry of health and long-term care (MOHLTC) and societal perspective.

4.2 Methods

4.2.1 Population

The population cohort was obtained as part of a multi-year knowledge mobilization project called the E-Stim Collaboration Project aimed to promote the uptake of best practices related to PrU care including the use of an advanced therapy called E-Stim. Participants were identified with mobility impairment including SCI who lived in the

community, had an open PrU (>1cm^2), and were receiving publicly funded home care services. Within this region, health care is coordinated by the South West Local Health Integrated Network (South West LHIN) which is funded by the MOHLTC. The South West LHIN provides home care services by contracting several provider agencies that employ nurses, allied health professionals, as well as unregulated support workers. Ethics approval was obtained from the Western University Health Science Research Ethics Board (REB # 106157), the Lawson Health Research Institute Research Ethics Board, and the Ethics Committee of participating agencies (see Appendix 3 and 4).

4.2.2 Resource Utilization

Participants who signed a written consent form underwent an in-home initial comprehensive PrU assessment which included a cost diary. All cost diary data was collected in person with participants conducted by the same lead author. Costs were analyzed from a MOHLTC and societal perspective including government assistance, patients and informal caregivers. Participants were instructed to answer cost diary questions based on recall for the six-month period prior to the initial assessment. They were also asked to indicate if they felt the costs they identified were related to their PrU. The following resources were collected (i) emergency room (ER) visits, (ii) inpatient hospitalization stays, (iii) family physician visits, (iv) physician specialist visits, (v) clinic visits, (vi) private pay nursing and allied health practitioner visits, (vii) laboratory tests, (viii) diagnostic imaging, (ix) medications, (x) paid employment time lost, (xi) homemaking or volunteer time lost, (xii) assistance with daily activities time (xiii) and cost of items purchased for pressure injury management. Home and community care (HCC) costs were provided for each enrolled participant using South West LHIN case costing database. HCC utilization included the costs of publicly funded wound care supplies and equipment, and the number of home visits by various health care providers (nursing, enterostomal therapy (ET), physiotherapy, occupational therapy, registered dietitian and personal support workers).

4.2.3 Costs

Sources used to estimate the cost of each item identified by the participants are summarized in Table 15. Costs for services provided by the publicly funded home and community care (HCC) were provided by the South West LHIN. Costs for physician visits, laboratory tests and medical procedures were obtained from the Ontario MOHLTC Schedule of Benefits, 2015.[18] Hospital costs were obtained from the OCCI.(19) ER visit costs were based on the results by Zoutman et al, 1998 with costs inflated to 2017 dollars.[19] These values were also used in the study by Chan et al, 2012 to assess ER visit costs. Average hourly wages for personal assistance and homemaking was obtained from the Human Resources and Skills Development Canada.[20] Unit costs for medications were obtained from the Ontario Drug Benefit Formulary. Equipment costs were specific to out of pocket expenses paid by the participant related to their PrU.

Table 15: Unit Costs and Reference

Unit Costs			
Variable	**Unit Cost**	**Definition**	**References**
Health Care Professionals			
Per visit			
Family Physician	$ 38.35	Code A004	(1)
Plastic Surgeon	$ 81.10	Code A085	(1)
Cardiologist	$ 157.00	Code A605	(1)
Physiatrist	$ 39.00	Code H312	(1)
Otolaryngologist	$ 77.90	Code A245	(1)
Infectious Disease Specialist	$ 157.00	Code A465	(1)
Wound Specialists	$ 38.35	Code A004	(1)
Urologist	$ 80.00	Code A355	(1)
Vascular Surgeon	$ 90.30	Code A175	(1)
General Surgeon	$ 90.30	Code A035	(1)
General emergency visit	$ 76.90	Code A100	(1)
Radiologist	$ 50.00	Code A335	(1)
Orthopedic Surgeon	$ 83.10	Code A065	(1)
Haematology	$ 157.00	Code A615	(1)
Ophthalmology	$ 82.30	Code A235	(1)
Medical Oncology	$ 157.00	Code A445	(1)
Psychiatry	$ 199.40	Code A195	(1)
Gastrologist	$ 157.00	Code A415	(1)
Per hour			

Average Salary in Ontario	$ 26.08		(2)
Private Pay Services			
Naturopath	$ 1,200.00	Over 6 months period	Patient report
RMT	$ 60.00	cost per visit	Patient report
Emergency Room			
ER visit per hour	$ 358.93		(3)
Hospitalization (per day)			
Pressure Injury infection	$ 1,030.60	OCCI code L893	(4)
AAA repair	$ 4,020.00	OCCI code I714	(4)
Urinary Tract Infection	$ 924.41	OCCI code N390	(4)
Dehydration	$ 885.91	OCCI code E860	(4)
Bowel Obstruction	$ 1,290.85	OCCI code K565	(4)
ALC bed	$ 842.00	CIHI code Z59	(5)
Clinic Visits			
Pain clinic	$ 38.35	Code A004	(1)
Wound clinic	$ 38.35	Code A004	(1)
Walk in clinic	$ 38.35	Code A004	(1)
Laboratory test and DI (per test)			
CBC	$ 16.00	Code L393	(6)
X-ray hip	$ 31.40	Code X060	(1)
X-ray chest	$ 32.65	Code X091	(1)
X-ray leg	$ 21.30	Code X063	(1)
CT scan hip	$ 43.25	Code X412	(1)
ECG	$ 11.05	Code G310, G313	(1)
Urine Culture	$ 7.00	Code L641	(6)
Wound Swab	$ 25.00	Code L628	(6)
PICC line	$ 168.00	Code Z456	(1)
MRI	$ 48.35	Code J163	(1)
Medications			
hydromorph contin	$ 0.97	4.5mg Cap	(7)
fentanyl	$ 3.66	25mcg/hr Trans Patch	(7)
percocet	$ 0.13	5mg/325mg Tab	(7)
oxyNEO	$ 0.18	5mg Tab	(7)
oxybutynin	$ 0.10	5mg Tab	(7)
zopiclone	$ 0.22	5mg Tab	(7)
lorazepam	$ 0.07	2mg Tab	(7)
haldol	$ 0.44	5mg Tab	(7)
gabapentin	$ 0.04	100mg Cap	(7)
amitriptyline	$ 0.15	50mg Tab	(7)
baclofen	$ 0.31	20mg Tab	(7)
ratio-Lenoltec	$ 0.05	300mg & 15 mg & 15 mg	(7)
tylenol	$ 0.03	500mg	(7)

co-citalopram	$ 0.13	20mg Tab	(7)
paroxetine	$ 0.33	20mg Tab	(7)
cymbalta	$ 0.48	300mg Cap	(7)
escitalopram	$ 0.33	20mg Tab	(7)
quetiapine	$ 0.78	150mg Tab	(7)
novo mirtazapine	$ 0.10	15mg Tab	(7)
levofloxacin	$ 1.37	500mg Tab	(7)
ciprofloxacin	$ 0.50	500mg Tab	(7)
xarelto	$ 2.87	20mg Tab	(7)
ferrous gluconate	$ 0.04	300mg	(7)
actonel	$ 11.66	35mg	(7)
cholecalciferol	$ 2.43	70mg Tab	(7)
docusate sodium	$ 0.03	100mg Cap	(7)
levothyroxine	$ 0.90	0.025mg	(7)
metoprolol	$ 0.06	50mg Tab	(7)
nabilone	$ 6.78	1mg	(7)
oxybutynin	$ 0.97	5mg Tab	(7)
warfarin	$ 0.67	2.5mg Tab	(7)
senokot	$ 0.03	8.6mg Tab	(7)
risedronate	$ 11.19	150mg Tab	(7)
biscodyl	$ 0.05	5mg Tab	(7)
salbutamol	$ 5.00	100mcg	(7)
colace	$ 0.13	100mg Cap	(7)
fumarate	$ 0.11	300mg Cap	(7)
lactulose	$ 0.01	30mLs	(7)
olanzapine	$ 7.56	20mg Tab	(7)
atorvastatin	$ 0.80	40mg Tab	(7)
furosemide	$ 0.04	20mg Tab	(7)
enablex	$ 1.61	7.5mg Tab	(7)
dutasteride	$ 0.30	20mg Tab	(7)
pantoloc	$ 2.08	40mg	(7)
diltiazen	$ 0.48	180mg Tab	(7)
eliquis	$ 1.63	5mg	(7)
toloxin	$ 0.21	0.125mg Tab	(7)
celebrex	$ 0.26	200mg Cap	(7)
lansoprazole	$ 0.50	30 mg Cap	(7)
rabeprazole	$ 0.13	20mg Tab	(7)
methotrexate	$ 0.63	2.5mg Tab	(7)
amlodipine	$ 0.13	5mg Tab	(7)
atorvastatin	$ 0.80	10mg Tab	(7)
midodrine	$ 0.44	2.5mg Tab	(7)

morphine	$ 2.09	15mg Tab	(7)
nitrofurontoin	$ 0.23	100mg	(7)
venlafaxine	$ 0.12	75 mg Cap	(7)
ranitidine	$ 0.12	150mg Tab	(7)
gliclazide	$ 0.06	60mg Tab	(7)
hydrochlorothiazide	$ 0.02	12.5mg Tab	(7)
rosuvastatin	$ 0.14	10mg Tab	(7)
metformin	$ 0.43	500mg Tab	(7)
losartan	$ 0.31	100mg Tab	(7)
sulfatrim	$ 0.15	800mg	(7)

4.3 Analysis

HCC costs were provided for 11 participants from South West LHIN case costing database. For the participants who did not have administrative data provided, the mean cost for HCC purchased services and purchased items calculated for 11 participants was used. The cost of zero ($0.00) was used when a participant did not report utilization of a resource in the cost diary. All cost diary items were entered into a Microsoft® Excel spreadsheet and average monthly costs per participant were calculated by summing the total costs over six months for each participant. The overall cost per patient per month for the 22 participants was calculated using the mean monthly cost for each participant. Average costs were also calculated based on costs identified as PrU specific and type of mobility impairment. Sensitivity analysis was conducted on costs subject to variability. This included HCC costs, hospitalization costs, and purchased equipment costs.

4.4 Results

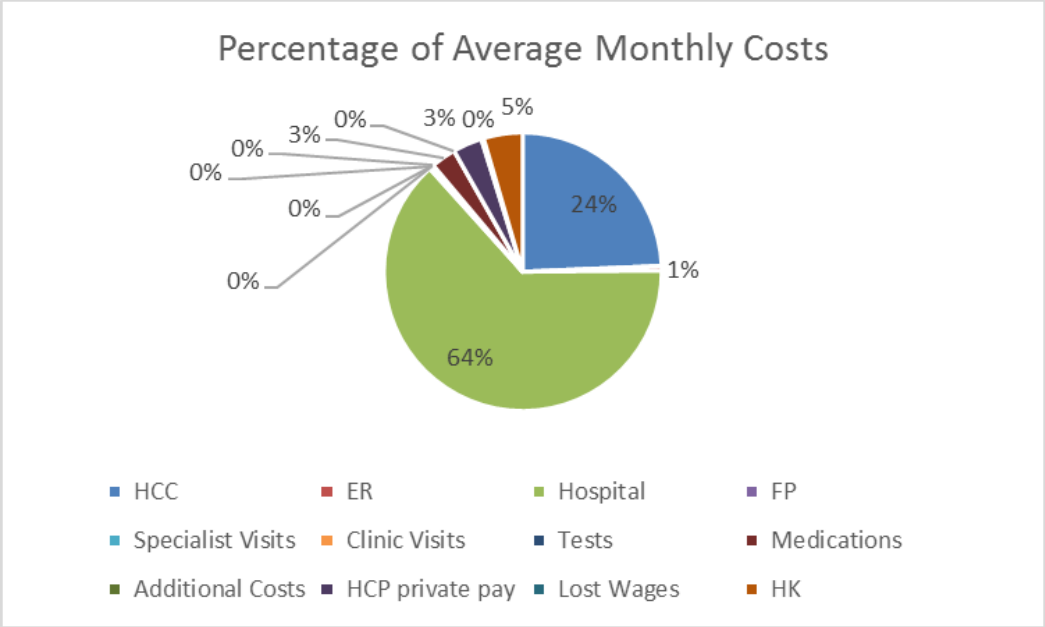
Twenty-two participants were included in the study (see Table 16). The average age was 58.5 years (+/-15.5) and 68.2% (15/22) were male. Eighty-two percent of were individuals who had a SCI for an average of 13.8 (+/-11.5) years, with majority (55%) having only lower extremity involvement (paraplegia). Four people had mobility restrictions due to other neurological conditions including stroke, Parkinson's disease, depression and a below knee amputation. Mean wound duration for the cohort was 21.2 (+/-24.2) months with a mean surface area of 6.6 (7.6) cm^2. PrU location included ischial

tuberosity (50%), coccyx (18.2%), sacrum (13.6%), foot/heel (9.1%), leg from prosthesis pressure (4.5%) and shoulder (4.5%). Participants had PrUs that were primarily stage III (40.9%) and IV (50%), one participant was diagnosed with a deep tissue injury, and one participant had eschar overlying the wound making the wound unstageable.

Table 16: Demographics

Age Mean (SD)	58.4(15.5)
Male/Female (%)	Male: 68.2; Female: 31.8
Injury (%)	
• Upper SCI (cervical spine injury)	27.0
• Lower SCI	55.0
• Catatonic Depression	4.5
• Below Knee Amputation	4.5
• Cerebrovascular Accident	4.5
• Parkinson's Disease	4.5
Years with SCI Mean (SD); n=18	13.8 (11.5)
Months with PrU Mean (SD)	21.2(24.2)
Wound Surface Area in cm^2 Mean (SD)	6.6(7.6)
Wound Site (%)	
• Ischial Tuberosity (n=11)	50.0
• Coccyx (n=4)	18.2
• Buttock (n=3)	13.6
• Other (n=4)	18.2
Stage of PI (%)	
• Unstageable (n=1)	4.5
• Deep Tissue Injury (n=1)	4.5
• Stage III (n=9)	40.9
• Stage IV (n=11)	50.0

Total average monthly costs for a person with limited mobility living in the community with a PrU were estimated to be $8,247.48 (+/-16,549.35) in 2017 Canadian dollars. Percentage of monthly costs for each cost diary item is shown in Figure 16.



HCC-home and community care; ER- emergency room; HCP- health care provider; FP-family physician; HK-housekeeping

Figure 166: Percentage of Average Monthly Costs

Hospitalization costs accounted for 64% of total costs with seven of the 22 study participants' having been hospitalized within six months prior to completing the cost diary. All study participants received HCC services which accounted for 24% of total costs. Eleven participants reported at least one visit to the ER, 17 participants went to their family doctor, 15 participants attended at least one specialist physician visit, and four participants reported having been to a medical clinic. Sixteen participants reported having had a laboratory test or underwent diagnostic imaging in the previous six months, and only three participants did not report any prescribed medications, however, all participants reported they paid out of pocket for supplements such as vitamins that were recommended to help manage their PrU. Ten participants recalled additional costs paid for expenses such as transportation or parking in order to attend medical appointments. Three participants paid out of pocket for private healthcare services including naturopath, personal support worker and physiotherapist not funded by the MOHLTC. Fourteen participants reported on out of pocket expenses they paid for equipment such as wheelchairs, specialized mattresses, dressings, and supplements. Five participants

reported homemaking, caregiving, or volunteer time lost due to their PrU. Two of the 22 participants were working at the time of the assessment, however only one participant reported wages lost due to their PrU.

Average cost per month per person was calculated from MOHLTC, social assistance and out of pocket costs for the patient (see Table 17). Average cost per month per person with tetraplegia was $10,122.22, with paraplegia was $9,106.06 and with other mobility impairment was $2,859.62. Cost per month per person when costs were specifically identified by participants for treatment of their PrU was $3107.73. The average cost of equipment purchased to manage pressure was $5,584.45 per person.

Table 17: Average Costs per Patient Per Month

Average Costs of Individuals with Mobility Impairment and Pressure Ulcers (N=22)		
	Average Cost per month per person	(Range)
Ministry of Health and Long-Term Care Costs		
HCC Purchased Services	$1478.55	($402.27-4,155.00)
HCC Purchased Items	$506.40	($157.00-1,807.00)
Emergency Room Visits	$43.51	($0-59.82)
Hospital Admissions	$5,173.88	($0-75,040.00)
Family Physician Visits	$9.88	($0-25.57)
Specialist Visits	$23.04	($0-107.70)
Clinic Visits	$3.78	($0-38.35)
Tests and Lab	$8.93	($0-44.93)
Government Subsidized Costs		
Medications	$236.46	($0-1,384.84)
Patient “out of pocket” Costs		
Additional Costs	$1.15	($0-8.33)
Health Care Providers-Private Pay	$367.27	($0-3,040.00)
Lost Wages	$23.71	($0-521.60)
Homemaking Time Lost	$370.93	($0-3,129.60)
TOTAL COSTS	**$8247.49**	**$559.27-89,362.74**

Table 18 shows the effects of the sensitivity analysis on average monthly costs. Costs remained relatively similar when there were no costs assumed for unpaid time lost for

homemaking, volunteering and caregiving. Monthly costs decreased when no cost for alternative level of care beds was assumed, no cost for private health care providers was assumed, and the lowest monthly cost for HCC was used. Monthly costs increased when it was assumed that the reported equipment was purchased by participants within the last six months and when the maximum monthly cost for HCC was used.

Table 18: Average Monthly Costs with Sensitivity Analysis

Variable Changed	Average Cost per month per person (SD)
No costs for unpaid time lost for homemaking, volunteering and primary caregiver	$8,054.37 ($16,619.16)
Equipment purchased assumed to be within the last 6 months	$9,178.22 ($16,368.19)
No cost for Alternate Level of Care beds	$7,086.54 ($16,002.06)
No cost for private Health Care Providers	$7,880.21 ($16,624.48)
Minimum HCC costs	$6,996.62 ($16,452.61)
Maximum HCC costs	$11,510.53($16,452.61)

Visits by different health care providers within the HCC system are shown in Table 19. The median number of HCC nursing visits was 17 per patient per month (range 5-34). The median monthly visit rate ET visits was one, zero for physiotherapy, one for occupational therapy, and zero for registered dietitian.

Table 19: Home and Community Care Service Utilization per Participant per Month

	Visiting Nurse	Enterostomal Therapist	Physiotherapist	Occupational Therapist	Registered Dietitian
Median	17	1	0	1	0
Range	5-34	0-2	0-3	0-4	0-2

4.5 Discussion

The results of this study have demonstrated that each individual who has a mobility impairment resulting in a PrU has an estimated monthly cost of over $8200.00 Canadian

dollars. For our cohort of 22 patients, whose average wound duration was 21.2 months, this would result in a total cost of $3,846,624.50 spent at the time of initial assessment.

To our knowledge, this is the first prospective study that used patient level data to estimate the cost of living in the community with a PrU from a MOHLTC and societal perspective. In an economic evaluation completed for the Spinal Cord Injury Research Evidence (SCIRE) evaluating health care resources, the total mean annual cost per individual with SCI in Ontario is approximately $180,000.[16] Our estimate of annual costs for health care treatments of the SCI group of participants in the present study was similar at $144,747.54. It is well known that PrUs are often a secondary complication of chronic disease, and consequently all health comorbidities impact an individual's ability to heal their PrU. Therefore, it is challenging to estimate costs specifically associated with a comorbidity such as PrUs. In this study, we choose to let participants designate which costs were directly associated with their PrU. This yielded an average annual cost of $38,111.88 per person. In addition, when we asked them to estimate out of pocket expenses for pressure redistribution equipment that they were currently using, an additional cost of $5,584.45 per person was calculated.

In our study, hospitalization costs accounted for 64% of total monthly costs with seven of the 22 study participants having been hospitalized within the six months prior to completing the cost diary. These results are similar to those reported by Chan and colleagues in 2012[17] who found the average monthly cost of community-based PrU ulcer management was $4745 and 62% of these costs were due to hospitalization, 15% due to healthcare provider costs, and 16% non MOHLTC costs.

Despite the similarities in percentages of both studies, our study estimated a monthly cost that was $2842.93 higher than the monthly cost reported by Chan et al, 2012 when converted to 2017 Canadian dollars. This difference is likely because we included more costs incurred by HCC such as equipment rental and out of pocket health care expenses of participants. In addition, participants included in the present study had serious medical conditions (e.g. osteomyelitis) that would have been excluded from previous studies that followed relatively healthy participants who were recruited into a randomized controlled

trial. The monthly cost estimate of our study is closer to the $9000/month cost for treating a stage III PrU in a case study about a person living in the community with a SCI and PrU[21]

In evaluating the HCC resource utilization, the median number of nursing visits was 17 per month with a range of 5-34 nursing visits per patient per month. Based on known practices within HCC in this region, these home visits were likely filled by RPNs who were changing the wound dressing. By comparison monthly visit rates of other interdisciplinary team members such as physical and occupational therapists, were very sparse. This is despite the fact that all the participants in the study had significant mobility impairments and either used a wheelchair or were bed fast. This demonstrates that patients in the community with a long standing PrU may not receive the interdisciplinary team approach recommended in local, national and international best practice guidelines.[22–24]

There were several limitations to our study. This report contains only a small sample of people who have a chronic PrU and are receiving HCC services in this region. Most of the items included in the cost analysis were based on participant report of the previous six months of health care interventions and therefore is subject to recall bias. We assumed if the participant could not recall any resource use in a particular category, that costs were zero. Cost estimates for health care resources the patient did not pay for (hospital and HCC costs) have to be based on many assumptions (see Table 15). The exception was for HCC costs where administrative costs were provided for 11 of the 22 subjects. Costs captured did not include government funding for assisted living residences which also funds personal support workers (PSW) support for residents. This would underestimate the cost of PSW support required for living with a PrU when assistance for transfers is increased to allow for offloading of the PrU.

4.6 Conclusion

Cost per month for an individual in the community suffering with a PrU is $8247.48 from a societal perspective. Costs that participants specifically attributed to PrU management were $3107.73/month. Patients with PrUs require high HCC resource utilization for PrU

management. Given the significant costs associated with long term PrUs, early intervention using best practices to maximize healing rates is encouraged.

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5 Cost of a Pressure Ulcer with Underlying Osteomyelitis: A Case Study

5.1 Introduction

Pressure ulcers (PrUs) are a common, secondary health complication occurring across all sectors of health care including hospitals, long term care, and home and community care.[1-3] A pressure ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.[4] Stage IV PrUs extend into muscle, bone or joint structures and are associated with considerable morbidity and mortality.[5] PrUs that remain open for months, or even years, are at risk for developing deep infection including osteomyelitis (OSM). [6,7]

Osteomyelitis is inflammation of the bone or bone marrow usually due to infection and is present in 17-32% of patients with PrUs.[6,7] This high prevalence is quite staggering given that OSM underlying PrUs can lead to wound chronicity, complications of flap reconstruction surgery, increased length of hospital stay, and increased costs.[8-10] Diagnosis of PrU related OSM is complex given that clinical assessments are often inaccurate, and there is no imaging technique (bone scan, X-ray, bone biopsy, MRI) that allow for an acceptable discernment between OSM and PrU related bone changes.[9,11] With little agreement amongst physicians about the best test to confirm the presence of OSM, patients with suspected OSM can undergo several tests during the diagnostic process, incur significant delays in treatment which can result in the progression of the bone involvement. OSM has traditionally been treated with 4-6 weeks of parenteral antibiotics which can be insufficient to manage these deep and complex infections.[12, 13] Repeated antibiotic treatments are often required. Many researchers believe untreated OSM will prevent wound closure even with the use of best practices for PrU treatment.[6,14,15]

Despite important research to date identifying the risks associated with pelvic OSM, most of research that has evaluated treatments for OSM have focused on surgical interventions such as surgical debridement and flap reconstruction surgery.[10, 12, 13]

There is little known about the cost of treating patients with OSM. In a study by Hirshberg et al in Michigan, USA; 12 individuals with OSM of the pelvis due to PrU were examined retrospectively to identify the cost of treatment. They found the average cost to treat an individual with OSM due to PrU was $59,600US and this cost did not include the cost of reconstruction surgery.[10] Once diagnosed with OSM, the cohort of 12 individuals required a total of 77 courses of antibiotics and 17 surgical debridement. The majority of debridement occurred in the operating room because of the need for extensive resection of the bone. Only six of the 12 (50%) individuals had successful closure of their PrU after receiving surgical flap closure.

The purpose of this paper was to bring a person lens to cost analysis and document a patient's lived experience and monthly costs associated with the diagnosis and treatment of a single case with a PrU and underlying OSM This cost analysis took a health care resource perspective.

5.2 Methods

"Ms. P" was a participant in a multi-year knowledge mobilization project aimed at implementing best practices into community based PrU care for individuals with spinal cord injury (SCI) living in one region of Ontario, Canada. Within this region, health care is coordinated by the South West Local Health Integrated Network (South West LHIN) which is funded publicly. The South West LHIN provides home care services by contracting several provider agencies that employ nurses, allied health professionals, as well as unregulated support workers. Participants who consented to participate in the study underwent an in-home initial comprehensive PrU assessment by the lead author, which included a cost diary. Ethics approval was obtained from the Western University Health Science Research Ethics Board, REB # 106157, the Lawson Health Research Institute Research Ethics Board, and the Ethics Committee of participating agencies (see Appendix 3).

Baseline resource utilization data was collected from the individual during an initial home assessment using a cost diary. The cost diary documented expenses incurred for the previous six months. The cost diary included the following items: (i) emergency

room (ER) visits, (ii) inpatient hospitalization stays, (iii) family physician visits, (iv) physician specialist visits, (v) clinic visits, (vi) laboratory tests, and (vii) diagnostic imaging. In home sessions were conducted to complete the cost diary each month from October 2015 to March 2016 until Ms. P had an MRI to confirm OSM. Ms. P was reassessed in July 2017 and baseline costs for the previous six months were estimated and then followed monthly from July to September 2017. A total of 10 cost diaries were completed over a total period of two and a half years. All cost diary information was based on recall.

Unit costs and resource use in 2017 Canadian dollars are outlined in Table 20. Home and community care (HCC) utilization and costs for this individual were obtained from the South West LHIN database for case costing. HCC costs were provided as cost of providers per month and cost of equipment/dressings per month. HCC costs were only provided for this individual at baseline, and therefore monthly HCC costs had to be assumed to be consistent for the two-and-a-half-year time period. Costs for physician visits, laboratory tests and medical procedures were obtained from the Ontario MOHLTC Schedule of Benefits, 2015.[16] Hospitalization costs were obtained from the Ontario Case Costing initiative.[17]

All cost diary items were entered in to a Microsoft® Excel spreadsheet and average monthly costs were calculated. For baseline cost diaries, the costs were averaged over the previous six months to establish a monthly cost estimate. The average monthly cost over 2.5 years was calculated using the mean cost for the 10 cost diaries.

Table 20: Costs and Resource Use

Unit Costs Expressed in 2017 Canadian Dollars				**Utilization over 2.5 years**
Variable	**Unit Cost**	**Definition**	**References**	
Specialist Physician Visits				
Family Physician	$ 38.35	Code A004	(1)	2
Plastic Surgeon	$ 81.10	Code A085	(1)	6
Physiatrist	$ 39.00	Code H312	(1)	3
Infectious Disease Specialist	$ 157.00	Code A465	(1)	4

Wound Specialists	$ 38.35	Code A004	(1)	5
Hospitalization (per day)				
Osteomyelitis, pelvic region	$ 1,239.59	OCCI code M8695	(4)	46 days
Laboratory test and Diagnostic Imaging (per test)				
CBC	$ 16.00	Code L393	(6)	3
Urine Culture	$ 7.00	Code L641	(6)	1
Wound Swab	$ 25.00	Code L628	(6)	3
PICC line	$ 168.00	Code Z456	(1)	5
MRI	$ 48.35	Code J163	(1)	2

5.3 Results

Ms. P is an active 69-year-old with complete L2-3 paraplegia following a catastrophic motor vehicle accident that occurred 22 years ago. At the time of initial assessment, Ms. P reported she was retired, lived alone, and completed her activities of daily living (ADLs) independently. Ms. P estimated that her wound began 5 years ago, and she had been receiving daily nursing visits from HCC for dressing changes for the 10 months prior to the initial assessment. Her PrU was over her ischial tuberosity, measured 0.9 cm2 and gritty bone was palpable in the base of the wound. Over the past 5 years, Ms. P reported that her wound had repeatedly closed for short periods of time but would recur. She reported that the copious amounts of drainage and odour coming from her PrU often made her feel uncomfortable in public areas such as the grocery store.

The total cost incurred to date for this single patient was $237,684.69 during the study period. The average monthly cost for this individual with a PrU and OSM was $ 7,916.70 per month (+/-12,566.96). The ranges in monthly costs were from $1987.08 to $37,873.65 over a two-and-a-half-year period. Seventy-two percent of total costs were due to three hospital admissions for a total of 46 days during the last three months of data collection. These admissions were required to treat septicemia directly caused by unresolved OSM. Eighteen percent of costs were due to HCC resources, and six percent due to HCC dressings (Figure 17).

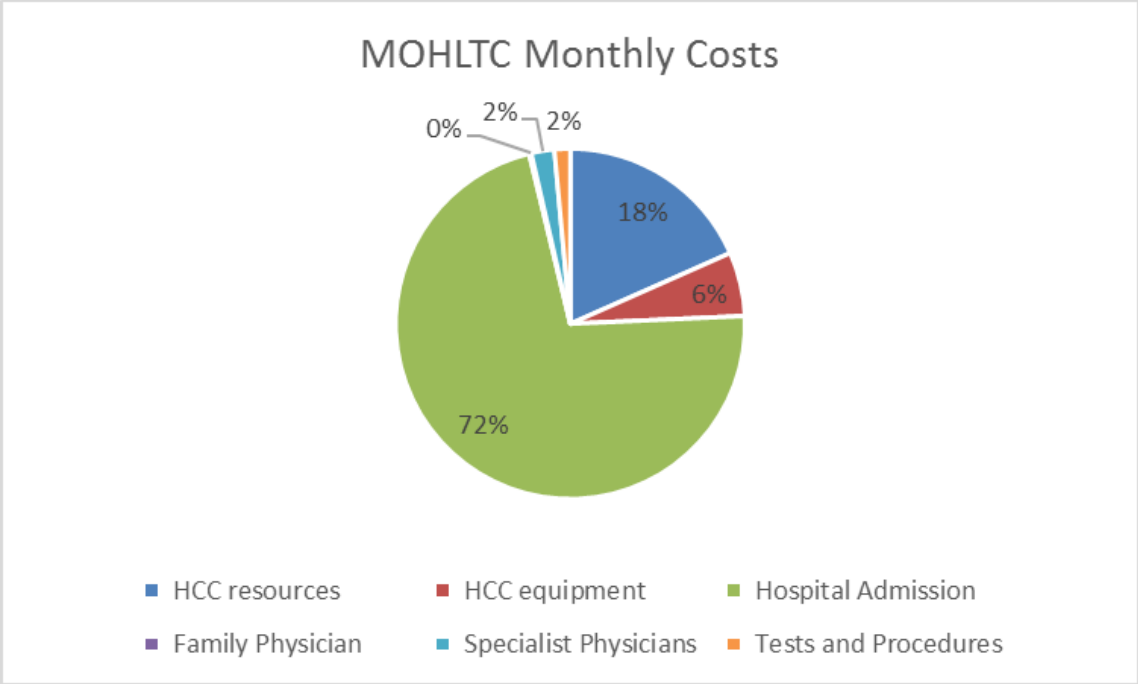

Figure 17: Allocation of Monthly Costs

Ms. P was clinically diagnosed with OSM during the initial assessment; however, an MRI to confirm diagnosis required a waiting period of 5 months. Ms. P was referred to an infectious disease specialist and plastic surgeon for surgical debridement to assist with management of her OSM. Ms. P reported having multiple courses of long term intravenous antibiotics while being treated for OSM and requiring five peripherally inserted central catheters (PICC) lines. Ms. P was also receiving synthetic erythropoietin injections 3x/week to increase her production of red blood cells.

After following Ms. P for two years, she continued to have two PrUs present. She developed a second PrU during one of her hospital admissions and at the time of the last re-assessment she was treated by HCC with negative pressure wound therapy (NPWT) applied to both PrUs. Ms. P was no longer independent with her bed transfers due to her inability to use a sliding board. She required use of a hoyer lift with an out of pocket expense of $4000 for installation. She was unable to drive herself and required personal

support for her ADLs and iADLs due to her PrUs. This was a drastic decline in her functional independence compared to her initial assessment in October 2015.

5.4 Discussion

To our knowledge, this is the only prospective study reporting patient level data on the cost of living with a PrU complicated by OSM. The cost of pelvic OSM treatment from a public payer perspective is close to $8,000.00 per month for this individual. This cost is significant with most of costs being due to hospital admission. Most significantly, this case study highlights the significant impact this complication of PrU has on the quality of life and independence of an individual living with PrU. Unfortunately, the OSM was still present in this individual and her PrU were not healed, therefore the costs continue, and her life continues to be impacted greatly.

Ms. P had three hospital admissions within two months over the two-and-a-half-year observation period. This is like the results found by Bodavula et al who completed a retrospective review of 220 individuals who were admitted to a teaching hospital in Missouri, Illinois with pelvic OSM. They reported that one third of individuals had two or more readmissions to hospital over the course of one year.[18] At the conclusion of our study, Ms. P had undergone six debridement procedures by the plastic surgeon in the out-patient hospital clinic. No plans for further surgical debridement had been established.

There is much debate about the type and duration of antibiotics and whether surgical intervention is needed to resolve OSM[12–15,19,–20]. Unfortunately, there are few studies that have evaluated the effectiveness of treatments of OSM

Diagnosis of OSM underlying PrU has also been challenging with different methods such as plain film x-ray, MRI, and bone biopsy being reported in the literature.[11,21,22] As a result many patients undergo several different diagnostic tests and must deal with conflicting results. Protracted course of OSM diagnosis results in delays in initiating treatments. Unresolved OSM has the potential to cause further bone involvement and puts the patient at greater risk of septic shock and even death. .

At the time of Ms. P's initial assessment where OSM was suspected, she reported having had her PrU for five years with periods of short term closure. She had been receiving daily dressing changes due to copious drainage for 10 previous months. Ms. P was clinically diagnosed by a specialized team at a local regional rehabilitation centre. Ms. P continued to wait a further five months for an MRI to radiologically diagnose OSM. Our case study demonstrated that pelvic OSM underlying PrUs is a clinical condition that is difficult to diagnose, as well as treat.

In a recent study by Andrianasolo and colleagues, 61 individuals with PrU-related OSM were evaluated. Patients underwent surgical debridement with flap reconstruction surgery 6.6 weeks after debridement.[13] All of the individuals required intravenous antibiotics for a mean total of 19.8 weeks. Fifteen treatment failures (23.4%) were diagnosed 12.4 weeks after flap coverage, with additional surgical procedures required in 14 cases (93.3%). Four patients died, including 2 deaths related to PrU-related infection. The authors concluded that PrU-related OSM outcomes are poor with an overall failure rate approaching 25%. Unfortunately, surgical intervention is not always an option for individuals with OSM because of a lack resources and expertise. Due to limited access for surgical intervention, pelvic OSM can result in a lifelong disease with a high risk of death from septic shock.

The cost in our case study is higher than previous monthly estimates found by Chan et al of $4745.00 to treat community dwelling individuals with SCI and PrUs.[23] Further increasing the discrepancy is that our cost estimate only considers public costs, whereas Chan's study estimated costs from a societal perspective. Additionally, our findings may be an underestimate of costs since it is based on Ms. P's recall. High rates of health care resource utilization have been observed in the literature for individuals with SCI, and this increased resource use is commonly due to secondary complications such as PrUs.(24–26) In our case study, Ms. P was observed to have only two family physician visits over two and a half years which is atypical for an individual with SCI and a PrU in reference to the literature.[25]

There is a high cost associated with OSM management in the community, and an even higher cost when individuals are offered surgical intervention such as flap coverage. Our case study was an accurate portrayal of individuals who live with PrU and OSM since opportunities for surgical intervention and the convalescence required post operatively are scarce in many locations in Ontario, Canada. This case study demonstrates the clinical reality that PrU with OSM are often a lifelong disease requiring high HCC resources and frequent hospital admissions for septic infection in immunocompromised populations such as people with SCI.

5.5 Conclusion

Costs associated with treating PrUs and OSM in the community are significant. A conservative estimate based on this case study is $8,000 per month per individual. The cumulative costs from a public payer perspective are staggering considering the challenges of curing OSM in individuals with PrUs. More needs to be done to prevent this devastating consequence of PrU including ensuring evidence informed PrU treatments that are known to promote rapid closure of PrUs.

5.6 References

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6 Thesis Discussion

This research was completed as part of a large, knowledge mobilization project with the aim of increasing the use of electrical stimulation (E-Stim) as evidence-based practice for the treatment of pressure ulcers (PrUs). This large, multifaceted project was directed at introducing practices that would improve wound healing outcomes for patients living with PrUs. Studies described in this thesis focus on two components of this research: an evaluation of an education program and cost analyses of pressure ulcer care and E-Stim use in a community located in South-western Ontario, Canada.

Chapter 2 reported on the outcomes on an education program developed to train health care providers on the use of E-Stim for the treatment of PrUs. The aim of the study was to determine if an online E-Stim education program can increase provider's knowledge and change attitudes and practice about the use of E-Stim to stimulate healing of chronic pressure ulcers. Results suggest that knowledge about E-Stim can be improved via a customized online education program. Measurement of attitudes that determine health care providers view for the use of E-Stim also improved with the educational program. Further revealed was that clinicians support the use of E-Stim for the treatment of PrUs, however additional hands-on training may be required to change practices.

While some attitudes were changed after completing online educational modules, certain other attitudes required completion of a hands-on workshop. Despite significant improvements in knowledge and attitudes about E-Stim, very few participants reported to the research team that they used E-Stim in their practice. While this result is not entirely unexpected, it suggests that further work is needed to influence practice. It also suggests other barriers exist that interfere with a clinician's ability to put new knowledge into practice.

Another barrier to implementation of an advanced wound care therapy is the perception that it is too costly. Chapters 3-5 investigate the outcome of cost as part of the E-Stim Collaboration Project. In Chapter 3 a cost analysis was conducted to evaluate the cost effectiveness of using E-Stim for the treatment of PrUs. Decision analytic modelling was used to evaluate the cost per quality adjusted life year of E-Stim and to compare the cost

effectiveness of this novel therapy to an advanced therapy commonly adopted in practice called negative pressure wound therapy (NPWT). E-Stim was found to be a dominant treatment over standard wound care (SWC) meaning it is a less costly and more effective treatment than SWC. By comparison a second decision analytic model was developed to compare NPWT to SWC and found adding NPWT was not cost effective compared to SWC. The cost analysis determined that E-Stim is a cost-effective treatment for PrUs.

Chapters 4 and 5 outline the costs associated with individuals who have a PrU from MOHLTC and societal perspective. Using cost diaries and specific case costing data, the monthly costs for a cohort of 22 community dwelling patients with PrU who were receiving HCC. The average monthly cost was calculated to be $8247.48 per patient . Chapter 5 provide a case example of the impact when OSM develops in unresolved PrU. Needless to say, the cumulated costs and health care resources utilized to diagnose and treat someone who has a PrU that becomes complicated with OSM are astronomical. Not to mention the devastating effects that having OSM has on a patient's quality of life. Considering participants in this study had their PrU for an average of 21 months, societal costs for unhealed PrU are enormous. This economic evidence provides the kind of justification that many health care decision makers require before implementing advanced therapies like E-Stim.

This thesis summarizes challenges in implementing pressure ulcer best practices fot two main practice drivers: education and costs. This research was guided by the KTA and NIRN frameworks using a standardized approach to implementation, adaptation, and practice change using PDSA cycles. Despite this approach to implementation, we were unable to demonstrate a significant change in practice for the use of E-Stim in the community. From this work, three key recommendations have been highlighted for future implementation projects. The first recommendation is to ensure that timing for implementation is appropriate. During the time of the E-Stim Collaboration Project, significant government structural changes were occurring within the South West LHIN which resulted in competing priorities and unclear stakeholder roles. The second recommendation is to engage stakeholders who are interested and willing to invest a significant amount of time towards the implementation initiative. Thirdly, establish key

aspects of the pressure ulcer care prior to implantation. For example, the training outlined in chapter 2 should have been completed prior to E-Stim implementation. A detailed account of the E-Stim Collaboration Project implementation challenges, barriers and facilitators is outlined in the thesis by Lala (2018).[1]

Implementation of best practices is important, however very challenging. During our research, we felt we had removed barriers identified by clinicians, such as lack of education and lack of resources, and maximized facilitators that had been identified at the beginning of the project. However, community engagement for the use of E-Stim continued to be elusive. An area of exploration for the increase in E-Stim use may be that of mentorship in a clinical setting. Establishing not only online and hands on education, but also mentorship may increase clinician's confidence in delivering this intervention to patients. Increased awareness of wound care interventions, specifically at nursing and physiotherapy schools, could include E-Stim for wound treatment as an early intervention given that it is a best practice intervention. We were also limited in our study due to ethics the ability to advertise at a patient level. Engaging patients and increasing the awareness for the use of E-Stim at a public level may also be a potential driver for change.

This thesis demonstrates that educational programs are an important intervention to increase the awareness of best practices, however education is not enough. Despite the provision of high level evidence that E-Stim is effective to speed the healing of PrUs, we did not see a significant change in practice. When the cost of best practice treatment interventions was evaluated, E-Stim was shown to be dominant by being less costly and more efficient when compared to SWC treatments. This further strengthens the need to increase the clinical use of E-Stim as a treatment intervention. Chapters 4 and 5 further show that when best practices are not utilized, PrUs progress to become a large financial burden to both the health care system.

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Appendices

Appendix 1: HSREB E-Stim Education Study

Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Pamela Houghton
Department & Institution: Health Sciences\Health & Rehabilitation Sciences,Western University

Review Type: Delegated
HSREB File Number: 107778
Study Title: Evaluation of Electrical Stimulation Therapy Education Program for the Healing of Chronic Wounds
Sponsor: Rick Hansen Foundation

HSREB Initial Approval Date: June 07, 2016
HSREB Expiry Date: June 07, 2017

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Data Collection Form/Case Report Form	Appendix D: KAP Questions	2016/02/11
Data Collection Form/Case Report Form	Appendix B: Demographics	2016/02/11
Data Collection Form/Case Report Form	Appendix C: Knowledge questions	2016/02/11
Data Collection Form/Case Report Form	Awareness Survey	2016/02/07
Recruitment Items	Email recruitment for awareness survey	2016/02/07
Letter of Information & Consent	Participant LOI	2016/05/30
Letter of Information & Consent	KAP LOI	2016/05/30

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

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 Practices (ICH E6 R1), 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.

Appendix 2: Letter of Information and Consent- E-Stim Education Study

PARTICIPANT
LETTER OF INFORMATION

Western UNIVERSITY · CANADA

Title of the study: Evaluation of an Electrical Stimulation Therapy Education Program for the Healing of Chronic Wounds
Primary Investigator: Pamela Houghton, PhD
Co-Investigators: Lyndsay Orr, MClSc; Paul Holyoke, PhD; Jillian Brooke, MClSc; Deena Lala, MSc

You are being invited to participate in a research study as a health care provider receiving education on the use of electrical stimulation therapy (EST) for the healing of chronic wounds. 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. 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
Chronic, non-healing wounds are one of the most common secondary health complications among individuals with immobility or those who require use of a wheelchair. 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. Multiple best practice guidelines recommend the use of EST to promote the closure of chronic wounds. EST promotes wound healing by increasing the blood supply into the wound and stimulates the wound healing process. Current wound care in individuals with neurological conditions living in the community occurs within the home. 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 improve health care provider's knowledge, attitudes and practice (KAP) in the use of EST to improve the healing of chronic wounds.

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

1. Questionnaire & Pre-test: You will be asked to complete a brief questionnaire and a knowledge test prior to receiving education on the use of EST. This test helps us understand your current situation and evaluates your level of knowledge. The questionnaire and pre-test should take no more than 15 minutes to complete.
2. Educational modules: You will then complete 4-6 educational modules that will be available via a secure website or delivered in person by a lecturer. Either of these learning opportunities will take approximately 4-6 hours to complete. The lectures will

be scheduled during a one-day workshop to be provided at a mutually convenient location and time. Online modules will be provided via internet so that they can be completed at your own pace.

3. Hands on Workshops: Once you have completed the education you will be able to attend a one-day hands-on practice session that will provide you an opportunity to practice application techniques and use equipment needed to use EST for wound care. Case based discussions will also occur in small groups that will advance your knowledge about EST and promote good clinical judgement that supports safe and effective clinical practice.
4. Post-test: You will be required to complete a post-test after receiving education on the use of EST to evaluate your new knowledge. This knowledge test will also be repeated after the hands on clinical skills session. The test will take approximately 15 minutes to complete.
5. Upon completion of this education, you will receive a certificate of achievement.
6. Post-test 2: You will be asked to complete a second test 6 months after completing the EST education. This test will allow us to evaluate the knowledge you have retained and what practices have been incorporated into your clinical practice. This test will be approximately 15 minutes in length.

You will be assigned a unique number identifier in order to track your test results. The results of your test will not influence your ability to receive a certificate of achievement upon completing the EST education. Both post-tests will ask for your feedback about the education received. The feedback you provide in the questionnaires will only be shared with the members of the research team.

POSSIBLE RISKS

There is the potential to encounter technical difficulties when completing the online modules. In such cases, technical support will be provided to ensure a working system is available.

BENEFITS

The benefit for participating in this study is the ability to provide valuable feedback to develop a comprehensive educational platform for the use of EST in the healing of pressure ulcers. The information collected in this study will be used to improve future educational resources.

CONFIDENTIALITY

Only the investigators of this project will have access to your data. We will not share any of your test results with anyone other than you. 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) will be saved on a Western University network.

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 office at Elborn College.

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. All data will be kept for 5 years following the publication.

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.

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. 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:

PARTICIPANT CONSENT FORM

Title of the study: Evaluation of an Electrical Stimulation Therapy Education Program for the Healing of Chronic Wounds

Primary Investigator: Pamela Houghton, PhD
Co-Investigators: Lyndsay Orr, MClSc; Paul Holyoke, PhD; Jillian Brooke, MClSc; Deena Lala, MSc

☐ **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 prefer the researchers contact me through email.**

_____
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

Appendix 3: HSREB E-Stim Collaboration Project

Western Research

Research Ethics

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

Date: March 08, 2016
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 -2017/02/28
Expiry Date -2017/03/27

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.

Appendix 4: Letter of Information and Consent- E-Stim Collaboration Project

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, MClSc; Jacqueline Marsh, PhD; Katie Mairs, MSc; Anne Shantz, RN.

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:

7. Pre-assessment: 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.
8. 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. 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.
9. Assessment: You will undergo a comprehensive assessment by a team of 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 and evaluating the wound size and appearance.
10. Care plan: A conference call will be set up between the team of health care professionals, the study participant, all 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 includes an EST treatment plan and schedule. 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 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 that is based on Canadian best practice guidelines.
11. Community follow-up: Based on the agreed care plan, you will be followed by members of your community care team according to a pre-determined service plan available via South West CCAC. This may include personal support workers, care attendants, family members, nurses, physical and occupational therapists, dietician, and psychologist or social workers supported by members of the research team.
12. 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.
13. 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.

14. 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.

PARTICIPANT
CONSENT FORM

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, MClSc; Jacqueline Marsh, PhD; Katie Mairs, MSc; Anne Shantz RN

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)

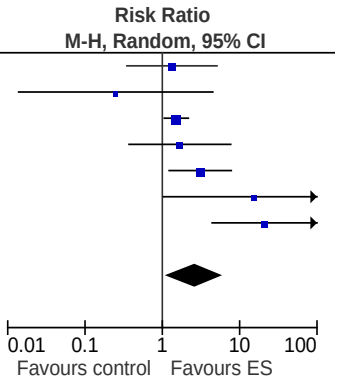
Appendix 5: Chapter 3 Unpublished Data

Forrest Plot Data, Pressure Ulcers

7 studies; 412 wounds / risk on healing: 139 (= 42,4%); 57,2% in the ES group & 21,3% in the SWC group.

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Adunsky 2005	5	35	3	28	15.5%	1.33 [0.35, 5.10]
Asbjornsen 1990	0	7	2	9	6.6%	0.25 [0.01, 4.50]
Baker 1996	68	125	24	67	23.7%	1.52 [1.06, 2.17]
Griffin 1991	3	8	2	9	14.0%	1.69 [0.37, 7.67]
Houghton 2010	11	16	4	18	19.3%	3.09 [1.23, 7.80]
Kloth 1988	9	9	0	7	7.3%	15.20 [1.03, 223.37]
Wood 1993	43	43	1	31	13.7%	21.09 [4.42, 100.64]
Total (95% CI)		**243**		**169**	**100.0%**	**2.61 [1.10, 6.18]**
Total events	139		36			

Heterogeneity: Tau² = 0.78; Chi² = 20.17, df = 6 (P = 0.003); I² = 70%
Test for overall effect: Z = 2.18 (P = 0.03)



Appendix 6: Chapter 4 Costing Reference Table

Participan	Age	Sex	? OSM	Level	Injury	SCI(years)	Wound Di	SA	Site	Stage	CCAC	ER	Hosp	FP	Specialis	Clinics	Tests	Meds	Additiona	HCP privat	Wage lost	HC lost	Total		Equipment
1001	47	Male		L1	Incomplet	0.5	1	1.4	coccyx	DTI	$ 1,984.95	$ 119.64	$ -	$ 6.39	$ 26.17	$ -	$ 10.78	$ 110.10	$ 1.33	$ -	$ -	$ -	**$ 2,259.36**		$ 10,150.00
1002	42	Male		C6-7	Complete	18	8	34	IT	III	$ 734.09	$ 119.64	$ 1,545.90	$ 6.39	$ 46.30	$ -	$ 8.00	$ 106.44	$ -	$ -	$ -	$ -	**$ 2,566.76**		$ 2,790.00
1003	69	Female	y	L2-3	Complete	22	60	0.9	IT	IV	$ 1,925.83	$ -	$ -	$ 6.39	$ 39.06	$ -	$ 2.67	$ 363.78	$ 0.67	$ -	$ -	$ -	**$ 2,338.39**		$ 43,900.00
1004	65	Female		T5	Incomplet	0.3	4	8.1	R buttock	III	$ 1,984.95	$ -	$ 75,040.00	$ -	$ -	$ -	$ -	$ 642.60	$ -	$ -	$ -	$ -	**$ 77,667.55**		$ -
1005	45	Male		C6-7	Complete	21	60	0.8	IT	III	$ 1,538.00	$ 59.82	$ -	$ 12.78	$ 12.89	$ 25.57	$ 44.93	$ 682.16	$ 3.33	$ -	$ -	$ -	**$ 2,379.48**		$ -
1006	35	Male	y	C4	Complete	6	48	0.2	IT	IV	$ 1,077.00	$ 59.82	$ 770.34	$ 12.78	$ 39.63	$ 38.35	$ 5.34	$ 1,384.84	$ 4.67	$ 3,040.00	$ -	$ -	**$ 6,432.77**		$ -
1007	70	Male	y	T	Incomplet	8	15	1.7	IT	IV	$ 2,249.00	$ -	$ -	$ 12.78	$ 6.39	$ -	$ 30.67	$ 601.67	$ 8.33	$ -	$ -	$ -	**$ 2,908.85**		$ 1,400.00
1008	63	Male			Cauda Equ	3	24	11.6	heel	unstageab	$ 1,275.24	$ 59.82	$ 1,033.56	$ 19.18	$ 65.76	$ -	$ 4.17	$ 102.60	$ 2.00	$ -	$ -	$ -	**$ 2,562.32**		$ 44,860.00
1009	36	Male		T5-6	Complete	8	60	14.8	Coccyx	IV	$ 824.50	$ 59.82	$ -	$ 19.18	$ 39.63	$ 6.39	$ 3.84	$ 60.00	$ -	$ -	$ -	$ 336.43	**$ 1,349.78**		$ 3,000.00
1010	41	Male	y	T4	Complete	5	72	0.3	buttock	III	$ 1,031.20	$ 59.82	$ -	$ 12.78	$ 19.91	$ -	$ 8.00	$ 78.90	$ 0.67	$ -	$ -	$ 3,129.60	**$ 4,340.88**		$ 3,100.00
1013	81	Female	y	T8	Complete	28	36	2.7	IT	IV	$ 1,984.95	$ -	$ -	$ -	$ 13.33	$ -	$ -	$ 69.60	$ -	$ -	$ -	$ 2,347.20	**$ 4,415.08**		$ 4,000.00
1014	53	Male		T4	Complete	35	1	3.8	IT	III	$ 1,984.95	$ -	$ -	$ 25.57	$ 107.70	$ 12.78	$ 10.47	$ 33.17	$ 1.67	$ -	$ -	$ -	**$ 2,176.31**		$ 300.00
1016	41	Male	y	T12	Complete	16	39	4.2	IT	IV	$ 1,984.95	$ 59.82	$ -	$ 19.18	$ -	$ -	$ 31.91	$ -	$ -	$ -	$ -	$ 1,564.80	**$ 3,660.66**		$ 850.00
1017	63	Male		C5-6	Complete	1	4	13.9	IT	III	$ 1,984.95	$ 119.64	$ 25,540.67	$ -	$ -	$ -	$ -	$ 116.01	$ -	$ -	$ -	$ -	**$ 27,761.27**		$ -
1018	87	Male	y		Cauda Equ	17	10	4.3	IT	IV	$ 1,984.95	$ -	$ 858.83	$ 6.39	$ 8.33	$ -	$ 1.17	$ 27.90	$ 1.33	$ -	$ -	$ -	**$ 2,888.91**		$ 400.00
1019	47	Male		C3	Complete	31	3	7	Coccys	IV	$ 4,842.37	$ -	$ 9,035.98	$ -	$ -	$ -	$ -	$ 47.70	$ -	$ -	$ -	$ -	**$ 13,926.05**		$ -
1020	69	Female			Buttock Prl, depressi		3	1.7	buttock	III	$ 1,984.95	$ -	$ -	$ 6.39	$ -	$ -	$ -	$ 239.70	$ -	$ -	$ -	$ -	**$ 2,231.04**		$ -
1024	61	Female		C5-6	Complete	2	3	1.1	R 5th toe	IV	$ 5,248.00	$ 59.82	$ -	$ 12.78	$ 6.50	$ -	$ 24.50	$ 315.40	$ -	$ 2,000.00	$ -	$ -	**$ 7,667.00**		$ 7,300.00
1026	69	Male			L BKA		3	6.5	L BKA	III	$ 1,089.21	$ -	$ -	$ 6.39	$ 45.15	$ -	$ -	$ 39.61	$ 1.33	$ -	$ -	$ 782.40	**$ 1,964.09**		$ -
1027	78	Female			CVA		4	8	Shoulder	IV	$ 1,984.95	$ 179.47	$ -	$ -	$ 30.10	$ -	$ 3.55	$ -	$ -	$ -	$ -	$ -	**$ 2,198.06**		$ 800.00
1028	74	Female			Parkinson's-Lewy Bo		6	10.88	Coccyx	IV	$ 1,984.95	$ -	$ -	$ 19.18	$ -	$ -	$ 1.17	$ -	$ -	$ -	$ -	$ -	**$ 5,045.29**		$ -
1029	48	Female		T7	Complete	27	2	7.9	IT	III	$ 1,984.95	$ -	$ -	$ 12.78	$ -	$ -	$ 5.34	$ 180.00	$ -	$ -	$ 521.60	$ -	**$ 2,704.67**		$ 8.00
Total						**248.8**	**466**	**145.78**			**$43,668.88**	**$ 957.14**	**$113,825.28**	**$ 217.32**	**$ 506.84**	**$ 83.09**	**$ 196.48**	**$ 5,202.18**	**$ 25.33**	**$ 8,080.00**	**$ 521.60**	**$ 8,160.43**	**$ 181,444.57**		**$ 122,858.00**
Mean	**58.36364**					**13.82222**	**21.18182**	**6.626364**			**$ 1,984.95**	**$ 43.51**	**$ 5,173.88**	**$ 9.88**	**$ 23.04**	**$ 3.78**	**$ 8.93**	**$ 236.46**	**$ 1.15**	**$ 367.27**	**$ 23.71**	**$ 370.93**	**$ 8,247.48**		**$ 5,584.45**
SD	**15.46284**					**11.5233**	**24.22639**	**7.580844**			**$ 1,091.89**	**$ 52.81**	**$ 16,591.52**	**$ 7.57**	**$ 27.24**	**$ 9.80**	**$ 12.51**	**$ 332.20**	**$ 2.03**	**$ 964.01**	**$ -**	**$ 857.76**	**$ 16,549.35**		**$ 12,828.19**

Appendix 7: Curriculum Vitae

Lyndsay Orr, BScPT, MClSc (Wound Healing), PhD

LICENSURE

College of Physiotherapists of Ontario, Registration # 10768

EDUCATION

PhD(c), Health & Rehabilitation Sciences Graduate Program (enrolled September 2014)
University of Western Ontario

Masters of Clinical Science (Wound Healing), School of Physical Therapy,
University of Western Ontario, 2008

Bachelor of Science in Physical Therapy, Department of Physical Therapy
University of Western Ontario, 2000

EMPLOYMENT HISTORY

2018-Present South West LHIN, South West Regional Wound Care Program
Clinical Lead

Jan-April 2017 Western University, Faculty of Health Sciences, School of Physical
Part Time Faculty Therapy, London, ON

2014- 2018 Rehab First Inc., London, ON
Physiotherapist/Regional Manager

2006-2014 Cambridge Memorial Hospital, Cambridge, ON
Wound Care Resource/Physiotherapist

2001-2006 William Osler Health Centre, Brampton, ON
Physiotherapist

2000-2001 Credit Valley Hospital, Mississauga, ON
Physiotherapist

2000-2000 ProMotion Physiotherapy, London, ON
Physiotherapist

TEACHING ASSISTANTSHIP

September-December, 2018, Teaching Assistant, Western University, Faculty of Health Sciences, School of Physical Therapy, Clinical Master's in Wound Healing Program, PT 9670b: Advanced Wound Treatment

September-December, 2017, Teaching Assistant, Western University, Faculty of Health Sciences, School of Physical Therapy, Clinical Master's in Wound Healing Program, PT 9660a: Wound Principles and Assessment

September-December, 2016, Teaching Assistant, Western University, Faculty of Health Sciences, School of Physical Therapy, Clinical Master's in Wound Healing Program, PT 9660a: Wound Principles and Assessment

May-August, 2016, Teaching Assistant, Western University, Faculty of Health Sciences, School of Physical Therapy, Clinical Master's in Wound Healing Program, PT9620: Clinical Mentorship

September-December, 2015, Teaching Assistant, Western University, Faculty of Health Sciences, School of Physical Therapy, Clinical Master's in Wound Healing Program, PT9660a: Wound Principles and Assessment

January-April, 2015, Teaching Assistant, Western University, Faculty of Health Sciences, School of Physical Therapy, Clinical Master's in Wound Healing Program, PT9670b: Advanced Wound Treatment

PROFESSIONAL ACTIVITIES AND RESEARCH

2016-present Ontario Physiotherapy Association
Wound Care Management Course
Educator

2014-2017 SWLHIN Electrical Stimulation Collaboration Project
Clinical Coordinator, PhD Student

2013 Integrated Complex Chronic Wound Clinic: Waterloo Wellington LHIN Pilot Project
Principal investigator

2009-2013 Evaluation of a hospital wide pressure ulcer prevention and treatment program
Yearly hospital wide prevalence and incidence studies conducted
Principal investigator

POSTER PRESENTATIONS SUBMITTED AND PEER-REVIEWED

Selected podium presentations

2018 Orr, L; Brooke, J; Colwell-Castles, S; Lacroix, H. Virtual Enterostomal Therapy (v-ET) Nurse Consultation in Long Term Care (LTC) Homes: A Pilot Study, HSSO Conference: 2018, Toronto, ON

2017 Orr, L; Brooke, J; Holyoke, P; Lala, D; Houghton, P. Evaluation of an Electrical Stimulation Therapy Education Program for the Healing of Chronic Wounds: Preliminary Results, Wounds Canada Conference: 2017, Mississauga, ON

2016 Lala, D; Orr, L; Holyoke, P; Houghton, PE; Kras-Dupruis, A; Wolfe, D. Implementation of electrical stimulation therapy for treating pressure ulcers in community dwelling individuals with limited mobility: preliminary findings. Canadian Association of Wound Care Conference: 2016, Niagara Falls, ON

2016 Orr, L; Klement, K; McCrossin,L; O'Sullivan-Drombolis,D; Houghton,P. Exercise intervention for the treatment of calf muscle impairment in individuals with chronic venous insufficiency: a systematic review and meta-analysis. HRS 9th Annual Graduate Research Conference: 2015, London, ON

2015 Orr, L; Klement, K; McCrossin,L; O'Sullivan-Drombolis,D; Houghton,P. Exercise intervention for the treatment of calf muscle impairment in individuals with chronic venous insufficiency: a systematic review and meta-analysis. Canadian Association of Wound Care Conference: 2015, Toronto, ON

2015 Orr, L. Physiotherapy interventions for offloading diabetic foot ulcers: A narrative review. HRS 8th Annual Graduate Research Conference: 2015, London, ON

2015 Orr, L. & O'Sullivan-Drombolis, D. Physiotherapists and the impairment based treatment of chronic wounds. HRS 8th Annual Graduate Research Conference: 2015, London, ON

2014 Orr, L & Winberg, V. Ontario Woundcare Interest Group, Fewer Wounds Faster Healing. Ontario Physiotherapy Association: InterACTION 2014, Mississauga, ON Co-presented with V. Winberg.

2014 Houghton, PE; Nussbaum, E; Orr, L. Promoting Physical Therapist Involvement in Wound Care, Ontario Physiotherapy Association: InterACTION 2014, Mississauga, ON Co-presented with Drs Houghton and Nussbaum

2013 Teague, L; Hanna-Bull, D; Laforet, K; Orr, L; Thompson R; Winberg, V. Evolution of a Wound Health Political Action Group: The Ontario Woundcare Interest Group, Canadian Association of Wound Care, Vancouver, BC Co-presented with D. Hanna-Bull, K. Laforet and V. Winberg.

Poster

2018 Orr, L; Brooke, J; Colwell-Castles, S. Virtual Enterostomal Therapy (v-ET) Nurse Consultation in Long Term Care Homes: A Pilot Study Involving Local Integrated Health Network and Nursing Service Provider. CAET Annual National Conference: Victoria BC.

2017 Orr, L; Brooke, J; Holyoke,P; Lala, D; Houghton, P. Evaluation of and Electrical Stimulation Therapy Education Program for the Healing of Chronic Wounds: Preliminary Results. National Spinal Cord Injury Conference: Niagara Falls, ON

2017 Orr, L; Brooke, J; Holyoke,P; Lala, D; Houghton, P. Evaluation of and Electrical Stimulation Therapy Education Program for the Healing of Chronic Wounds: Preliminary Results. Ontario Spinal Cord Injury Research Network Meeting: Toronto, ON

2014 Orr, L & O'Sullivan-Drombolis, D. Physiotherapy Interventions for Offloading of Diabetic Foot Ulcers, Canadian Association of Wound Care conference, Toronto, ON

2014 O'Sullivan-Drombolis, D & Orr, L. Physiotherapists and the Impairment Based Treatment of Chronic Wounds, Canadian Association of Wound Care conference, Toronto, ON

2012 Orr, L & O'Sullivan-Drombolis, D. Electrical Stimulation Therapy versus Negative Pressure Wound Therapy: A comparison of adjunctive therapies utilized in home care for chronic wound healing, Canadian Association of Wound Care conference, London, ON

2012 O'Sullivan-Drombolis, D; Orr, L; Houghton, PE; Nussbaum, E. Wound Care and the Amendments to the Physiotherapists Scope of Practice in Ontario, Canadian Association of Wound Care conference, London, ON

2010 Orr, L & O'Sullivan-Drombolis, D. The Underutilization of Physical Therapists and Biophysical Agents in Wound Healing, Canadian Association of Wound Care conference, Calgary, AB

2008 Hon J; Lagden K; McLaren AM; O'Sullivan D; Orr L; Houghton P; Woodbury G. A prospective, multicenter Study to Validate Use of the Pressure Ulcer Scale for Healing (PUSH) in patients with Diabetic, Venous and Pressure Ulcers, World Union of Wound Healing Societies, Toronto, ON

PUBLICATIONS

Orr, L; Klement, K; McCrossin,L; O'Sullivan-Drombolis,D; Houghton,P. Exercise intervention for the treatment of calf muscle impairment in individuals with chronic venous insufficiency: a systematic review and meta-analysis. **2017**; Aug 63(8): 30-43.

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HONORS AND AWARDS

2017 Ontario Graduate Scholarship

2016 HRS Graduate Conference Travel Award, Western University, Faculty of Health Sciences.

2016 Siskinds Studentship in Spinal Cord Injury Endowment Fund Award, Parkwood Institute Research Program: Awarded from the St. Joseph's Health Care Foundation.

2015 HRS Graduate Conference Travel Award, Western University, Faculty of Health Sciences.

2004 Professional Practice Clinical Practice Award of Excellence, William Osler Health Centre, Brampton, ON: Awarded to one clinician who is recognized for their excellence for clinical practice. William Osler Health Centre organization which provided programs and services to over 900,000 residents with a health care team of more than 900 physicians, 4,300 staff and 1,00 volunteers.