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## Predicting Response to Medial Branch Blocks: A Clinical Decision Making Tool

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A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Health and Rehabilitation Sciences

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# Abstract

Chronic neck pain can lead to long-term disability and socio-economic burden. Several demographic, clinical, and psychosocial factors have been implicated in the development of neck pain disability. These factors may also influence management of neck pain. Optimal treatment often requires targeting interventions based on specific diagnosis. One of the most common cause of neck pain is cervical facet joint injury. Currently, the gold standard for diagnosing facetogenic injury is through the medial branch block (MBB) procedure. Though the procedure is relatively safe, it is still invasive and may result in adverse effects. In Canada, access to this procedure is limited through referrals to a specialist pain clinic with wait times of over six months. It is important to help reduce wait times and provide access to the MBB procedure for those likely to respond. The objective of the current study is two folds 1) to develop a comprehensive interdisciplinary regression model to better describe factors that correlate with neck pain disability (Chapter 2 and 3); and 2) to create a decision tree to help clinicians screen for facetogenic neck injury using a receiver operator curve (Chapter 4). In the first two studies of the dissertation, a model was developed using a hierarchical multiple regression. The final model which included: sex, pain duration, etiology, pain intensity, pressure pain detection threshold, number of restricted planes, Spurlings's test, medical legal status, and pain catastrophizing, explained 62% of the variance in neck disability as measured by the Neck Disability Index (NDI). The last study provided a decision tree that included two factors, pain intensity and pain catastrophizing, to help clinicians identify those patients likely to respond to cervical MBBs. These findings have important implications for front-line clinicians to help rule out patients not likely to benefit from the cervical MBBs and potentially reducing wait times for those likely to respond. However, additional work is still warranted on both the regression model and the decision tree before endorsing it's use in clinical practice.

## Keywords

Chronic pain, neck disability, medial branch blocks, cervical facet joint, regression, receiver operator curve

## Co-Authorship Statement

The studies contained in this dissertation were designed, analyzed, interpreted, and written by me with invaluable input and guidance from my supervisor, Dr. David Walton. My co-supervisor, Dr. Eldon Loh, provided integral guidance into study design and interpretation. Dr. Loh also delivered medial branch blocks to patients recruited for Chapter 4. Dr. Warren Nielson provided guidance for the overall methodology and analysis. Data from Chapter 2-3 was collected by Dr. David Walton and myself. I was the data collector for Chapter 4. All three also provided final approval of the document.

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## Chapter 1

### 1 Introduction

#### 1.1 Preamble

The dissertation focuses on biopsychosocial conceptualizations of neck pain and related disability and on developing a decision aid to help front-line clinicians identify patients that are likely to respond to diagnostic cervical facet medial branch blocks (MBB). This introductory chapter presents the necessary foundational information to prepare the reader for the 3 main studies. It begins by exploring the impact chronic neck pain has on the individual and society. Next, the underlying pathophysiology of pain is examined and the current model of neck pain is discussed. Lastly, evidence is provided for the effectiveness of MBBs in diagnosing cervical facetogenic pain.

#### 1.2 Incidence and Impact of Chronic Neck Pain

Chronic neck pain is a common condition that leads to long term disability and economic burden. A review by Hoy et al. found the one-year prevalence of chronic neck pain in the general population to be between 17.0-66.3%.<sup>1</sup> The wide range reported for incidence and prevalence are likely due to the variation in inclusion criteria among the studies and the definition of neck pain used. Factors such as minimum duration of pain or frequency of episodes can affect these rates. Many studies only included those individuals where neck pain resulted in activity limitations, while others included anyone with neck pain. Regardless of the true prevalence, chronic neck pain remains a significant health problem in the general population affecting various aspects of a person's life. Although many people experience a resolution of neck pain within 2 months of onset; close to 50% of individuals continue to experience neck pain for at least one year after onset.<sup>2</sup> Furthermore, chronic pain is a recurrent condition; 93.7% of sufferers report recurrent problems within their lifetime with periods of relative ease followed by periods of significant impact.<sup>3</sup>

In a review on the global burden of diseases, Hoy and colleagues<sup>4</sup> found that out of 291 conditions assessed, chronic neck pain ranked 21<sup>st</sup> in global burden and 4<sup>th</sup> in terms of overall disability. While not exclusive to chronic neck pain, a multicenter Canadian study (STOP-PAIN) determined median direct (e.g. drug treatment) and indirect costs (e.g. lost labour time) to the system per patient with chronic pain at \$1,462 per month.<sup>5</sup> Much of the burden is due to the high level of activity limitations among people with chronic neck pain. Bjornsdottir and colleagues<sup>6</sup> found that people with chronic pain were limited in normal everyday activities such as lifting groceries, bending or stooping, and getting dressed. Furthermore, the study found that people with chronic pain perceived that they had less physical strength and endurance compared to their age matched healthy individuals. Fredheim and colleagues<sup>7</sup> found that Health-related Quality of Life (HRQoL) in patients with chronic nonmalignant pain was at least as low, and according to some tools, worse, than a comparison group of palliative patients with cancer. Adding to the burden is evidence that primary care providers are ill-equipped to manage the problem; a pan-European survey of primary care providers found that 84% perceive chronic nonmalignant pain to be one of the most challenging conditions to treat.<sup>8</sup>

Additionally, several psychological issues may be present among people with chronic pain. Demyttenaere et al.<sup>9</sup> conducted surveys in 17 countries of 85,000 people to examine the comorbidity of chronic pain and mental disorders. After controlling for age and sex, the study found that those with neck or back pain had 2.3 times higher odds for mood disorders, 2.2 times more for anxiety disorders, and 1.6 times more for alcohol abuse or dependence compared to those without neck or back pain. A longitudinal cohort study followed 652 participants with neck pain that had never experienced depressive or anxiety disorders over a 2- and 4-year period. The study found that new-onset depression and anxiety disorders occurred in 15.5% of participants with neck pain. The study also found that specific pain locations, such as the neck, were more likely to be associated with depression and anxiety (HRR = 2.72,  $p < .001$ ).<sup>10</sup>

Important questions remain regarding the mechanisms that can explain the development of chronic neck pain after an acute episode. Much of the current evidence has found strong relationships between fear of pain and pain related anxiety in the development of

chronic pain and disability.<sup>11</sup> These associations can be at least partly explained through the fear avoidance model of chronic pain. The fear avoidance model of chronic pain emphasizes the role of exaggerated fear of pain and avoidant behaviour in the development of chronic pain issues. The model states that though avoidance of some activities may be beneficial in the acute phase, catastrophic beliefs and fear of further injury lead to prolonged avoidance behaviours, disuse and disability.<sup>12</sup>

Kinesiophobia and other fear avoidance beliefs are common among those with chronic neck pain.<sup>13</sup> Kinesiophobia can be defined as, “an excessive, irrational, and debilitating fear of physical movement and activity resulting from a feeling of vulnerability due to painful injury or reinjury.”<sup>14</sup> In a longitudinal study, Domenech et al.<sup>15</sup> found that decrease in levels of catastrophizing and kinesiophobia was associated with improvement in pain and disability. Hence, the persistence of these factors into the chronic phase may have important implications for their role as prognostic factors for long term disability.

### 1.3 Model of Neck Pain

Neck pain can be categorized in several ways including duration, etiology, and type. Chronic pain is often considered pain that persists beyond 3 to 6 months. Duration has been an important predictor of disease burden, with longer duration predicting poorer outcomes.<sup>16</sup> In terms of etiology, traumatic neck pain can be defined as that resulting from injuries such as motor vehicle collisions (MVC) or falls; while causes of non-traumatic neck pain include repetitive strain, disc degeneration, osteoarthritis, or disease processes (e.g. cancer). Neck pain can also be classified by type as mechanical, neuropathic, or secondary. Mechanical neck pain is pain originating from the spine or supporting structures including ligaments and muscles, facet joints, intervertebral discs, or compression (without damage) of spinal nerve roots. Neuropathic pain refers to pain thought to arise due to an injury to peripheral nerves possibly resulting from trauma, compression, traction or certain disease states.<sup>2</sup> Secondary pain refers to pain felt about the neck region but has its primary driver somewhere else (e.g. emotional driver, referral from viscera, etc.).

Although the definitions above help categorize patients into manageable subgroups, the Bone and Joint Task Force on Neck Pain and Its Associated Disorders<sup>17</sup> noted that categorizing neck pain is not sufficient to fully understand the factors affecting the individual's subjective experience and burden. The task force proposed a conceptual model that examined the onset, course, and care of neck pain (Figure 1). The model incorporates previously developed frameworks such as those by the International Classification of Functioning Disability and Health (ICF), Quebec Task Force, and others. The aim was to develop a comprehensive biopsychosocial model that integrates physical, psychological, social, environmental, and economic factors faced by people with neck pain. The premise behind the model was that neck pain is not usually a single event. Rather, most neck pain can be more accurately conceptualized as having an "episodic course" that recurs throughout one's lifetime.<sup>17</sup> The conceptual model consists of 5 main components including: factors involved in the onset and course of developing neck pain; the "care" complex; the "participation" complex; the "claim" complex; and neck pain related outcomes. These components are part of an overarching concept called the outer frame which is influenced by the person's physical, cultural, attitudinal, and social environment.<sup>17</sup> The model helps clinicians understand the various influences on a patient's neck pain experience, and is intended to help inform evaluation and treatment decisions.

## 1.4 Diagnosis and Management of Cervical Facet Joint Pain

Several treatment options have been examined for the management of chronic neck pain including manual therapy,<sup>18</sup> pharmacotherapy,<sup>19</sup> and psychological therapy.<sup>20</sup> However, many of these studies include a heterogeneous population of people with neck pain and thus have only shown small to medium effects in related outcomes. In order to effectively manage chronic neck pain, it is important to target treatments to specific populations based on classification.

Facet joint dysfunction may be a common source of persistent spinal pain. Manchikanti and colleagues<sup>21</sup> found that facet joint dysfunction could explain pain in 15-45% of their patients with chronic low back pain and 36-60% of chronic neck pain. Cervical facet

joints are innervated by medial branches off the segmental dorsal ramus of the associated segmental spinal nerve and have free nerve endings that appear to express both high-threshold (nociceptive) channels and low-threshold mechanosensitive channels.<sup>21</sup> Changes to the joint following injury occur through a cascade of events that lead to stretching of the capsule beyond normal physiological range thereby altering joint structure and function.<sup>22</sup> Nociceptive transmission in a facet injury has been attributed to inflammation due to pro-inflammatory factors in the area released when fibres are damaged through stretch or compression.<sup>23</sup>

Radiofrequency denervation is considered the optimal treatment for facetogenic pain and has been supported as a safe and effective treatment strategy.<sup>24,25</sup> In some patients it can offer significant relief of pain for 6 months to over 1 year. It uses electrical current passed through a superheated probe to create a lesion that safely interrupts propagation of the action potential in the afferent innervating the problematic joint(s). Several studies have demonstrated the effectiveness of RF in reducing pain due to facetogenic injury, though many suffer from methodological issues such as small sample sizes. Stovner and colleagues<sup>26</sup> found that 4 out of 6 patients in the RF denervation group compared to 2 out of 6 in the sham control group remained pain free at 3 month follow up. Another study reported that 6 months post RF denervation treatment, greater number of patients in the treatment group remained pain free compared to the control group (7 vs 1).<sup>27</sup>

Though RF denervation appears to be effective for highly selected patients with facetogenic neck pain, it still represents burden in terms of cost, wait-times, and safety. It is invasive by nature (a heated probe is inserted into the neck) leaving patients vulnerable to risk of pain, inflammation, infection, somatic or motor nerve dysfunction, dizziness, or even severe complications such as permanent nerve damage or stroke if not performed correctly. It is therefore important to appropriately screen patients for the likelihood of facetogenic pain before providing treatment.

Diagnosis of facetogenic neck pain itself is not straightforward. Neck pain may be associated with pathology identified during diagnostic imaging; however, most often diagnosis through these tools does not provide adequate certainty for the pathoanatomical

cause. Furthermore, clearly defined diagnostic criteria for facetogenic neck pain on imaging have not been established. The majority of people with neck pain lacking an observable pathoanatomic cause (lesion) for their injury are classified as having a non-specific mechanical neck disorder. However, before classifying a patient's pain as mechanical it is important to rule out any differential diagnoses that may require a different approach for management. These include cervical myelopathy, cervical instability, fracture, or systemic disease.<sup>28</sup>

Physical and neurological examinations along with local tenderness are also not able to discriminate between facetogenic and other sources of mechanical neck pain.<sup>25</sup> Certain types of manual examinations including cervical range of motion (CROM), palpation, and strength tests have been shown to be important indicators of impairment in facet injury; however, they are not sufficient in diagnosing. Hence, there is a strong need for a tool that can reliably and accurately discriminate between people with and without facetogenic neck pain.

Several individual studies and reviews have provided evidence for the diagnostic utility of medial branch blocks (MBBs) in assessing cervical facetogenic injury. A systematic review by Rubinstein and colleagues<sup>29</sup> reported that there is strong evidence for the diagnostic accuracy of MBBs in diagnosis of neck pain. Another review by Boswell and colleagues<sup>30</sup> found level II evidence supporting the use of cervical MBBs for diagnosis of facetogenic neck pain, however they found high rates of false positives when using a dual controlled MBB procedure, ranging from 27% (when 100% pain relief was the criterion for success) to 63% (when 80% pain relief was the criterion for success). In a review of the diagnostic utility of MBB, Falco et al.<sup>31</sup> found that there is good evidence based on 9 high-quality studies examining neck pain patients that dual diagnostic blocks are useful as diagnostic procedures. Based on this evidence, MBBs may be the most effective diagnostic exam for cervical facet injury but lack specificity (high false positive rate).

Cervical MBBs are administered by a specialized physician usually in a tertiary care pain clinic. Analgesic agents such as lidocaine are injected into the medial branches of the dorsal rami innervating the targeted facet joint. Criteria for considering the test positive



for facetogenic pain are mostly focused on pain behaviour following the block, with thresholds for pain reduction set between 50 and 80% lasting only the expected duration of the anesthetic after which pain of facetogenic origin should return close to baseline values.<sup>30</sup> Several studies have recommended the use of double blocks to increase level of accuracy. In a double block procedure, patients are first injected with a diagnostic block of a short-acting lidocaine followed by a longer-acting anesthetic like bupivacaine. Those positive to the first block are then provided the alternative block after 3-4 weeks, with duration of pain relief considered as important diagnostic criteria – relief from lidocaine should be of shorter duration than that of bupivacaine.<sup>32</sup> The use of two different anesthetics is recommended in order to reduce the false positive rate associated with a single block.<sup>33</sup>

Although MBBs appear to be adequately useful for diagnosing facetogenic neck pain, there are logistic challenges that prevent widespread use. It is widely considered a safe and effective procedure,<sup>31</sup> but MBB, like RFN, is still invasive and exposes the patient to complications such as local bleeding, local hematoma, bruising, and nerve root irritation. Furthermore, they may be expensive and inaccessible in certain parts of the world.<sup>25</sup> One of the largest concerns in Canada specifically is long wait times to have the procedure completed by a specialist physician. Lynch and colleagues<sup>34</sup> reported wait times of 3 months to 5 years for patients to see a pain specialist physician. The stimulus for the work described in this thesis is a belief that developing a better method to evaluate neck pain in general and diagnose facetogenic neck pain specifically stands to improve access to those most likely to benefit and removing those least likely to benefit, thereby reducing exposure to a potentially risky procedure.

## 1.5 Chapter Overview

The aims of chapters 2 and 3 of this dissertation are to better describe the phenomenon of neck-related disability through construction and evaluation of regression models using both clinical (Chapter 2) and psychosocial (Chapter 3) predictor variables. Chapter 2 starts by developing a base model which includes patient demographics and injury factors. Important clinical assessments were then added to determine their individual role in predictive disability. Chapter 2 ends with a final model that incorporates both the base

model and the significant clinical predictors of disability. Chapter 3 starts with a separate model focusing on psychosocial factors. It ends with creation of a combined model including both physical signs and psychosocial variables to provide a more holistic biopsychosocial perspective of neck-related disability. The models are cross-validated with a test sample and fit indices are provided. The model has important implications for management of people with chronic neck pain. It can be used by front line clinicians during evaluation of patients with neck pain to identify the strongest contributors, and thereby inform clinical decisions that may lead to more informed treatment and optimized patient outcomes.

In terms of treatment, accurate diagnosis of the type of neck pain is integral. Hence, in Chapter 4 of the dissertation a predictive tool is developed to help clinicians screen for facetogenic neck pain. The intention is that a simple clinical screening tool will offer opportunity to identify those very likely and very unlikely to respond to the MBB (and, by extension, likely to have or not have facetogenic neck pain), with a goal of reducing exposure to unnecessary testing in those unlikely to respond, remove those people from the queue, and increase accessibility for those most likely to respond. The chapter begins by developing a hierarchical regression model of predictive factors for response to MBB procedure. Next, significant predictors are examined using a receiver operator curve (ROC) to determine clinically relevant cut-off points. Sensitivity, specificity, positive predictive value, and negative predictive value are provided for the decision aid.

## 1.6 References

1. Hoy DG, Protani M, De R, Buchbinder R. The epidemiology of neck pain. *Best Practice & Research Clinical Rheumatology*. 2010;31:24:783-92.
2. Cohen SP. Epidemiology, diagnosis, and treatment of neck pain. *Mayo Clinic Proceedings* 2015;90:284-299.
3. Picavet HS, Schouten JS. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC 3-study. *Pain*. 2003;102(1):167-78.
4. Hoy D, March L, Woolf A, Blyth F, Brooks P, Smith E, Vos T, Barendregt J, Blore J, Murray C, Burstein R, Buchbinder R. The global burden of neck pain: estimates from the global burden of disease 2010 study. *Annals of the Rheumatic Disease*. 2014;73:1309-1315.
5. Guerriere DN, Choinière M, Dion D, Peng P, Stafford-Coyte E, Zagorski B, Banner R, Barton PM, Boulanger A, Clark AJ, Gordon AS. The Canadian STOP-PAIN project—Part 2: What is the cost of pain for patients on waitlists of multidisciplinary pain treatment facilities? *Canadian Journal of Anesthesia/Journal canadien d'anesthésie*. 2010;57(6):549-58.
6. Björnsdóttir SV, Jónsson SH, Valdimarsdóttir UA. Functional limitations and physical symptoms of individuals with chronic pain. *Scandinavian journal of rheumatology*. 2013;42(1):59-70.
7. Fredheim OM, Kaasa S, Fayers P, Saltnes T, Jordhoy M, Borchgrevink PC. Chronic non-malignant pain patients report as poor health-related quality of life as palliative cancer patients. *Acta Anaesthesiologica Scandinavica*. 2008;52:143-148.

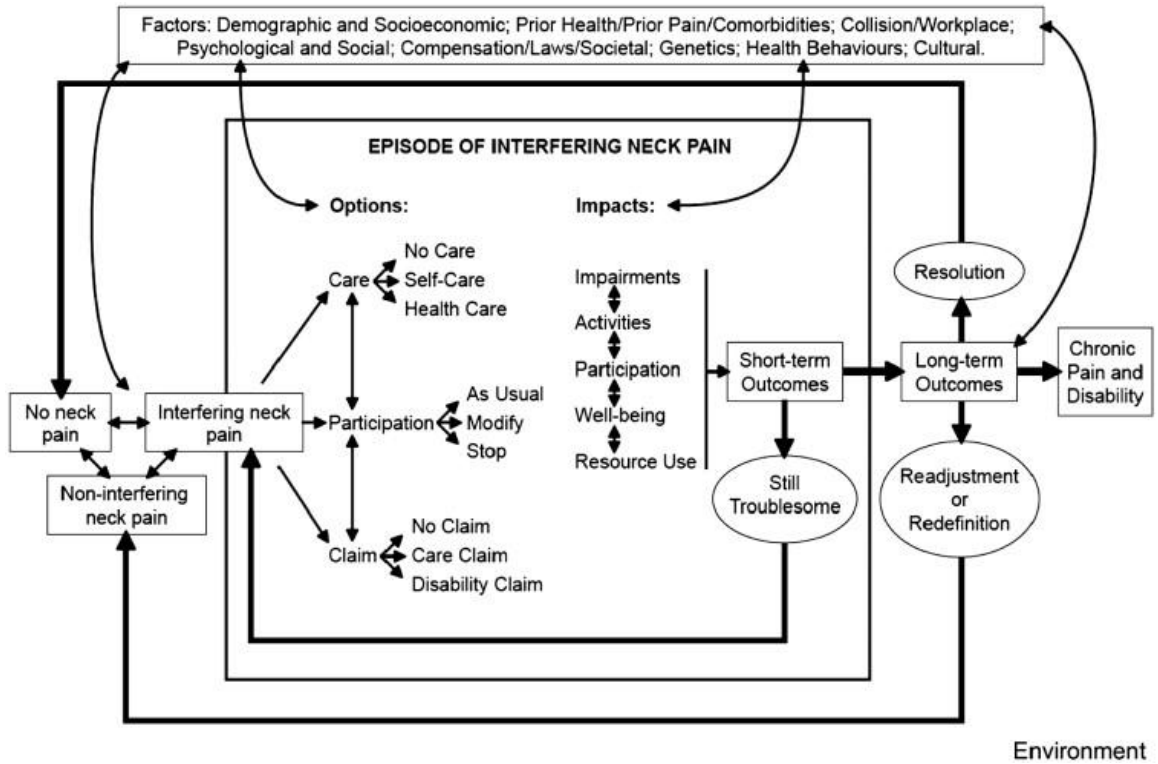
8. Johnson M, Collett B, Castro-Lopes JM. The challenges of pain management in primary care: a pan-European survey. *Journal of Pain Research*. 2013;6:393-401.
9. Demyttenaere K, Bruffaerts R, Lee S, Posada-Villa J, Kovess V, Angermeyer MC, Levinson D, de Girolamo G, Nakane H, Mneimneh Z, Lara C. Mental disorders among persons with chronic back or neck pain: results from the World Mental Health Surveys. *Pain*. 2007;129(3):332-342.
10. Wenzel HG, Haug TT, Mykletun A, Dahl AA. A population study of anxiety and depression among persons who report whiplash traumas. *Journal of psychosomatic research*. 2002;53(3):831-835.
11. Hasenbring MI, Chehadi O, Titze C, Kreddig N. Fear and anxiety in the transition from acute to chronic pain: there is evidence for endurance besides avoidance. *Pain management*. 2014;4(5):363-74.
12. Vlaeyen JW, Linton SJ. Fear-avoidance model of chronic musculoskeletal pain: 12 years on. *Pain*. 2012;153(6):1144-1147.
13. Kamper SJ, Maher CG, Costa LD, McAuley JH, Hush JM, Sterling M. Does fear of movement mediate the relationship between pain intensity and disability in patients following whiplash injury? A prospective longitudinal study. *Pain*. 2012;153(1):113-119.
14. Kori SH, Miller RP, Todd DD. Kinesiophobia: a new view of chronic pain behavior. *Pain Management*. 1990;3(1):35-43.
15. Doménech J, Sanchis-Alfonso V, Espejo B. Changes in catastrophizing and kinesiophobia are predictive of changes in disability and pain after treatment in

- patients with anterior knee pain. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2014;22(10):2295-2300.
16. Enthoven P, Skargren E, Carstensen J, Oberg B. Predictive factors for 1-year and 5-year outcome for disability in a working population of patients with low back pain treated in primary care. *Pain*. 2006;122(1):137-144.
  17. Guzman J, Hurwitz EL, Carroll LJ, Haldeman S, Côté P, Carragee EJ, Peloso PM, van der Velde G, Holm LW, Hogg-Johnson S, Nordin M. A new conceptual model of neck pain: linking onset, course, and care: the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders. *Journal of manipulative and physiological therapeutics*. 2009;32(2):S17-28.
  18. Gross AR, Kay T, Hondras M, Goldsmith C, Haines T, Peloso P, Kennedy C, Hoving J. Manual therapy for mechanical neck disorders: a systematic review. *Manual Therapy*. 2002;7(3):131-149.
  19. Kroenke K, Krebs EE, Bair MJ. Pharmacotherapy of chronic pain: a synthesis of recommendations from systematic reviews. *General hospital psychiatry*. 2009;31(3):206-219.
  20. Morley S, Eccleston C, Williams A. Systematic review and meta-analysis of randomized controlled trials of cognitive behaviour therapy and behaviour therapy for chronic pain in adults, excluding headache. *Pain*. 1999;80(1):1-13.
  21. Manchikanti L, Singh V, Falco FJ, Cash KM, Fellows B. Cervical medial branch blocks for chronic cervical facet joint pain: a randomized, double-blind, controlled trial with one-year follow-up. *Spine*. 2008;33(17):1813-1820.

22. Kallakuri S, Singh A, Lu Y, Chen C, Patwardhan A, Cavanaugh JM. Tensile stretching of cervical facet joint capsule and related axonal changes. *European Spine Journal*. 2008;17(4):556-63.
23. Curatolo M, Bogduk N, Ivancic PC, McLean SA, Siegmund GP, Winkelstein B. The role of tissue damage in whiplash associated disorders: discussion paper 1. *Spine*. 2011;36(25 Suppl):S309-315.
24. Cohen SP, Huang JH, Brummett C. Facet joint pain—advances in patient selection and treatment. *Nature Reviews Rheumatology*. 2013;9(2):101-16.
25. Manchikanti L, Hirsch JA, Kaye AD, Boswell MV. Cervical zygapophysial (facet) joint pain: effectiveness of interventional management strategies. *Postgraduate medicine*. 2016;128(1):54-68.
26. Stovner LJ, Kolstad F, Helde G. Radiofrequency denervation of facet joints C2-C6 in cervicogenic headaches: a randomized, double-blind, sham-controlled study. *Cephalalgia*. 2004;24:821-830.
27. Lord SM, Barnsley L, Wallis BJ, McDonald GJ, Bogduk N. Percutaneous radiofrequency neurotomy for chronic cervical zygapophyseal-joint pain. *The New England Journal of Medicine*. 1996;335:1721-1726.
28. Childs JD, Cleland JA, Elliott JM, Teyhen DS, Wainner RS, Whitman JM, Sopky BJ, Godges JJ, Flynn TW. Neck pain: Clinical practice guidelines linked to the International classification of functioning, disability, and health from the Orthopedic Section of the American Physical Therapy Association. *Journal of Orthopedic Sports Physical Therapy*. 2008;38:A1-A34.

29. Rubinstein SM, van Tulder M. A best-evidence review of diagnostic procedures for neck and low-back pain. *Best Practice & Research Clinical Rheumatology*. 2008;22:471-482.
30. Boswell MV, Manchikanti L, Kaye AD, Bakshi S, Gharibo CG, Gupta S, Jha SS, Nampiarampil DE, Simopoulos TT, Hirsch JA. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain physician*. 2015;18(4):E497-533.
31. Falco FJ, Manchikanti L, Datta S, Wargo BW, Geffert S, Bryce DA, Atluri S, Singh V, Benyamin RM, Sehgal N, Ward SP. Systematic review of the therapeutic effectiveness of cervical facet joint interventions: an update. *Pain Physician*. 2012;15(6):E839-68.
32. Manchikanti L, Damron K, Cash K, Manchukonda R, Pampati V. Therapeutic cervical medial branch blocks in managing chronic neck pain: A preliminary report of a randomized, double-blind, controlled trial: clinical trial nct0033272. *Pain Physician*. 2006;9:333-346.
33. Barnsley L, Lord S, Wallis B, Bogduk, N. False-positive rates of cervical zygapophysial joint blocks. *Clinical Journal of Pain*. 1993;9(2):124-130.
34. Lynch ME, Campbell F, Clark AJ, Dunbar MJ, Goldstein D, Peng P, Stinson J, Tupper H. A systematic review of the effect of waiting for treatment for chronic pain. *Pain*. 2008;136:97-116.

**Figure 1: Simplified graphical representation of the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and its Associated Disorders Conceptual Model for the onset, course, and care of neck pain.**



(Reprinted from: A New Conceptual Model of Neck Pain: Linking Onset, Course, and Care: The Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders, by Guzman et al. 2009, Elsevier 2009. Reprinted with permission.)



## Chapter 2

# 2 Demographic and Clinical Predictors of Chronic Pain Related Disability

## 2.1 Introduction

Neck and low back pain have been reported to be the fourth leading cause of disability among chronic conditions as measured by years lived with disability.<sup>1</sup> The 1-year incidence rate for neck pain in adults ranges from 10.4 to 21.3%.<sup>2</sup> Symptoms of more than 50% of individuals improve over a 2-month period. However, about 50% of individuals do not experience full recovery and continue to experience pain.<sup>3</sup> Neck pain can be conceptualized as, “*episodes occurring over a lifetime with variable degrees of recovery in between episodes*”.<sup>4</sup> This definition speaks to the view that neck pain is not a one-time injury but a recurrent condition.

Several studies have shown that chronic neck pain results in significant personal, economic, and social burdens.<sup>4</sup> The estimated cost for chronic neck pain in Canada is \$15 billion dollars per year and in North America \$165 billion per year.<sup>5</sup> In addition to the financial burden, chronic neck pain has important implications for various aspects of an individual’s life. People with chronic neck pain may not be able to carry out their normal activities of daily living such as self-care, household chores, or participation in social activities.<sup>6</sup> Studies also report poorer sleep quality and quality of life among people with neck pain<sup>7,8</sup> Cote and colleagues<sup>9</sup> reported that every year up to 14.1% of people are limited in their activities at work due to chronic neck pain.

Due to the significant impact neck pain has on various aspects of a person’s daily living, it is important to evaluate which factors may contribute to disability. Examination of these factors can help clinicians better identify individuals that may be at risk for long term disability and develop more personalized management plans. Sterling and colleagues<sup>10</sup> assessed the gaps in literature related to prognostic models and presented a list of priority factors for future studies to examine among the whiplash population; these included demographic and clinical factors such as self-reported pain levels, cervical range of motion (CROM), mechanical pressure pain threshold, and sex.

Though CROM has been cited as a priority area of research, there is a lack of evidence for its importance among individuals with chronic neck pain. Kauther et al.<sup>11</sup> did not find a correlation between neck pain and cervical range of motion. While Lee and colleagues<sup>12</sup> found reduction in rotation and extension was correlated with neck pain. Mechanical hypersensitivity is another factor that has been correlated with neck disability among individuals with whiplash and cervical radiculopathy.<sup>13</sup> Scott et al.<sup>14</sup> found that cervical spine sites had a decrease in pressure pain detection thresholds (PPDT) in individuals with chronic pain compared to matched pain free controls. Studies looking at sex differences have shown that females tend to report greater level of stress and pain than males in clinical pain populations.<sup>15</sup> Studies have shown that the presence of both higher pain scores and radicular symptoms are related to chronicity and poorer outcomes for those with neck pain.<sup>3</sup> Based on previously reported evidence, the objective of the current study is to identify cross-sectional predictors of disability among people with chronic neck pain to examine the individual contributions of demographics (age, sex), injury characteristics (etiology, pain duration, pain intensity), and clinical factors (CROM, (PPDT), radicular symptoms) in the prediction of self-rated disability among individuals with chronic neck pain.

## 2.2 Methods

### 2.2.1 Participants

Participant data were collected between 2008 and 2016. Participants were initially approached by their primary clinician from either community physiotherapy clinics or a specialized academic pain clinic. Interested participants were then referred to the study coordinator for more information and to provide informed consent if interested and eligible to participate. Approval was obtained from Western University's Institutional Review Ethics Board. Inclusion criteria for participant recruitment were: age 18 years or older, chronic mechanical neck pain (as diagnosed by a specialist pain physician) for at least 3 months, and ability to read and write in English. Individuals with neck pain due to cancer or neuromuscular disease and those with cognitive issues that precluded valid self-report were excluded.

## 2.2.2 Procedure

Participants completed a set of self-report questionnaires which included information on demographics (age, sex), injury characteristics (etiology, duration of pain, pain intensity), and psychosocial factors (medical legal status, neck disability, depression symptoms, anxiety symptoms, catastrophizing). Participants also underwent a standardized clinical assessment that included Spurling's test, CROM, and PPDT by a trained assessor. The current study extracted only data related to participant demographics (age, gender), injury characteristics (etiology, duration of pain, pain intensity), and clinical variables (Spurlings test, CROM, PPDT) from the database to evaluate the unique explanatory value of common clinical assessments to neck related disability after controlling for demographic and injury related variables.

## 2.2.3 Dependent Variable

**Neck Disability Index (NDI):** the NDI is a self-report tool which has previously been shown to have strong psychometric properties<sup>16,17</sup> with high internal consistency (Cronbach's  $\alpha=0.92$ ).<sup>18</sup> It is a scale that consists of 10 items including: pain, reading, headaches, concentration, personal care, lifting, work, driving, sleep, and recreation. Seven of the ten items relate to activities of daily living, two items relate to pain, and one item is related to concentration. The items are measured on a 6-point scale from 0 (no disability) to 5 (full disability).

## 2.2.4 Predictor Variables

**Demographic factors:** age was provided in years; sex was coded as: female=0, male=1; etiology was coded as: non-trauma=0, trauma=1; pain duration was coded in years.

**Pain intensity:** assessed using a written 11-point numeric rating scale (NRS; 0 = no pain, 10 = worst pain). The NRS has been shown to be a reliable and valid assessment tool for pain.<sup>19</sup>

**Spurling's test:** this test has been described for clinical diagnosis of radicular pain.<sup>20</sup> Studies show that it has moderate sensitivity and high specificity for cervical radiculopathy.<sup>20,21</sup> A trained assessor conducted the Spurling's test by first bending the

participant's neck to the side to be tested (approx. 20% of total range) and then providing a compression force to determine if any symptoms were provoked. Those with radicular symptoms were considered positive to the test. It was categorized as 0=negative both sides, 1=positive 1 side, and 2=positive both sides.

***Cervical Range of Motion (CROM):*** assessed using an inclinometer (Acumar Dual Inclinometer Model ACU002) on 4 different planes: flexion, extension, left side flexion, and right side flexion. Tousignant and colleagues<sup>22</sup> found this technique to be highly correlated with a static plane radiographic method ( $r=0.97$ ). CROM was coded as 'positive' if patients reported pain or discomfort on any direction. It was coded linearly as 0=no positive planes, 1=1 positive plane, 2=2 positive planes, 3=3 positive planes, and 4=4 positive planes.

***Pressure Pain Detection Threshold (PPDT):*** The PPDT is used to determine the lowest stimulus that would give rise to the perception of pain when a participant is exposed to a noxious stimulus. A single trained assessor conducted the PPDT assessment by placing a digital algometer (Wagner FDX-25, Wagner Instruments, Greenwich CT) on the site and providing a constant force at an increasing rate of  $1\text{kg}/\text{cm}^2/\text{s}$ . Participants were instructed to indicate the moment the sensation changed from pressure to pain by saying "stop". The procedure was repeated 3 times at each location and an average was taken. Previous studies have shown this device to be adequately precise and reliable for clinical use.<sup>23-25</sup>

### 2.2.5 Statistical Analysis

The database was randomly divided into a training sample and a cross validation sample, based on sample size calculation for up to 13 predictive factors and a ratio of 15:1 participants per factor.<sup>26</sup> Based on this estimate, total sample were randomly selected for the training model (N=214) and the remaining for the cross validation (N=224). Cross-validation was conducted on the final comprehensive model described in Chapter 3. Descriptive analysis was conducted to determine baseline demographic and injury characteristics. Pearson correlation coefficients were used to assess bivariate associations between NDI score and each predictor variable. Hierarchical multiple regression was first conducted to assess the ability of demographic and injury factors (age, sex, pain duration,

etiology, and pain intensity, entered in that order) to predict level of neck disability. A base model of demographic and injury characteristics was developed based on previous evidence.<sup>10</sup> Variables were retained if the significance of change in F by adding that item was  $p \leq .10$  and were removed if  $p > .10$ . Next, a second regression was conducted to examine the additional unique variance explained by clinical assessments for neck disability (PPDT, number of restricted planes, and Spurling's test) after controlling for demographic and injury variables (the base model factors). First-pass evaluation focused on multicollinearity (tolerance and variance inflation factor (VIF)), Mahalanobis distances, and Normal Probability Plot to confirm assumptions of multiple regression were not violated. A value of less than .10 for tolerance and greater than 10 for VIF suggests possibility of multicollinearity. Scatterplot of standardized residuals should not have outliers beyond the recommended  $\pm 3.3$  standardized units.<sup>26</sup> The final model was interpreted using  $R^2$  to estimate total variance in NDI explained by the retained variables. A regression equation was constructed using unstandardized beta values. All analyses were conducted using SPSS 23.0 (Chicago, IL).

## 2.3 Results

### 2.3.1 Sample Characteristics

Table 1 provides information on the participant characteristics in both the training and cross-validation samples. The database consisted mostly of females (67%). Average age of participants was 44.6 years (SD=12.6) and average duration of pain was 3.6 years (SD=6.7). Participants' average pain intensity at baseline was 5.0 (SD=2.2). The modal etiology was traumatic injury (57%) and most were not pursuing medical legal action (67%).

### 2.3.2 Pre-Analysis

The analysis demonstrated that the assumption of multicollinearity was not violated. Assumptions of normality, linearity, and outliers were also not violated. Normal P-P plot of regression showed normal distribution. Scatterplot of standardized residuals showed no outliers beyond the recommended  $\pm 3.3$ . Furthermore, maximum Mahalanobis

distances value of the data did not exceed critical value of 24.32 for 7 independent variables .<sup>26</sup>

### 2.3.3 Development of the Predictive Model

Only pain intensity, pain duration, and etiology resulted in significant F change ( $p < .05$ ); while sex did not (Table 2). The final base model explained 36.0% of the total variance ( $F(4,209)=32.6$ ,  $p < .01$ ). Variance explained by each individual factor ( $R^2$ ) was as follows: 0.8 % for sex,  $sr^2=0.01$ ; 4.3% for pain duration,  $sr^2=0.04$ ; 5.0% for etiology,  $sr^2=0.05$ ; 25.9% for pain intensity,  $sr^2=0.26$ .

Next, the addition of clinical assessments (PPDT, number of restricted planes, and Spurling's test) significantly contributed to the prediction neck disability beyond that explained by the base model. The amount of additional variance explained by PPDT explained 3.3% ( $sr^2=0.03$ ), restricted planes was 3.5% ( $sr^2=0.04$ ), and Spurling's test was 4.7% ( $sr^2=0.5$ ). The final model explained 48.3% of variance in neck disability ( $F(7,57)=7.60$ ,  $p < .01$ ) and consisted of sex, pain duration, etiology, pain intensity, PPDT, restricted planes, and Spurling's test (Table 3). The addition of the clinical factors resulted in 12.3% more variance explained compared to the initial base model. The regression equation for the model was generated by including only those variables in the final model. The final equation including constant is presented below:

$$\text{Neck disability} = 5.282 - (0.619 * \text{sex}) + (0.474 * \text{pain duration}) + (0.874 * \text{etiology}) + (1.785 * \text{pain intensity}) - (0.309 * \text{PPDT}) + (1.035 * \text{restricted planes}) + (2.892 * \text{Spurling's test})$$

## 2.4 Discussion

The current study examined the influence of demographic, injury, and clinical factors on current disability among individuals with chronic mechanical neck pain. In contrast to previous studies that have examined recovery from injury or transition into chronic pain with inception in the acute stage of injury, the current study evaluated factors that continue to show an association with disability in the chronic phase. Female sex, etiology, pain duration, pain intensity, PPDT ( $\text{kg}/\text{cm}^2$ ), number of restricted planes, and

Spurling's test were used to develop the model. The model explained 48.3% of variance in NDI score.

Previous studies have found that self-rated disability appears to differ between traumatic and non-traumatic etiologies.<sup>27,28</sup> Hoving and colleagues<sup>27</sup> found that those with traumatic injury were more likely to report interfering neck disability than those without. This is consistent to findings in the current study.

The current study found average pain intensity explained the greatest variance in neck disability ( $\beta=.41$ ,  $p<0.001$ ). This is supported by a previous regression on pain intensity which found similar predictive capacity for pain intensity ( $\beta=.49$ ).<sup>24</sup> This is unsurprising since pain intensity may influence other factors related to disability such as ROM. Hence, pain intensity may have a direct and indirect relationship with disability among those with chronic neck pain.

The regression analysis found an inverse relationship between PPDT and neck related disability (lower pain threshold, higher disability). A previous study found no such relationship between pressure pain sensitivity and neck disability.<sup>29</sup> However, other studies report that among individuals with chronic pain, pressure pain thresholds are associated with higher disability<sup>24,30,31</sup> Similar to the current study, Fernandez-Perez and colleagues<sup>30</sup> found that individuals with neck injury had lower PPDTs than healthy controls. The study also found that these lower PPDTs were widespread in that they remained lower even when tested at other locations including metacarpal and tibialis anterior muscle. Unfortunately, the current study only assessed PPDTs at the neck; hence we are unable to provide a comparison. Future studies may want to include this factor and determine how well it fits in the disability model. The use of substitute measurement at different locations may help identify people that are at risk for disability but unable to conduct a PPDT test on the neck.

Cervical range of motion also significantly predicted neck disability in the current study. This is in contrast to an earlier study that found no such relationship.<sup>32</sup> Conversely, other studies have reported significant negative correlations between neck disability and ROM.<sup>30,31,33</sup> Kasch et al.<sup>33</sup> found individuals with decreased CROM were 4.6 times more likely

to have chronic handicap than those with full CROM. Furthermore, Olson et al.<sup>31</sup> found that decreased neck rotation was associated with increased disability. These findings suggest that those with restricted CROM may not be able to participate in their activities of daily living, limiting their ability to function and leading to disability. There is theoretical support for this argument as the primary outcome in our study (the NDI) includes several activities of daily living that are expected to be impaired by limited mobility. The current study did not assess neck rotation, which may potentially improve the predictive capacity of CROM for disability.

Previous studies have reported that females tend to rate higher pain related disability than males.<sup>33,34</sup> Walton and colleagues<sup>35</sup> also reported a significantly higher risk among females than males in developing persistent problems following acute whiplash injury (OR=1.64; 95% CI: 1.27,2.12). In contrast, the current study found no association between sex and neck pain related disability among those with chronic pain. Despite no bivariate association, sex was retained in the base and final regression models due to strong previous research.

The current study had several limitations that warrant caution in interpretation. The study may be limited by recruitment bias. Participants were recruited from a tertiary pain clinic. The characteristics of our sample is likely different from those in the community not seeking specialty tertiary care. Secondly, the study was observational and cross-sectional hence we cannot draw causal inferences. Impact of other important factors such as psychological and social influences were not assessed. It is possible that these other factors explain even greater variance in neck-related disability which is a direction for additional research.

In conclusion, the current study found that a model consisting of sex, etiology, pain duration, average pain intensity, PPDT, restricted range of motion, and Spurling's test explained over 48% of variance in neck-related disability scores. The current model provides important clinical implications. Front line clinicians can use this model to explore factors that are likely to result in long term disability among patients with chronic neck pain, and to adjust their management accordingly. The model may have value in



clinical practice. The variables in our model are routinely captured during a clinical assessment, hence it does not create a greater burden on the clinician to conduct additional tests. While causal inferences cannot be made, clinical experience and theory suggest that targeting modifiable variables may result in reduced self-ratings of neck disability.

## 2.5 References

1. Hoy D, March L, Woolf A, Blyth F, Brooks P, Smith E, Vos T, Barendregt J, Bloore J, Murray C, Burstein R, Buchbinder R. The global burden of neck pain: estimates from the global burden of disease 2010 study. *Annals of the Rheumatic Disease*. 2014;73:1309-1315.
2. Hoy DG, Protani M, De R, Buchbinder R. The epidemiology of neck pain. *Best Practice & Research Clinical Rheumatology*. 2010;31:24:783-92.
3. Cohen SP. Epidemiology, diagnosis, and treatment of neck pain. *Mayo Clinic Proceedings* 2015;90:284-299.
4. Guzman J, Hurwitz EL, Carroll LJ, Haldeman S, Côté P, Carragee EJ, Peloso PM, van der Velde G, Holm LW, Hogg-Johnson S, Nordin M. A new conceptual model of neck pain: linking onset, course, and care: the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders. *Journal of manipulative and physiological therapeutics*. 2009;32(2):S17-28
5. Turk DC. Clinical effectiveness and cost-effectiveness of treatments for patients with chronic pain. *The Clinical journal of pain*. 2002;18(6):355-365.
6. van Randeraad-van der Zee C, Beurskens A, Swinkels R, Pool J, Batterham R, Osborne R, de Vet H. The burden of neck pain: its meaning for persons with neck pain and healthcare providers, explored by concept mapping. *Quality of Life Research*. 2016;25:1219-1225.
7. Kovacs FM, Seco J, Royuela A, Melis S, Sánchez C, Díaz-Arribas MJ, Meli M, Núñez M, Martínez-Rodríguez ME, Fernández C, Gestoso M, Mufraggi N, Moyá J,

- Rodríguez-Pérez V, Torres-Unda J, Burgos-Alonso N, Gago-Fernández I, Abraira V. Patients with neck pain are less likely to improve if they experience poor sleep quality: a prospective study in routine practice. *Clinical Journal of Pain*. 2015;31:713-721.
8. Muñoz-Muñoz S, Muñoz-García MT, Albuquerque-Sendín F, Arroyo-Morales M, Fernández-de-las-Peñas C. Myofascial trigger points, pain, disability, and sleep quality in individuals with mechanical neck pain. *Journal of manipulative and physiological therapeutics*. 2012;35(8):608-613.
  9. Côté P, van der Velde G, Cassidy JD, Carroll LJ, Hogg-Johnson S, Holm LW, Carragee EJ, Haldeman S, Nordin M, Hurwitz EL, Guzman J. The burden and determinants of neck pain in workers. *European Spine Journal*. 2008;17(1):60-74.
  10. Sterling M, Carroll LJ, Kasch H, Kamper SJ, Stemper B. Prognosis after whiplash injury: where to from here? Discussion paper 4. *Spine*. 2011;36:S330-4.
  11. Kauther MD, Piotrowski M, Hussmann B, Lendemans S, Wedemeyer C. Cervical range of motion and strength in 4,293 young male adults with chronic neck pain. *European Spine Journal*. 2012;21(8):1522-7.
  12. Lee H, Nicholson LL, Adams RD. Cervical range of motion associations with subclinical neck pain. *Spine*. 2004;29(1):33-40.
  13. Sterling M. Testing for sensory hypersensitivity or central hyperexcitability associated with cervical spine pain. *Journal of manipulative and physiological therapeutics*. 2008;31(7):534-9.

14. Scott D, Jull G, Sterling M. Widespread sensory hypersensitivity is a feature of chronic whiplash-associated disorder but not chronic idiopathic neck pain. *The Clinical journal of pain*. 2005;21(2):175-81.
15. Stenberg G, Lundquist A, Fjellman-Wiklund A, Ahlgren C. Patterns of reported problems in women and men with back and neck pain: similarities and differences. *Journal of rehabilitation medicine*. 2014;46(7):668-75.
16. Gay RE, Madson TJ, Cieslak KR. Comparison of the Neck Disability Index and the Neck Bournemouth Questionnaire in a sample of patients with chronic uncomplicated neck pain. *Journal of Manipulative and Physiological Therapeutics*. 2007;30(4):259-62.
17. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. *Journal of manipulative and physiological therapeutics*. 1991;14(7):409-15.
18. Hains F, Waalen J, Mior S. Psychometric properties of the neck disability index. *Journal of manipulative and physiological therapeutics*. 1998;21(2):75-80.
19. Von Korff M, Jensen MP, Karoly P. Assessing global pain severity by self-report in clinical and health services research. *Spine*. 2000;25(24):3140-51.
20. Rubinstein SM, Pool JJ, van Tulder MW, Riphagen II, de Vet HC. A systematic review of the diagnostic accuracy of provocative tests of the neck for diagnosing cervical radiculopathy. *European Spine Journal*. 2007;16(3):307-19.
21. Malanga GA, Landes P, Nadler SF. Provocative tests in cervical spine examination: historical basis and scientific analyses. *Pain Physician*. 2003;6(2):199-206.

22. Tousignant M, de Bellefeuille L, O'Donoghue S, Grahovac S. Criterion validity of the cervical range of motion (CROM) goniometer for cervical flexion and extension. *Spine*. 2000;25(3):324-30.
23. Chesterton LS, Sim J, Wright CC, Foster NE. Interrater reliability of algometry in measuring pressure pain thresholds in healthy humans, using multiple raters. *The Clinical journal of pain*. 2007;23(9):760-6.
24. Walton D, MacDermid J, Nielson W, Teasell R, Chiasson M, Brown L. Reliability, standard error, and minimum detectable change of clinical pressure pain threshold testing in people with and without acute neck pain. *Journal of orthopaedic & sports physical therapy*. 2011;41(9):644-50.
25. Walton DM, Levesque L, Payne M, Schick J. Clinical pressure pain threshold testing in neck pain: comparing protocols, responsiveness, and association with psychological variables. *Physical therapy*. 2014;94(6):827-37.
26. Tabachnick, B. G., and Fidell, L. S. (2013). *Using multivariate statistics*, 6th ed. Boston: Pearson.
27. Hoving JL, de Vet HC, Twisk JW, Devillé WL, van der Windt D, Koes BW, Bouter LM. Prognostic factors for neck pain in general practice. *Pain*. 2004;110(3):639-45.
28. Miró J, Nieto R, Huguet A. Predictive factors of chronic pain and disability in whiplash: a Delphi poll. *European Journal of Pain*. 2008;12:30-47.
29. Gonçalves MC, Chaves TC, Florencio LL, Carvalho GF, Dach F, Fernández-De-Las-Penãs C, Bevilaqua-Grossi D. Is pressure pain sensitivity over the cervical

- musculature associated with neck disability in individuals with migraine? *Journal of bodywork and movement therapies*. 2015;19(1):67-71.
30. Fernández-Pérez AM, Villaverde-Gutiérrez C, Mora-Sánchez A, Alonso-Blanco C, Sterling M, Fernández-de-las-Peñas C. Muscle trigger points, pressure pain threshold, and cervical range of motion in patients with high level of disability related to acute whiplash injury. *journal of orthopaedic & sports physical therapy*. 2012;42(7):634-41.
31. Olson SL, O'Connor DP, Birmingham G, Broman P, Herrera L. Tender point sensitivity, range of motion, and perceived disability in subjects with neck pain. *Journal of Orthopaedic & Sports Physical Therapy*. 2000;30(1):13-20.
32. Kooijman MK, Barten DJ, Swinkels IC, Kuijpers T, de Bakker D, Koes BW, Veenhof C. Pain intensity, neck pain and longer duration of complaints predict poorer outcome in patients with shoulder pain—a systematic review. *BMC musculoskeletal disorders*. 2015;16(1):1.
33. Kasch H, Qerama E, Kongsted A, Bendix T, Jensen TS, Bach FW. Clinical assessment of prognostic factors for long-term pain and handicap after whiplash injury: a 1-year prospective study. *European journal of neurology*. 2008;15(11):1222-30.
34. Côté P, Cassidy JD, Carroll LJ, Kristman V. The annual incidence and course of neck pain in the general population: a population-based cohort study. *Pain*. 2004;112(3):267-73.
35. Walton DM, MacDermid JC, Giorgianni AA, Mascarenhas JC, West SC, Zammit CA. Risk factors for persistent problems following acute whiplash injury: update of

a systematic review and meta-analysis. *journal of orthopaedic & sports physical therapy*. 2013;43(2):31-43.

**Table 1: Participant Characteristics of the Neck Disability Index Model**

<b>Variable</b>	<b>Training Sample (n=214)</b>	<b>Crossvalidation Sample (n=224)</b>
<b>Age (yrs)</b>	44.6 (12.6)	44.1 (13.2)
<b>Sex (%)</b>		
<b>Females</b>	66.8	75.1
<b>Males</b>	33.2	24.9
<b>Pain Duration (yrs)</b>	3.6 (6.7)	4.3 (7.6)
<b>Pain Intensity</b>	4.9 (2.2)	5.4 (2.0)
<b>Etiology (%)</b>		
<b>Trauma</b>	58.7	63.3
<b>Non-Trauma</b>	41.3	36.7
<b>Medical Legal (%)</b>		
<b>Currently pursuing</b>	33.3	35.4
<b>Not currently pursuing</b>	66.7	64.6
<b>PPDT</b>	7.2 (4.2)	7.1 (3.9)
<b>Spurlings (%)</b>		
<b>Negative both sides</b>	41.9	33.3
<b>Positive one side</b>	36.5	38.1
<b>Positive both sides</b>	21.6	28.6
<b>Restricted Planes (%)</b>		
<b>None</b>	51.6	50.8
<b>1</b>	12.1	15.2
<b>2</b>	15.4	13.7
<b>3</b>	8.8	13.2
<b>4</b>	12.1	7.1
<b>NDI (N=338)</b>	17.1 (9.5)	18.0 (9.7)

*Note:* NDI=Neck Disability Inventory; PPDT=pressure pain detection threshold



**Table 2: Hierarchical Multiple Regression of Base Model Factors Predicting Neck Disability Index**

<b>Variables</b>	<b>B</b>	<b>B(SE)</b>	<b><math>\beta</math></b>	<b><math>R^2\Delta</math></b>	<b><math>F\Delta</math></b>	<b><math>p</math></b>
<b>Sex</b>	-.97	1.12	-.046	.01	1.82	.18
<b>Pain Duration</b>	.40	.11	.19	.04	10.60	<.01
<b>Etiology</b>	2.39	1.06	.12	.05	12.88	<.01
<b>Pain Intensity</b>	2.32	.25	.52	.26	94.03	<.01

**Table 3: Final Hierarchical Regression Model of Demographic, Injury, and Clinical Factors Predicting Neck Disability Index**

<b>Variables</b>	<b>B</b>	<b>B(SE)</b>	<b><math>\beta</math></b>	<b>R<sup>2</sup></b>	<b>R<sup>2</sup> <math>\Delta</math></b>	<b>F <math>\Delta</math></b>	<b>p</b>
<b>Step 1</b>				.34	.34	9.30	<.01
<b>Sex</b>	-.62	1.98	-.03				
<b>Pain Duration</b>	.47	.24	.20				
<b>Etiology</b>	.87	2.07	.05				
<b>Pain Intensity</b>	1.78	.46	.41				
<b>Step 2</b>				.48	.10	3.67	.02
<b>PPDT</b>	-.31	.24	-.14				
<b>Restricted Planes</b>	1.04	.66	.16				
<b>Spurling's</b>	2.90	1.32	.23				

*Note:* PPDT=pressure pain detection threshold

## Chapter 3

### 3 Psychosocial Predictors of Chronic Pain Related Disability

#### 3.1 Introduction

Neck pain is a common concern with approximately 67% of people in Canada reporting neck pain at some point during their lifetime.<sup>1</sup> Forty-four percent of people with acute neck pain experience unresolved pain leading to moderate levels of disability.<sup>2</sup> Treatment of chronic neck pain has often been reported to be ineffective. A previous systematic review reported weak to moderate benefit with pharmacotherapy and only short term benefits using medical injections.<sup>3</sup> Additionally, Graham and colleagues<sup>4</sup> reported only short term benefits of physical modalities such as acupuncture and traction for neck pain. Hence, a multidimensional and biopsychosocial model may be important to understand the factors that contribute to activity limitations of people with chronic neck pain.

With these findings in mind, the Neck Pain Clinical Practice Guidelines by the Orthopaedic Section of the American Physical Therapy Association recommend that relevant psychosocial factors be identified during the rehabilitation of chronic neck pain to develop more optimized management plans.<sup>5</sup> Furthermore, van Randeraad-van der Zee and colleagues<sup>6</sup> recently developed a concept map examining the burden of neck pain on people and healthcare providers. The study reported that several domains including physical complaints, psychological consequences, coping with neck pain, neck pain intensity, activities of daily living, care provider relationship, and finance encompassed the burden of neck pain, suggesting a more holistic view of the problem is necessary to improve understanding and care.

Psychosocial factors have been shown to be important prognostic indicators for long term disability.<sup>7,8</sup> In an international survey, experts cited mood, catastrophizing, and fear avoidance as predictive factors of chronic pain and disability.<sup>9</sup> Catastrophizing is when an individual has an exaggerated negative orientation towards pain.<sup>10</sup> It has been consistently shown to be related to increased disability among people with chronic pain.<sup>11</sup>

Another potential, yet inconsistent, psychosocial factor related to disability is injury compensation. In a systematic review, Spearing and colleagues<sup>12</sup> found that of the 16 studies assessed, 9 reported a significant negative association between health-related outcomes and compensation status. In a follow up study, the same group used advanced regression modeling to identify shared variance between health status and compensation, suggesting that the relationship between the two is not likely a direct cause of one on the other.<sup>13</sup> When looking at disability related outcomes specifically, other studies found no significant relationship between function and medical legal status.<sup>14,15</sup> Hence, it may be important to examine this relationship further, especially since financial burden can be a great impact on neck pain.<sup>6</sup>

Previous literature has supported the correlation between psychosocial factors and long term disability; however, which of these factors may put patients at risk for neck related disability is yet to be determined. The purpose of the current study is to develop a more comprehensive model of neck pain disability. The current study will build upon our previously developed model (Chapter 2) which looked at demographic, injury, and clinical factors' ability to explain variance in neck disability by incorporating the effect of psychosocial factors.

## 3.2 Methods

### 3.2.1 Participants

The database consisted of chronic pain participants from two different databases recruited between 2008-2016 from either community physiotherapy clinics or a specialized academic pain clinic. Approval from the Western University Institutional Ethics Review Board was obtained prior to data collection. Recruitment inclusion criteria consisted of: age 18 years or older, chronic neck pain for at least 3 months, ability to read and write in English. Participants with cognitive deficits or neck pain due to cancer or neuromuscular disease were excluded.

### 3.2.2 Procedure

Participants completed a set of questionnaires which included information on demographic and injury characteristics (age, sex, duration of pain, etiology, pain intensity) and psychosocial factors (medical legal status, neck disability, depressive symptoms, anxiety symptoms, catastrophizing, kinesiophobia). Clinical data (radicular pain, range of motion, pressure pain detection threshold (PPDT)) was collected by an experienced assessor.

### 3.2.3 Dependent Variable

**Neck Disability:** The Neck Disability Index (NDI) was used to assess neck disability. Previous studies have demonstrated that the tool has strong internal consistency with a Cronbach alpha ranging from .74 to .93.<sup>16</sup> The tool contains 10 items, including: pain, reading headaches, concentration, personal care, lifting, work, driving, sleep, and recreation. The items are measured on a 6-point scale from 0 (no disability) to 5 (full disability) with a total potential score of 50.

### 3.2.4 Predictor Variables

**Demographic factors:** age was provided in years; sex was coded as: female=0, male=1; etiology was coded as: non-trauma=0, trauma=1; pain duration was coded in years.

**Current medical legal status:** Participants were asked if they were currently involved in a legal case or not. Legal status was coded as yes=1, no=0.

**Depressive symptoms:** Magnitude of depressive symptoms was captured through two self-report depression scales: The Hospital Anxiety and Depression Scale (HADS-D) *depression subscale* and the Patient Health Questionnaire-9 (PHQ9). The HADS self-report measure has strong psychometric properties for the depressive symptoms subscale with internal consistency ranging from 0.81 to 0.90.<sup>17</sup> The PHQ9 shows strong psychometric properties for measuring severity of depression with internal consistency ICC=0.88.<sup>18</sup> It can also be used as a diagnostic tool.<sup>19</sup> The HADS-D and PHQ-9 have previously shown to have strong convergent validity with significant correlations of

0.68.<sup>20</sup> The scores for both measures were standardized using a z-transformation to be used for the analysis.

**Anxiety symptoms:** Symptoms of anxiety were captured by the Hospital Anxiety and Depression Scale (HADS) anxiety subscale and Pain Anxiety Symptoms Scale short form 20 (PASS). The HADS tool anxiety subscale has shown good factor structure,<sup>21</sup> homogeneity, and internal consistency ranging from 0.80 to 0.93.<sup>17</sup> The PASS shows strong reliability and validity in measuring fear and anxiety responses related to pain.<sup>22</sup> Internal consistency of the five subscales ranged from alpha 0.75 to 0.87. Correlations between the original and the shortened version were high,  $r=0.95$ .<sup>22</sup>

**Catastrophizing:** Catastrophizing was assessed using the Pain Catastrophizing Scale (PCS). The PCS consists of 13 items which determine an individual's tendency to misinterpret and exaggerate the threat of pain sensations. The PCS contains three subscales: rumination, magnification, and helplessness. The current study used total PCS score in the analysis. The PCS has been shown to have strong internal consistency (coefficient alpha 0.87).<sup>23</sup>

**Kinesiophobia:** The fear of movement or (re)injury was assessed using the Tampa Scale for Kinesiophobia (TSK-11). The TSK is frequently used in the pain population to assess irrational activity-related fear. It is an 11-item self-report measure that has good psychometric properties in people with neck pain.<sup>9,24</sup> The tool demonstrated strong internal consistency (alpha = 0.79).<sup>24</sup> The demographic and clinical factors used in the model were described previously in Chapter 2 of this dissertation.

### 3.2.5 Statistical Analysis

The database was randomly divided into a training sample and a cross validation sample, based on sample size calculation for potentially 13 predictive factors and a ratio of 15:1 participants per factor.<sup>25</sup> Based on this calculation a total sample was randomly selected for the training model (N=214) and the remaining for the cross validation (N=243). Descriptive analyses were conducted to describe demographic and injury characteristics. Pearson correlation coefficients were used to assess bivariate associations between

disability and the psychosocial predictor variables. A hierarchical multiple regression was conducted. The model assessed the individual contributions of psychosocial factors (medical legal status, depression, anxiety, catastrophizing, kinesiphobia) to predict level of neck disability after controlling for demographics, injury characteristics, and clinical assessments developed in Chapter 2 of this dissertation. Model variables were selected based on measures that correlated with disability and based on previous evidence. Data were pre-screened to confirm assumptions for multiple regression were met using tests for multicollinearity (tolerance and variance inflation factor (VIF)), Mahalanobis distances, and Normal Probability Plot. A value of less than .10 for tolerance and greater than 10 for VIF suggests possibility of multicollinearity. Scatterplot of standardized residuals should not have outliers beyond the recommended  $\pm 3.3$ .<sup>25</sup> The final regression equation was used to calculate predicted scores in the cross-validation sample. A Bland-Altman plot was also used to assess agreement between the two samples by plotting mean difference between predicted and observed against mean observed, with 95% limits of agreement as omnibus indicators of model fit. The analysis was conducted using SPSS 23.0 (Chicago, IL).

### 3.3 Results

#### 3.3.1 Participant Characteristics

Table 4 provides information on the participant characteristics. The database consisted mostly of females (67%). Average age of participants was 44.6 years (SD=12.6) and average duration of pain was 3.6 years (SD=6.7). Participants' average pain intensity at baseline was 4.9 (SD=2.2). Most participants had traumatic injury (57%) and were not pursuing legal action (67%).

#### 3.3.2 Pre-Analysis

The assumptions of multicollinearity were not violated. Tolerance levels were  $>.53$  and VIF  $<1.9$  for the predictors. Assumptions of normality, linearity and outliers were not violated. Normal P-P plot of regression showed normal distribution. Maximum value of the Mahalanobis distances did not exceed critical value of 32.91 for 12 potential

independent variables.<sup>25</sup> The scatterplot of standardized residuals did not show any outliers beyond the recommended  $\pm 3.3$ .

### 3.3.3 Development of Predictive Model

Table 5 provides information on the bivariate correlation analysis. Significant associations were found between disability and medical legal status ( $r= 0.43$ ), depression ( $r= 0.33$ ), and anxiety ( $r= 0.33$ ). Both catastrophizing and kinesiophobia were found to be strongly correlated with disability ( $r= 0.57$ ;  $0.69$  respectively,  $p < .05$ ). Medical legal status, depression, anxiety, catastrophizing, and kinesiophobia were added to the original model developed by Mehta and colleagues (Chapter 2) in that order. Depression, anxiety, and kinesiophobia did not result in a significant F change ( $<.01$ ); hence, these were not retained in the final overall model (Table 6). The final model explained 62% of the variance in NDI score ( $F(9,55)=9.97$ ,  $p<.01$ ), with 13.7% uniquely attributed to the retained psychosocial factors: 2.6% for medical legal status ( $sr^2=.03$ ) and 11.1% for PCS ( $sr^2=.11$ ). Below is the regression equation based on the model:

$$\text{Neck disability}=6.794-(1.33*\text{sex})+(0.51*\text{pain duration})-(0.01*\text{etiology})+(0.57*\text{pain intensity})-(0.26*\text{PPDT})+(0.72*\text{restricted planes})+(1.22*\text{Spurling's})+(1.44*\text{medlegal})+(0.33*\text{PCS})$$

The cross-validation of the model in the second independent cohort resulted in a strong correlation between the predicted NDI scores and the actual NDI scores ( $r= 0.73$ ,  $p <.01$ ). Student's t-test found no significant difference between NDI observed and NDI predicted scores (Mean difference=  $0.62$ ,  $p= .24$ ). However, only 53.3% ( $R^2$ ) of the calibration is determined with 46.7% subject to random variation. The Bland-Altman plot (Figure 2) demonstrated that most values fit between the 95% Limits of Agreement with only 7 outliers. Visual inspection of the plot reveals no obvious systematic bias in predictive vs. observed values.

## 3.4 Discussion

The current study developed a comprehensive biopsychosocial model to predict neck related disability among people with chronic neck pain. The impact of demographic, injury, and clinical factors were discussed in Chapter 2 of this dissertation. The current



paper built upon the previously developed model in part 1 by examining the effects of psychosocial variables in predicting neck related disability. Only two of the five psychosocial predictors initially examined were retained in the final model (medical legal status, catastrophizing).

Catastrophizing was a strong and significant predictor of neck related disability in the final model. This is in concordance with other previous studies that have demonstrated that catastrophizing significantly predicts pain related disability.<sup>26,27</sup> Walton and colleagues,<sup>28</sup> in a meta-analysis, also demonstrated that high levels of catastrophizing prospectively predicted poor outcomes among people with acute whiplash related pain (OR 3.77; 95% CI: 1.33-10.74). Nieto and colleagues<sup>29</sup> found that catastrophizing predicted disability even after controlling for depression among patients with whiplash disorders.

Landers and colleagues<sup>30</sup> reported that those in a medical legal case for their injury were 9.5 times more likely to have functional limitations than those without legal involvement. Swartzman et al.<sup>31</sup> found patients with pending lawsuits were more likely to report greater impact of pain on daily activities than those with settled lawsuits. Blyth et al.<sup>32</sup> reported that people with chronic pain and disability involved in litigation report greater pain related disability, medication use, and healthcare service use than those not involved in a legal case. Similarly, the current study also found legal status to be a predictor of neck related disability. It has previously been argued that many people may amplify their symptoms for secondary gains.<sup>33,34</sup> However, alternative hypotheses may be that those people with greater disability are more likely to pursue legal actions to obtain much needed services they would not be able to obtain without the financial support resulting from the legal case. Moreover, it may be that the experience of being involved in litigation is highly stressful leading to legitimately elevated experience of pain.

The current study found that addition of the predictive factors depression and anxiety did not significantly improve the fit of the overall model ( $F > .10$ ). This is in contrast to previous findings supporting the predictive capacity of depression and anxiety for neck related disability. Johansen et al.<sup>35</sup> found that emotional distress was the strongest

individual explanatory variable of NDI (37%). Other studies have demonstrated that depression and anxiety are highly linked to an individual's perceived pain.<sup>36,37</sup> Therefore, it may be that these variables have a predictive capacity for an individual's pain rather than functional disability.

Kinesiophobia was not a significant predictor of neck related disability in the current model. This lack of predictive relationship may be explained by previous findings. Bahat et al.<sup>38</sup> found that fear of motion was significantly correlated with pain intensity and CROM. Since those factors were already controlled for in the previously developed model, it may be that fear of motion did not explain any additional variance in the model. However, in a stepwise regression, Saavedra-Hernandez et al.,<sup>39</sup> found that fear of movement as measured by the TSK accounted for an additionally 3.5% of explained variance in neck disability, with pain intensity contributing 11.4%, and extension CROM contributing 2.3%. This relationship should be examined further to obtain a more conclusive explanation.

The current study was not without its limitations. Since this was a cross-sectional study, causal pathways can't be examined. Rather the model provides information on associations rather than directionality. Many of the factors assessed in the model potentially have a bidirectional relationship with neck disability. Hence, future studies should develop a longitudinal analysis looking at the interacting effects of the potential predictive factors.

Secondly, the study is limited in its use of two different databases, which may have resulted in a potential differential sample demographics. An attempt was made to have an overlap in recruitment strategy among the databases. Use of two databases also resulted in capturing of depression and anxiety through different scales which may introduce variability. The measures used demonstrated strong convergent validity and scores were standardized to reduce this variability.

Despite these limitations, the current model provides important clinical implications for everyday practice. The results from the study provide evidence for a biopsychosocial model of neck related disability. The model allows clinicians to be aware of the different

influences on their patients' experience of neck pain and disability. Along with normal clinical assessments (CROM, pain ratings, PPDT), the addition of the PCS and recognition of the expected differences between litigants/non-litigants may help clinicians develop more comprehensive treatment protocols. Treatment options geared towards these factors may provide more effective care, or help to prevent long term negative outcomes.

### 3.5 References

1. Côté P, Cassidy JD, Carroll L. The Saskatchewan health and back pain survey: the prevalence of neck pain and related disability in Saskatchewan adults. *Spine*. 1998;23(15):1689-1698.
2. Snodgrass SJ, Cleland JA, Haskins R, Rivett DA. The clinical utility of cervical range of motion in diagnosis, prognosis, and evaluating the effects of manipulation: a systematic review. *Physiotherapy*. 2014;100(4):290-304.
3. Peloso PM, Khan M, Gross AR, Carlesso L, Santaguida L, Lowcock J, MacDermid JC, Walton D, Goldsmith CH, Langevin P, Shi Q. Pharmacological interventions including medical injections for neck pain: An overview as part of the ICON § Project. *The open orthopaedics journal*. 2013;7(1):473-493.
4. Graham H, Gross A, Carlesso L, Santaguida L, MacDermid J, Walton D, Ho E, Reid DA. An ICON overview on physical modalities for neck pain and associated disorders. 2013;7:440-460.
5. Childs JD, Cleland JA, Elliott JM, Teyhen DS, Wainner RS, Whitman JM, Sopky BJ, Godges JJ, Flynn TW. Neck pain: Clinical practice guidelines linked to the International classification of functioning, disability, and health from the Orthopedic Section of the American Physical Therapy Association. *Journal of Orthopedic Sports Physical Therapy*. 2008;38:A1-A34.
6. van Randeraad-van der Zee C, Beurskens A, Swinkels R, Pool J, Batterham R, Osborne R, de Vet H. The burden of neck pain: its meaning for persons with neck

- pain and healthcare providers, explored by concept mapping. *Quality of Life Research*. 2016;25:1219-1225.
7. Salom-Moreno J, Ortega-Santiago R, Cleland JA, Palacios-Ceña M, Truyols-Domínguez S, Fernández-de-las-Peñas C. Immediate changes in neck pain intensity and widespread pressure pain sensitivity in patients with bilateral chronic mechanical neck pain: a randomized controlled trial of thoracic thrust manipulation vs non-thrust mobilization. *Journal of manipulative and physiological therapeutics*. 2014;37(5):312-319.
  8. Trott CA, Aguila ME, Leaver AM. The clinical significance of immediate symptom responses to manual therapy treatment for neck pain: Observational secondary data analysis of a randomized trial. *Manual therapy*. 2014;19(6):549-554.
  9. Walton DM, MacDermid JC, Giorgianni AA, Mascarenhas JC, West SC, Zammit CA. Risk factors for persistent problems following acute whiplash injury: update of a systematic review and meta-analysis. *Journal of orthopaedic & sports physical therapy*. 2013;43(2):31-43.
  10. Sullivan MJ, D'Eon JL. Relation between catastrophizing and depression in chronic pain patients. *Journal of abnormal psychology*. 1990;99(3):260-263.
  11. Turner JA, Jensen MP, Romano JM. Do beliefs, coping, and catastrophizing independently predict functioning in patients with chronic pain? *Pain*. 2000;85(1):115-125.
  12. Spearing NM, Connelly LB, Gargett S, Sterling M. Does injury compensation lead to worse health after whiplash? A systematic review. *Pain*. 2012;153(6):1274-1282.

13. Spearing NM, Gyrd-Hansen D, Pobereskin LH, Rowell DS, Connelly LB. Are people who claim compensation "cured by a verdict"? A longitudinal study of health outcomes after whiplash. *Journal of law and medicine*. 2012;20(1):82-92.
14. Kasch H, Bach FW, Jensen TS. Handicap after acute whiplash injury A 1-year prospective study of risk factors. *Neurology*. 2001;56(12):1637-1643.
15. Sterling M, Hendrikz J, Kenardy J. Compensation claim lodgement and health outcome developmental trajectories following whiplash injury: A prospective study. *Pain*. 2010;150(1):22-28.
16. Vernon H. The Neck Disability Index: state-of-the-art, 1991-2008. *Journal of manipulative and physiological therapeutics*. 2008;31(7):491-502.
17. Herrmann C. International experiences with the Hospital Anxiety and Depression Scale-a review of validation data and clinical results. *Journal of psychosomatic research*. 1997;42(1):17-41.
18. Zuithoff NP, Vergouwe Y, King M, Nazareth I, van Wezep MJ, Moons KG, Geerlings MI. The Patient Health Questionnaire-9 for detection of major depressive disorder in primary care: consequences of current thresholds in a crosssectional study. *BMC family practice*. 2010;11(1):1.
19. Kroenke K, Spitzer RL, Williams JB, Löwe B. The patient health questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. *General hospital psychiatry*. 2010;32(4):345-359.
20. Cameron IM, Crawford JR, Lawton K, Reid IC. Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. *Br J Gen Pract*. 2008;58(546):32-36.

21. Mykletun A, Stordal E, Dahl AA. Hospital Anxiety and Depression (HAD) scale: factor structure, item analyses and internal consistency in a large population. *The British journal of psychiatry*. 2001;179(6):540-4.
22. McCracken LM, Dhingra L. A short version of the Pain Anxiety Symptoms Scale (PASS-20): preliminary development and validity. *Pain Research and Management*. 2002;7(1):45-50.
23. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. *Psychological assessment*. 1995;7(4):524.
24. Woby SR, Roach NK, Urmston M, Watson PJ. Psychometric properties of the TSK-11: a shortened version of the Tampa Scale for Kinesiophobia. *Pain*. 2005;117(1):137-44.
25. Tabachnick, B. G., and Fidell, L. S. (2013). *Using multivariate statistics*, 6th ed. Boston: Pearson.
26. Buitenhuis J, de Jong PJ, Jaspers JP, Groothoff JW. Catastrophizing and causal beliefs in whiplash. *Spine*. 2008;33(22):2427-33.
27. Dimitriadis Z, Kapreli E, Strimpakos N, Oldham J. Do psychological states associate with pain and disability in chronic neck pain patients? *Journal of back and musculoskeletal rehabilitation*. 2015;28(4):797-802.
28. Walton DM, Pretty J, MacDermid JC, Teasell RW. Risk factors for persistent problems following whiplash injury: results of a systematic review and meta-analysis. *Journal of orthopaedic & sports physical therapy*. 2009;39(5):334-350.

29. Nieto R, Miró J, Huguet A, Saldaña C. Are coping and catastrophising independently related to disability and depression in patients with whiplash associated disorders? *Disability and rehabilitation*. 2011;33(5):389-398.
30. Landers MR, Cheung W, Miller D, Summons T, Wallmann HW, McWhorter JW, Druse T. Workers' compensation and litigation status influence the functional outcome of patients with neck pain. *The Clinical journal of pain*. 2007;23(8):676-682.
31. Swartzman LC, Teasell RW, Shapiro AP, McDermid AJ. The effect of litigation status on adjustment to whiplash injury. *Spine*. 1996;21(1):53-58.
32. Blyth FM, March LM, Nicholas MK, Cousins MJ. Chronic pain, work performance and litigation. *Pain*. 2003;103(1):41-47.
33. Allaz AF, Vannotti M, Desmeules J, Piguet V, Celik Y, Pyroth O, Guex P, Dayer P. Use of the label "litigation neurosis" in patients with somatoform pain disorder. *General hospital psychiatry*. 1998;20(2):91-97.
34. Bellamy R. Compensation neurosis: financial reward for illness as placebo. *Clinical orthopaedics and related research*. 1997;336:94-106.
35. Johansen JB, Røe C, Bakke ES, Mengshoel AM, Storheim K, Andelic N. The determinants of function and disability in neck patients referred to a specialized outpatient clinic. *The Clinical journal of pain*. 2013;29(12):1029-1035.
36. Blozik E, Laptinskaya D, Herrmann-Lingen C, Schaefer H, Kochen MM, Himmel W, Scherer M. Depression and anxiety as major determinants of neck pain: a cross-sectional study in general practice. *BMC musculoskeletal disorders*. 2009;10(1):1.



37. Shahidi B, Curran-Everett D, Maluf KS. Psychosocial, physical, and neurophysiological risk factors for chronic neck pain: A prospective inception cohort study. *The Journal of Pain*. 2015;16(12):1288-1299.
38. Bahat HS, Weiss PL, Sprecher E, Krasovsky A, Laufer Y. Do neck kinematics correlate with pain intensity, neck disability or with fear of motion? *Manual therapy*. 2014;19(3):252-258.
39. Saavedra-Hernández M, Castro-Sánchez AM, Cuesta-Vargas AI, Cleland JA, Fernández-de-las-Peñas C, Arroyo-Morales M. The contribution of previous episodes of pain, pain intensity, physical impairment, and pain-related fear to disability in patients with chronic mechanical neck pain. *American Journal of Physical Medicine & Rehabilitation*. 2012;91(12):1070-1076.

**Table 4: Participant Characteristics**

<b>Variable</b>	<b>Training Sample (n=214)</b>	<b>Crossvalidation Sample (n=224)</b>
<b>Age (yrs)</b>	44.6 (12.6)	44.1 (13.2)
<b>Sex (%)</b>		
<b>Females</b>	66.8	75.1
<b>Males</b>	33.2	24.9
<b>Pain Duration (yrs)</b>	3.6 (6.7)	4.3 (7.6)
<b>Pain Intensity</b>	4.9 (2.2)	5.4 (2.0)
<b>Etiology (%)</b>		
<b>Trauma</b>	58.7	63.3
<b>Non-Trauma</b>	41.3	36.7
<b>Medical Legal (%)</b>		
<b>Currently pursuing</b>	33.3	35.4
<b>Not currently pursuing</b>	66.7	64.6
<b>PPDT</b>	7.2 (4.2)	7.1 (3.9)
<b>Spurlings (%)</b>		
<b>Negative both sides</b>	41.9	33.3
<b>Positive one side</b>	36.5	38.1
<b>Positive both sides</b>	21.6	28.6
<b>Number Restricted Planes (%)</b>		
<b>None</b>	51.6	50.8
<b>1</b>	12.1	15.2
<b>2</b>	15.4	13.7
<b>3</b>	8.8	13.2
<b>4</b>	12.1	7.1
<b>NDI</b>	17.1 (9.5)	18.0 (9.7)
<b>PCS</b>	16.8 (13.1)	17.8 (13.4)
<b>TSK</b>	14.7 (6.5)	14.5 (6.7)

*Note:* NDI=Neck Disability Inventory; PCS=Pain Catastrophizing Scale; PPDT=pressure pain detection threshold; TSK=Tampa Scale of Kinesiophobia

**Table 5: Bivariate Correlations among Psychosocial Factors**

	<b>NDI</b>
<b>Medical Legal</b>	.43**
<b>TSK</b>	.57**
<b>PCS Total</b>	.69**
<b>StdDepression</b>	.33**
<b>StdAnx</b>	.33**

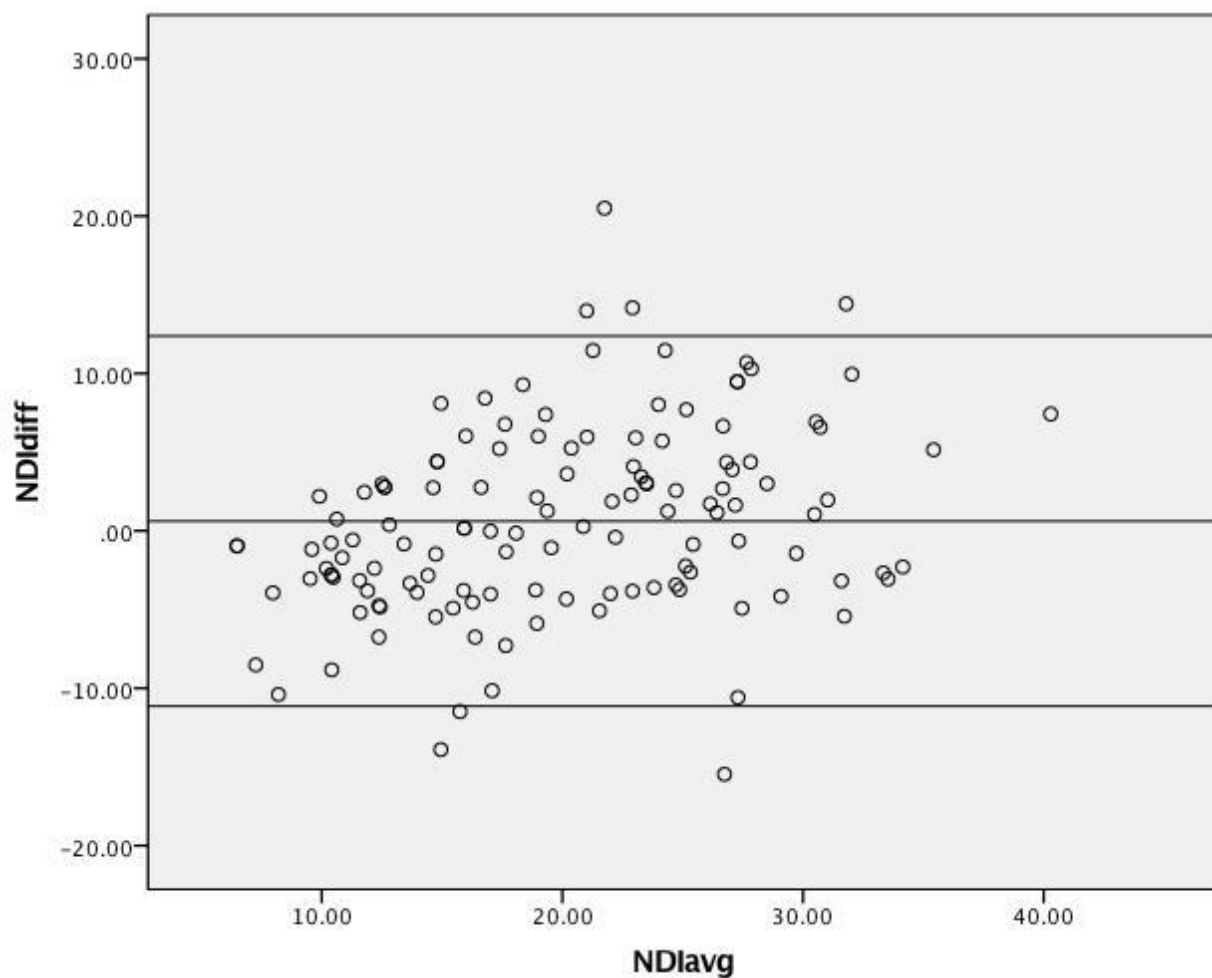
*Note:* PCS=Pain Catastrophizing Scale; TSK=Tampa Scale of Kinesiophobia

**Table 6: Overall Hierarchical Regression Model Predicting Neck Disability Index**

<b>Variables</b>	<b>B</b>	<b>B(SE)</b>	<b><math>\beta</math></b>	<b>R<sup>2</sup></b>	<b>R<sup>2</sup> <math>\Delta</math></b>	<b>F <math>\Delta</math></b>	<b>p</b>
<b>Step 1</b>				.48	.48	7.60	<.01
<b>Sex</b>	-1.33	1.74	-.07				
<b>Pain Duration</b>	.51	.21	.22				
<b>Trauma</b>	-.01	1.925	.00				
<b>Pain Intensity</b>	.57	.48	.13				
<b>PPDT</b>	-.26	.21	-.11				
<b>No. Restricted Planes</b>	.72	.58	.11				
<b>Spurlings</b>	1.22	1.24	.10				
<b>Step 2</b>				.62	.14	9.93	<.01
<b>Medical Legal Status</b>	1.44	.94	.15				
<b>PCS</b>	.33	.08	.46				

*Note:* PCS=Pain Catastrophizing Scale; PPDT=pressure pain detection threshold

**Figure 2: Bland-Altman Plot. The differences between the observed NDI score and the predicted NDI score in relation to the mean of the two scores. The lines are plotted with limits of agreement at 95% CI.**



*Note:* NDI=Neck Disability Inventory

## Chapter 4

### 4 Predicting Response to Medial Branch Blocks: A Clinical Decision Making Tool

#### 4.1 Introduction

Acute neck pain will persist in approximately 50% of sufferers, transitioning to become chronic pain. Chronic neck pain can result in significant impact on various aspects of an individual's life. People with chronic neck pain report higher levels of disability and lower quality of life than the general population.<sup>1</sup> Chronic neck pain has been associated with high societal and economic burden.<sup>2</sup>

Though very little is still known about the cause of chronic neck pain, it is considered to be affected by a multitude of factors. Yin and Bogduk<sup>3</sup> found that 42% of neck pain is related to the cervical facet (or zygapophyseal) joint. Manchikanti and colleagues<sup>4</sup> reported an increase of 10.7% per year in facet joint and sacroiliac joint interventions in the Medicare population from 2000 to 2014.

Radiofrequency neurotomy has been shown to be effective in reducing neck pain in a subgroup of this population with a discernible cervical facet injury.<sup>5</sup> Hence, identifying people with cervical facet injury is important in determining management strategies. However, evidence to support traditional tests such as radiography and clinical history in diagnosing cervical facet injury is inconsistent. Alternatively, several systematic reviews have demonstrated strong evidence for the accuracy of medial branch blocks (MBB) in diagnosing cervical facet joint injury.<sup>6,7</sup> The procedure involves anesthetizing the sensory nerve innervating the facet joint (the dorsal ramus of the medial branch of the spinal nerve).<sup>8</sup> The procedure is largely considered safe, although rare complications occur including hemorrhage, infection, paralysis, facet capsule rupture, and hematoma formation.<sup>9,10</sup> They are invasive and resource intensive in comparison to many clinical diagnostic tests, but are currently the accepted standard for diagnosing neck pain of facetogenic origin.

Due to the specialized nature of these diagnostic MBB, they can only be conducted by a trained physician in a tertiary pain clinic. In Canada, Lynch et al.<sup>11</sup> found that wait times to be seen at a specialist pain clinic ranges from 3 months to 5 years. Furthermore, the study found that wait times of greater than 6 months are associated with higher deterioration of health-related quality of life and psychological well-being.<sup>11</sup> The development of a clinical decision tree to triage patients based on their likelihood to respond to the block can help to reduce wait times for those likely to respond while reducing exposure for those unlikely to respond. A previous study by Schneider and colleagues<sup>12</sup> developed a clinical decision guide to identify patients suitable for MBB. However, the study examined only physical clinical tests including cervical extension and rotation, palpation of segmental tenderness, and manual spinal examination by an expert-level examiner. It is now widely recognized that neck pain is best viewed as a biopsychosocial construct, thus a more holistic decision tree which includes demographic, clinical, and psychosocial variables is warranted.

The aim of the current study is to examine the predictive accuracy of key physical, psychological and social factors in discriminating between those who do and do not respond to diagnostic MBB. The secondary aim is to develop a clinical decision tree to help clinicians identify those individuals who are not likely to respond to a MBB.

## 4.2 Methods

### 4.2.1 Participants

Participants were recruited from an academic clinic in London, Ontario between April 2014 through October 2016. The study was approved by the Western University Institutional Ethics Review Board. Eligible participants were 18 years or older with a diagnosis of chronic mechanical or myofascial neck pain (diagnosed by a physician) of greater than 3 months duration and had at least 1 active trigger point about the cervico-thoracic or shoulder girdle region, as defined by a taut band of muscular tissue which is painful on palpation and leads to characteristic patterns of referred pain.<sup>13</sup> Mechanical or myofascial neck pain was identified based on clinician diagnosis when the neck pain cannot be explained by tumour (benign or otherwise), infection, fracture, dislocation, or

chronic widespread pain condition (e.g. fibromyalgia, rheumatic disease). Participants currently involved in active litigation, worker's compensation claims, or currently receiving salary indemnity benefits through motor vehicle insurance providers regarding their neck pain were not excluded.

Potential participants were excluded if they had received radiofrequency ablation of any cervical nerve within the past year, intra-articular cortisone facet injection within the past 3 months, trigger point injection into the cervical/shoulder girdle muscles within the past 3 months, or by the presence of any known contraindication to injection. All participants provided informed consent prior to the start of the study.

#### 4.2.2 Procedure

Participants completed a comprehensive set of psychosocial questionnaires and underwent a standardized physical assessment protocol prior to receiving the MBB. A trained assessor conducted all physical assessments on the participants at the initial session. Once the patients completed the questionnaires and physical assessments the fluoroscopy guided MBB was performed on the participants twice, each at least two weeks apart by a specialized interventionist physiatrist with 8 years of experience. Two different anesthetics, one short-acting (lidocaine) and one longer-acting (bupivacaine) were used to reduce the false positive rate associated with a single block.<sup>14</sup> Participants were asked to complete a numeric rating scale (NRS) before and after each block, with part of the diagnostic criteria related the duration of pain relief that should be proportional to the anticipated duration of effect of each anesthetic agent.

#### 4.2.3 Dependent Variable

“Successful response to block” was defined as a reduction in pain of  $\geq 50\%$  after both blocks for a duration of  $\geq 2$  hr for lidocaine or  $\geq 3$  hr for marcaine.

#### 4.2.4 Predictor Variables

Predictor variables were selected based on previous evidence and clinically relevant factors. These included patient demographic factors such as age, sex, pain duration, and cervical segmental level most affected. Segmental level was determined by the trained



physiatrist through palpation of cervical joints. Palpation of joints and muscles is an established gold standard for assessing cervical facet syndrome.<sup>15</sup>

Clinical factors included pain intensity, cervical range of motion (CROM), and pressure pain detection threshold (PPDT). Pain intensity was assessed using a written 11-point numeric rating scale (NRS; 0 = no pain, 10 = worst pain). The numeric rating scale has been shown to be a reliable and valid assessment tool for pain.<sup>16</sup> Range of Motion (ROM) was assessed using an inclinometer (degrees) but for the purposes of this study was coded as restricted or not restricted in 4 different planes: flexion, extension, left side flexion, and right side flexion. It was coded linearly as 0=no restricted planes, 1=1 restricted plane, 2=2 restricted planes, 3=3 restricted planes, and 4=4 restricted planes. Patients were coded restricted if their ROM was below the normative values provided by Youdas et al.<sup>17</sup> or if they reported pain in that direction. A trained assessor conducted the PPDT assessment by placing a digital algometer (Wagner FDX-25, Wagner Instruments, Greenwich, CT) on the site and providing a constant force at an increasing rate of 1kg/cm<sup>2</sup>/s. Participants were instructed to verbally indicate the moment the sensation changed from pressure to pain, at which time pressure was immediately removed and the peak pressure recorded on the algometer was used as the variable of interest. The PPDT was assessed 3 times and an average of the 3 was used in the analysis. Previous studies have shown this device to be adequately precise and reliable for clinical use.<sup>18-21</sup>

Potential psychosocial factors included neck disability, depressive symptoms, and catastrophizing. The Neck Disability Index (NDI) was used to assess neck-specific disability. It is a 10-item self-report tool including items related to reading, lifting, sleeping and working. Each item is scored on a 0 (no problem) to 5 (complete inability) scale, with a score range from 0-50. Previous studies have demonstrated that the tool has adequate reliability and validity for use in this population.<sup>22,23</sup> The Patient Health Questionnaire – 9 item version (PHQ9) shows strong psychometric properties for screening for depression and measuring severity of depressive symptoms.<sup>24</sup> Pain-related catastrophizing was assessed using the Pain Catastrophizing Scale (PCS). The PCS consists of 13 items that are intended to quantify exaggerated negative orientation towards pain. The PCS contains 3 subscales: rumination, magnification, and helplessness.

The current study used total PCS score in the analysis. The PCS has been shown to have strong psychometric properties.<sup>25,26</sup>

#### 4.2.5 Analysis

Descriptive analysis was conducted comparing baseline characteristics of participants in the responder vs non-responder group. Potential predictor variables were examined individually through a receiver operating characteristic curve (ROC) analysis. Variables with an area under the curve (AUC) of at least 0.60 were retained, where an AUC of 0.50 indicates chance. For nominal data, a chi-squared analysis was conducted and variables with a  $p < .10$  was retained. Optimal cut scores were identified from the ROC curve for those predictor variables that met threshold for retention. A common technique to determine cut scores is the Youden Index which gives equal weight to sensitivity and specificity. However, since the current study aims to develop a decision tree to rule out negative responders, cut-off points were selected with greater preference for sensitivity (reducing the rate of false negatives). A classification table was then created to determine sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the retained test protocol.

### 4.3 Results

#### 4.3.1 Participant Characteristics

A total of 65 participants consented to the study and met inclusion criteria. Average age was 49.9 ( $\pm 13.3$ ) yrs, pain duration of 8.5 ( $\pm 9.4$ ) yrs and mean pain intensity was 5.5 ( $\pm 1.7$ ) among participants. Participants consisted of 55.4% females and 63.3% identified trauma as the etiology. After injection, 41 people responded to the MBB, while 23 people did not. Table 7 provides detailed information on participant characteristics.

#### 4.3.2 Analysis

The results from the chi-squared test (Table 8) and the initial ROC analysis (Table 9) found that etiology, level of block, number of restricted planes, PPDT, NDI, and PHQ-9 were not significant predictors of response. Two significant variables, pain intensity and PCS, met threshold and were selected to define branches (Figure 3). Cut scores of  $\geq 39$  on

the PCS and  $\geq 8$  for pain intensity were selected to limit false negatives. Classification tables were created to compare the observed vs. predicted responders to MBB based on the pain intensity (Table 10) and PCS (Table 11) cut scores. A PCS score above  $\geq 39$  resulted in 94.9% sensitivity, 33.3% specificity, 72.5% PPV, and 77.8% NPV. Pain intensity of 8 or above resulted in 84.6% sensitivity, 33.3% specificity, 70.2% PPV, and 53.8% NPV. The overall decision tree resulted in two levels with two nodes at the first level and 3 at the second level. The overall decision tree accurately classified 73.8% of participants and had 90.0% sensitivity, 33.3% specificity, 77.1% PPV, and 57.1% NPV. The positive and negative likelihood ratio of the tree was 1.35 and 0.30, respectively. As an illustrative example, if a patient has a 1 in 2 (50%) chance of responding to a block and scores negative on the decision tree (PCS  $\geq 39$  and NRS  $\geq 8$ ), post-test odds reduce the likelihood of success to 23.1%. The decision tree was able to rule out 8.6% of participants not likely to respond and 65.5% likely to respond to MMBs. Only, 25.9% were left in the unsure category.

## 4.4 Discussion

The current study developed a biopsychosocial clinical decision aid for predicting response to cervical MBB among individuals with chronic mechanical neck pain. Pain catastrophizing and pain intensity were the only variables that met threshold. In contrast to previous studies, the current study did not find an association between cervical MBB response and PPDT, CROM, neck disability, and depression. The decision aid has strong sensitivity and classified 74% of patients as either responders or non-responders, leaving only 25.9% of patients that may require further clinical examination to determine their likely response to cervical MBBs.

Not only can the tool classify patients for referral but it can also be used to help determine which approaches are needed to help improve patient's likelihood for response. For example, the decision tree demonstrates that patients with high pain catastrophizing are associated with low response. Catastrophizing is a modifiable factor, therefore, with appropriate management such as cognitive behavioural therapy (CBT) or mindfulness<sup>27,28</sup> participants may improve in their likelihood to respond to MBBs. Furthermore, pain

intensity and catastrophizing have been previously shown to be related.<sup>29</sup> Thus targeting catastrophizing may also help reduce a patient's perceived pain intensity.

Previous studies have also reported that high levels of catastrophizing can influence treatment outcomes. Smith and colleagues,<sup>30</sup> recently found similar odds for PCS in predicting response to cervical radiofrequency neurotomy among people with chronic whiplash (OR=0.94 (95%CI: 0.89 to 0.99)). Smith et al.<sup>31</sup> reported elevated scores of PCS among non-responders of MBB compared to responders ( $p=.006$ ). However, it may be important to be cautious when interpreting these results. Smith and colleagues<sup>32</sup> found that effective pain relief through cervical radiofrequency neurotomy may result in reduction in pain catastrophizing. In another study, the group also reported that as pain returns after radiofrequency neurotomy, levels of catastrophizing also return.<sup>33</sup>

No significant association was found between CROM and PPDT and MBB response. Consistent with the finding of the current study, Smith and colleagues<sup>31</sup> found no significant difference between the responders and non-responders in CROM ( $p=.37$ ). In contrast, Schneider et al.<sup>12</sup> found extension-rotation was a significant predictor of response to MBB (OR=6.85, 95%CI 2.91-16.13). However, the study found that a positive finding on extension-rotation did not provide diagnostic accuracy to conclude facet injury. Hence, further evaluation may be warranted.

Smith et al.<sup>31</sup> also found that there was no difference in PPDTs between those that responded to cervical MBB and those that did not ( $p=.64$ ) though the levels were lower among individuals with chronic neck pain overall compared to healthy controls ( $p<.001$ ). This is consistent with another study that demonstrated lack of significant predictive ability for cervical PPDT for response to radiofrequency neurotomy.<sup>30</sup> However, Cohen and colleagues<sup>34</sup> found that PPDT did successfully predict response to cervical facet radiofrequency denervation. The difference in association between PPDT and response may be since Cohen et al.<sup>34</sup> used a single block to determine response while the current study and Smith et al.<sup>30</sup> used a double block. Hence, the current study may provide a more rigorous threshold for response. Lastly, the current study can only make

conclusions of associations of the predictors to MBB not to radiofrequency denervation. Predictors of MBB may be different from those for radiofrequency denervation.

Psychological distress has previously been shown to effect treatment response and recovery among people with chronic pain. Wasan and colleagues<sup>35</sup> found that those patients undergoing MBB with high level of psychopathology, as determined by the Hospital Anxiety and Depression Scale (HADS), had worsening pain and reported less improvement in outcomes compared to those in the low psychopathology group. This is contrary to the current studies finding that level of depressive symptoms did not significantly predict response to MBB. There were several differences between the current study and that of Wasan et al.<sup>35</sup> that may explain the differences. First, Wasan and colleagues<sup>35</sup> used a measure that combined both depression and anxiety symptoms. Hence, it may be that since some of the items on the HADS overlap with those on the PCS, it may be those more catastrophizing items (ie. worrying, magnification etc) that are associated with response rather than depressed mood. Secondly, Wasan et al.<sup>35</sup> categorized the continuous variable of psychopathology, while the current study did not. Schellingerhunt et al.<sup>36</sup> previously found that categorizing continuous variables can result in different levels of association and poorer performance of the final model. Lastly, Wasan et al.<sup>35</sup> used corticosteroid blocks, while the current study used analgesics (lidocaine/marcaine).

The current study has several limitations. Firstly, the sample size in the study may be limited. Future studies should focus on developing a larger database. Secondly, the validation of this decision tree is warranted in order to test the accuracy and generalizability. Lastly, the study included only those patients suspicious of facetogenic pain. Hence, this decision tree may not be generalizable to all patients with mechanical neck pain. Recognizing these limitations, the current study provides a useful tool for clinicians to predict which patients are likely to respond to MBBs with a low burden, only 2 self-report scales.

In conclusion, the current decision tool provides an efficient way to identify those patients with chronic mechanical neck pain less likely to respond to MBBs. The visual

representation and intuitive explanation makes it easy to follow. Agreement with actual observed clinical outcomes is strong. The tool suggests that high levels of pain intensity and catastrophizing may result in people less likely to respond to MBBs. The evidence also suggests that during this phase, clinical measures such as PPDT or ROM may not be effective in determining eligibility of a patient to receive cervical MBB, although these tests may serve as valuable follow-ups especially in those who fall into the ‘unsure’ category. This has important implications for front-line clinicians making decision when referring patients for this procedure. Hence, implementation of the decision tool can help clinicians rule out patients likely to not benefit from the cervical MBB, thereby also reducing wait times for patients more likely to benefit, and potentially identifying treatment targets so that blocks may be more effective in the future.

## 4.5 References

1. Muñoz-Muñoz S, Muñoz-García MT, Albuquerque-Sendín F, Arroyo-Morales M, Fernández-de-las-Peñas C. Myofascial trigger points, pain, disability, and sleep quality in individuals with mechanical neck pain. *Journal of manipulative and physiological therapeutics*. 2012;35(8):608-613.
2. Cohen SP. Epidemiology, diagnosis, and treatment of neck pain. *Mayo Clinic Proceedings* 2015;90:284-299
3. Yin W, Bogduk N. The nature of neck pain in a private pain clinic in the United States. *Pain Medicine*. 2008;9(2):196-203.
4. Manchikanti L, Hirsch JA, Pampati V, Boswell MV. Utilization of Facet Joint and Sacroiliac Joint Interventions in Medicare Population from 2000 to 2014: Explosive Growth Continues!. *Current pain and headache reports*. 2016;20(10):58.
5. Lord SM, Barnsley L, Wallis BJ, McDonald GJ, Bogduk N. Percutaneous radiofrequency neurotomy for chronic cervical zygapophyseal-joint pain. *The New England Journal of Medicine*. 1996;335:1721-1726.
6. Falco FJ, Manchikanti L, Datta S, Wargo BW, Geffert S, Bryce DA, Atluri S, Singh V, Benyamin RM, Sehgal N, Ward SP. Systematic review of the therapeutic effectiveness of cervical facet joint interventions: an update. *Pain Physician*. 2012;15(6):E839-68.
7. Rubinstein SM, van Tulder M. A best-evidence review of diagnostic procedures for neck and low-back pain. *Best Practice & Research Clinical Rheumatology*. 2008;22:471-482.

8. Sehgal N, Dunbar EE, Shah RV, Colson J. Systematic review of diagnostic utility of facet (zygapophysial) joint injections in chronic spinal pain: an update. *Pain Physician*. 2007;10(1):213-28.
9. Boswell MV, Manchikanti L, Kaye AD, Bakshi S, Gharibo CG, Gupta S, Jha SS, Nampiaparampil DE, Simopoulos TT, Hirsch JA. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain physician*. 2015;18(4):E497-533.
10. Falco FJ, Erhart S, Wargo BW, Bryce DA, Atluri S, Datta S, Hayek SM. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. *Pain Physician*. 2008;12(2):323-44.
11. Lynch ME, Campbell F, Clark AJ, Dunbar MJ, Goldstein D, Peng P, Stinson J, Tupper H. A systematic review of the effect of waiting for treatment for chronic pain. *Pain*. 2008;136:97-116.
12. Schneider GM, Jull G, Thomas K, Smith A, Emery C, Faris P, Cook C, Frizzell B, Salo P. Derivation of a clinical decision guide in the diagnosis of cervical facet joint pain. *Archives of physical medicine and rehabilitation*. 2014;95(9):1695-701.
13. Tough EA, White AR, Richards S, Campbell J. Variability of criteria used to diagnose myofascial trigger point pain syndrome—evidence from a review of the literature. *The Clinical journal of pain*. 2007;23(3):278-86.
14. Barnsley L, Lord S, Wallis B, Bogduk, N. False-positive rates of cervical zygapophysial joint blocks. *Clinical Journal of Pain*. 1993;9(2):124-130.



15. Fukui S, Ohseto K, Shiotani M, Ohno K, Karasawa H, Naganuma Y, Yuda Y. Referred pain distribution of the cervical zygapophyseal joints and cervical dorsal rami. *Pain*. 1996;68(1):79-83.
16. Von Korff M, Jensen MP, Karoly P. Assessing global pain severity by self-report in clinical and health services research. *Spine*. 2000;25(24):3140-51
17. Youdas JW, Garrett TR, Suman VJ, Bogard CL, Hallman HO, Carey JR. Normal range of motion of the cervical spine: an initial goniometric study. *Physical therapy*. 1992;72(11):770-80.
18. Chesterton LS, Sim J, Wright CC, Foster NE. Interrater reliability of algometry in measuring pressure pain thresholds in healthy humans, using multiple raters. *The Clinical journal of pain*. 2007;23(9):760-6.
19. Kinser AM, Sands WA, Stone MH. Reliability and validity of a pressure algometer. *The Journal of Strength & Conditioning Research*. 2009;23(1):312-4.
20. Walton D, MacDermid J, Nielson W, Teasell R, Chiasson M, Brown L. Reliability, standard error, and minimum detectable change of clinical pressure pain threshold testing in people with and without acute neck pain. *journal of orthopaedic & sports physical therapy*. 2011;41(9):644-50.
21. Walton DM, Levesque L, Payne M, Schick J. Clinical pressure pain threshold testing in neck pain: comparing protocols, responsiveness, and association with psychological variables. *Physical therapy*. 2014;94(6):827-37.
22. Gay RE, Madson TJ, Cieslak KR. Comparison of the Neck Disability Index and the Neck Bournemouth Questionnaire in a sample of patients with chronic

- uncomplicated neck pain. *Journal of Manipulative and Physiological Therapeutics*. 2007;30(4):259-62.
23. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. *Journal of manipulative and physiological therapeutics*. 1991;14(7):409-15
  24. Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. *Psychiatric annals*. 2002;32(9):509-15.
  25. Sullivan MJ, D'Eon JL. Relation between catastrophizing and depression in chronic pain patients. *Journal of abnormal psychology*. 1990;99(3):260-263.
  26. Walton DM, MacDermid JC, Giorgianni AA, Mascarenhas JC, West SC, Zammit CA. Risk factors for persistent problems following acute whiplash injury: update of a systematic review and meta-analysis. *journal of orthopaedic & sports physical therapy*. 2013;43(2):31-43.
  27. Smeets RJ, Vlaeyen JW, Kester AD, Knottnerus JA. Reduction of pain catastrophizing mediates the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *The Journal of Pain*. 2006;7(4):261-71.
  28. Thorn BE, Pence LB, Ward LC, Kilgo G, Clements KL, Cross TH, Davis AM, Tsui PW. A randomized clinical trial of targeted cognitive behavioral treatment to reduce catastrophizing in chronic headache sufferers. *The Journal of Pain*. 2007;8(12):938-49.
  29. Severeijns R, Vlaeyen JW, van den Hout MA, Weber WE. Pain catastrophizing predicts pain intensity, disability, and psychological distress independent of the level of physical impairment. *The Clinical journal of pain*. 2001;17(2):165-72.

30. Smith AD, Jull GA, Schneider GM, Frizzell B, Hooper RA, Sterling MM. Low Pain Catastrophization and Disability Predict Successful Outcome to Radiofrequency Neurotomy in Individuals with Chronic Whiplash. *Pain practice: the official journal of World Institute of Pain*. 2016;16(3):311-9.
31. Smith AD, Jull G, Schneider G, Frizzell B, Hooper RA, Sterling M. A comparison of physical and psychological features of responders and non-responders to cervical facet blocks in chronic whiplash. *BMC musculoskeletal disorders*. 2013;14(1):1.
32. Smith AD, Jull G, Schneider G, Frizzell B, Hooper RA, Dunne-Proctor R, Sterlin M. Cervical radiofrequency neurotomy reduces psychological features in individuals with chronic whiplash symptoms. *Pain physician*. 2014;17(3):265-74.
33. Smith AD, Jull G, Schneider GM, Frizzell B, Hooper RA, Sterling M. Modulation of cervical facet joint nociception and pain attenuates physical and psychological features of chronic whiplash: a prospective study. *PM&R*. 2015;7(9):913-21.
34. Cohen SP, Bajwa ZH, Kraemer JJ, Dragovich A, Williams KA, Stream J, Sireci A, McKnight G, Hurley RW. Factors predicting success and failure for cervical facet radiofrequency denervation: a multi-center analysis. *Regional anesthesia and pain medicine*. 2007;32(6):495-503.
35. Wasan AD, Jamison RN, Pham L, Tipirneni N, Nedeljkovic SS, Katz JN. Psychopathology predicts the outcome of medial branch blocks with corticosteroid for chronic axial low back or cervical pain: a prospective cohort study. *BMC musculoskeletal disorders*. 2009;10(1):1.
36. Schellingerhout JM, Heymans MW, de Vet HC, Koes BW, Verhagen AP. Categorizing continuous variables resulted in different predictors in a prognostic

model for nonspecific neck pain. *Journal of clinical epidemiology*. 2009;62(8):868-74.

**Table 7: Medial Branch Block Participant Characteristics**

<b>Variable</b>	<b>Non-Responders</b>	<b>Responders</b>
<b>Age (yrs)</b>	49.4 (16.3)	50.1 (11.9)
<b>Sex</b>		
<b>Females</b>	14	21
<b>Males</b>	9	20
<b>Pain Duration (yrs)</b>	8.4 (10.6)	8.7 (8.9)
<b>Pain Intensity</b>	5.9 (1.8)	5.3 (1.6)
<b>Etiology</b>		
<b>Trauma</b>	10	27
<b>Non-Trauma</b>	9	13
<b>PPDT</b>	5.3 (2.5)	5.3 (2.7)
<b>Level of Block</b>		
<b>C2/3, 3/4</b>	9	19
<b>C3/4, 4/5</b>	4	2
<b>C4/5, 5/6</b>	9	12
<b>C5/6, 6/7</b>	1	7
<b>Restricted Planes (%)</b>		
<b>None</b>	5	5
<b>1</b>	6	11
<b>2</b>	3	10
<b>3</b>	6	7
<b>4</b>	0	5
<b>NDI</b>	24.6 (7.1)	24.1 (6.3)
<b>PCS</b>	29.4 (13.4)	17.4 (12.6)
<b>PHQ9</b>	14.5 (7.0)	12.5 (5.8)

*Note:* NDI=Neck Disability Inventory; PCS=Pain Catastrophizing Scale; PHQ9=Patient Health Questionnaire 9; PPDT=pressure pain detection threshold

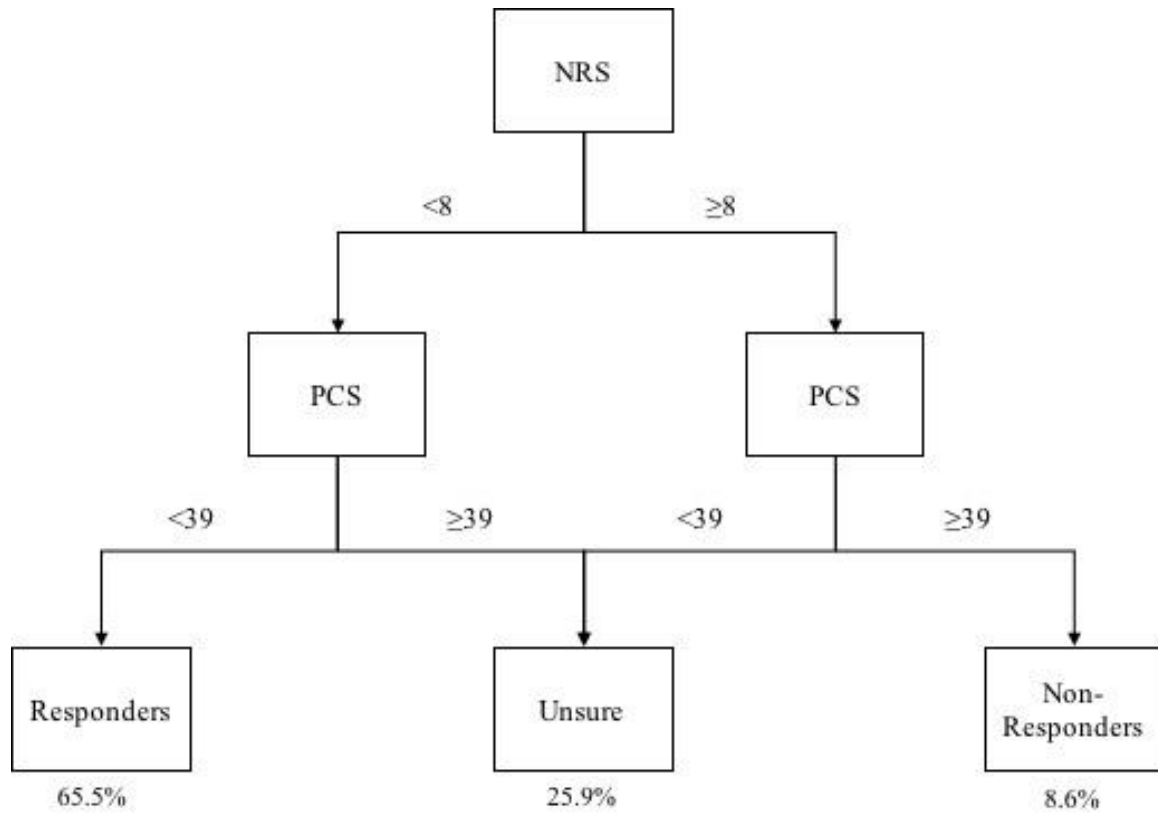
**Table 8: Chi-Squared Tests of Nominal Predictor Variables for Medial Branch  
Block Response**

<b>Variable</b>	<b>Non-Responders</b>	<b>Responders</b>	<b><i>p</i></b>
<b>Etiology</b>			.27
<b>Trauma</b>	10	27	
<b>Non-Trauma</b>	9	13	
<b>Level of Block</b>			.18
<b>C2/3, 3/4</b>	9	19	
<b>C3/4, 4/5</b>	4	2	
<b>C4/5, 5/6</b>	9	12	
<b>C5/6, 6/7</b>	1	7	
<b>Restricted Planes (%)</b>			.26
<b>None</b>	5	5	
<b>1</b>	6	11	
<b>2</b>	3	10	
<b>3</b>	6	7	
<b>4</b>	0	5	

**Table 9: Receiver Operator Curve Analysis of Predictor Variables for Medial Branch Blocks**

<b>Variable</b>	<b>Area</b>	<b>95% CI</b>
<b>NDI</b>	0.49	0.32-0.62
<b>Pain Intensity</b>	0.61	0.45-0.77
<b>PCS</b>	0.74	0.61-0.87
<b>PHQ9</b>	0.43	0.26-0.61
<b>PPDT</b>	0.52	0.35-0.69

*Note:* NDI=Neck Disability Inventory; PCS=Pain Catastrophizing Scale; PHQ9=Patient Health Questionnaire 9; PPDT=pressure pain detection threshold

**Figure 3: Decision Tool for Selecting Patients for Cervical Medial Branch Blocks**

*Note:* NRS=Numeric Rating Scale; PCS=Pain Catastrophizing Scale



**Table 10: Classification Table Based on the Cut-off Point of  $\geq 8$  on the Pain Intensity**

		<b>Observed</b>	
<b>Pain Intensity Classified</b>		Yes	No
	Yes	33	14
	No	6	7

**Table 11: Classification Table based on the Cut-off Point of  $\leq 39$  on the PCS**

		<b>Observed</b>	
<b>PCS Classified</b>		Yes	No
	Yes	37	14
	No	2	7

*Note:* PCS=Pain Catastrophizing Scale

## Chapter 5

### 5 Summary

The first two studies in this dissertation developed a biopsychosocial model to predict neck related disability. The current model shows strong correlation to the cross-validated test sample. However, validation in an independent sample is an important next step. Furthermore, an obvious extension to this project would be to use the predictive factors from the model and classify people using a cluster analysis. The identification of unique subgroups can provide insight into the specific characteristics that may put a person at risk for long term disability. Additionally, developing phenotypes among the population can help target appropriately tailored personalized management plans.

The current model can be used to develop, *a priori*, hypothesized models to examine the pathways among the predictive factors. Several studies have previously established the effect of catastrophizing on an individual's perceived pain experience. Kamper and colleagues<sup>1</sup> found that fear avoidance as measured by the TSK mediates the effect of pain intensity on disability among people with chronic neck pain. Therefore, though the model provided explained variance per factors, many of these factors may interact with each other to influence the outcome of neck pain disability. Examining the mediation and moderation pathways among the identified factors may help provide a better understanding of the direct and indirect relationships influencing neck pain related disability. We are currently in the process of developing a structural equation model to help fill the gap in the literature on the interacting effects of the factors in the current model.

Based on the idea that neck pain related outcomes are influenced by several biopsychosocial factors, the last study evaluated which of these may predict response to diagnosis of cervical facet joint injury. This is an important study for researchers and clinicians working with people with chronic neck pain. Identifying the correct diagnosis of injury is integral for identifying optimal treatment plans in order to reduce long term disability among people with chronic neck pain. The decision tool presented in Chapter 4 has strong implications for the practice of referrals among patients thought to have neck

pain driven by a cervical facet dysfunction. The tool can help reduce unnecessary exposure to risky procedures for patients not likely to benefit. The reduction in referrals can also help improve wait times and access to specialized facilities for those patients more likely to respond. Cross-validation in an independent sample is still warranted to assess the generalizability of its findings.

An interesting finding of the study was that the clinical assessments captured were not found to be significant predictors of response. This may suggest that clinical assessments are not important predictors of response. However, it could also mean that our sample was not large enough to find important effects in small but relevant subgroups, or may speak to a lack of precision of the clinical tests used despite rigorous application. Another possibility is that other clinical factors not captured in the current study influence response. Hence, it may be important to explore the additional predictive capacity offered by the more lab-based factors found by Schneider and colleagues<sup>2</sup> in order to develop a stronger and more comprehensive tool.

Interestingly, a common factor found in both the disability and response models was pain catastrophizing. Furthermore, it was also the strongest predictor in both models. Catastrophizing has previously been shown to effect outcomes including pain intensity, disability, and response to treatment among individuals with neck pain by several studies.<sup>3-6</sup> Though it is hard to determine the directionality of these relationships, the mounting and consistent evidence would suggest that it is time to explore potential mechanisms or causal pathways through which catastrophizing is linked to important clinical outcomes. While this may be a true and causal relationship, it is also possible that it is artificially generated due to a potential recruitment bias in most chronic pain studies. Crombie and Davies<sup>7</sup> reported that individuals seen at a specialist pain clinic are highly selected and systematically different from those seen by a primary care physician. The study also found that patients likely to participate in studies may be differently motivated and may have different personality traits compared to those that are unwilling to participate. Holzman and colleagues<sup>8</sup> found that associations between pain related variables were seen at some centers but not others. It may be important to examine if the relationships seen in the current analysis exist among those neck pain patients seen only

at a primary care setting rather than a specialized setting. However due to the specialized nature of the MBB procedure, exploration of this relationship may not be possible in the primary care setting.

## 5.1 Conclusion and Implication

In summary, the three studies in this dissertation suggest a more comprehensive interdisciplinary approach to understanding chronic neck pain. The first two studies have developed a comprehensive model to predict neck disability. The model has important clinical implications for assessing psychosocial factors that may place patients at higher risk for long term disability. The last study provides a decision tool for routine use by front-line clinicians to predict response to cervical MBBs. Though additional work is warranted before endorsing the decision tool, it has potential to help clinicians triage patients awaiting procedures for suspected facetogenic neck pain. The tool is easy to administer and does not result in added burden on the clinician, the clinical practice, and most importantly, the patient themselves.

## 5.2 References

1. Kamper SJ, Maher CG, Costa LD, McAuley JH, Hush JM, Sterling M. Does fear of movement mediate the relationship between pain intensity and disability in patients following whiplash injury? A prospective longitudinal study. *Pain*. 2012;153(1):113-9.
2. Schneider GM, Jull G, Thomas K, Smith A, Emery C, Faris P, Cook C, Frizzell B, Salo P. Derivation of a clinical decision guide in the diagnosis of cervical facet joint pain. *Archives of physical medicine and rehabilitation*. 2014;95(9):1695-701.
3. Bostick GP, Carroll LJ, Brown CA, Harley D, Gross DP. Predictive capacity of pain beliefs and catastrophizing in Whiplash Associated Disorder. *Injury*. 2013;44(11):1465-71.
4. Buitenhuis J, de Jong PJ, Jaspers JP, Groothoff JW. Catastrophizing and causal beliefs in whiplash. *Spine*. 2008;33(22):2427-33.
5. Dimitriadis Z, Kapreli E, Strimpakos N, Oldham J. Do psychological states associate with pain and disability in chronic neck pain patients? *Journal of back and musculoskeletal rehabilitation*. 2015;28(4):797-802.
6. Smith AD, Jull G, Schneider G, Frizzell B, Hooper RA, Sterling M. A comparison of physical and psychological features of responders and non-responders to cervical facet blocks in chronic whiplash. *BMC musculoskeletal disorders*. 2013;14(1):1.
7. Crombie IK, Davies HT. Selection bias in pain research. *Pain*. 1998;74(1):1-3.

8. Holzman AD, Rudy TE, Gerber KE, Turk DC, Sanders SH, Zimmerman J, Kerns RD. Chronic pain: a multiple-setting comparison of patient characteristics. *Journal of behavioral medicine*. 1985;8(4):411-22.

# Appendices

## Appendix A: Reprint Permission

9/27/2016

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Licensed Content Author	Jaime Guzman, Eric L. Hurwitz, Linda J. Carroll, Scott Haldeman, Pierre Côté, Eugene J. Carragee, Paul M. Peloso, Gabrielle van der Velde, Lena W. Holm, Sheilah Hogg-Johnson, Margareta Nordin, J. David Cassidy
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Expected completion date	Jan 2017
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## **Appendix B: Ethics Board Approval**



**Western  
Research**

Research Ethics

**Use of Human Participants - Ethics Approval Notice**

Principal Investigator: Dr. Dave Walton  
 File Number: 103683  
 Review Level: Full Board  
 Approved Local Adult Participants: 44  
 Approved Local Minor Participants: 0  
 Protocol Title: Facet versus trigger point injection for management of chronic muscular neck pain: A pilot randomized clinical trial and creation of a clinical prediction algorithm - Pilot Study  
 Department & Institution: Health Sciences\Physical Therapy, Western University  
 Sponsor:  
 Ethics Approval Date: July 04, 2013  
 Ethics Expiry Date: December 31, 2014

**Documents Reviewed & Approved & Documents Received for Information:**

Document Name	Comments	Version Date
Other	List of contraindications	2013/03/27
Other	Exercise pamphlet	2013/03/27
Other	Telephone script for initial contact	2013/04/22
Western University Protocol		
Other	Adverse events checklist, Participant characteristics form, Chronic pain coping inventory, Pain Anxiety Symptoms Scale-20, Pain Catastrophizing Scale, Pain Self Efficacy Questionnaire, Pain Stages of Change Questionnaire, Patient Health Questionnaire-9, Clinical Assessment form, Neck Disability Index, Headache Impact Test – 6, Global Perceived Rating of Change (primary outcome), Symptom Intensity	2013/04/26
Letter of Information & Consent		2013/06/28

This is to notify you that the University of Western Ontario Health Sciences Research Ethics Board (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this HSREB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request form.

Member of the HSREB that are named as investigators in research studies, or declare a conflict of interest, do not participate in discussions related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the

\_\_\_\_\_

**Signature**

**Ethics Officer to Contact for Further Information**

Erika Basile (ebasile@uwo.ca)	Grace Kelly (grace.kelly@uwo.ca)	Shantel Walcott (swalcol@uwo.ca)
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*This is an official document. Please retain the original in your files.*

Western University, Research, Support Services Bldg., Rm. 5150  
 London, ON, Canada N6A 3K7 t. 519.661.3036 f. 519.850.2466 www.uwo.ca/research/services/ethics

## **Appendix C: Letter of Information**

**April 21, 2016**

### **Letter of Information**

#### **Facet vs. Trigger Point injections or exercise for management of chronic muscular neck pain: A randomized clinical trial**

Principal Investigator: Dr. David M. Walton

Co-Investigator: Dr. Eldon Loh

Dear Sir/Madam,

You are being invited to participate in a pilot study in which we are evaluating 3 different approaches to managing chronic muscular neck pain. Currently there is little consensus or guidance amongst clinicians to help them understand the 'best' treatment for this kind of neck pain. The primary purpose of this study is to determine the feasibility of conducting a larger study in this area, with the final goal of improving outcomes for people with chronic muscular neck pain.

#### **Why is this study being conducted?**

Neck pain is common and costly. To date there is little consensus amongst the health care community regarding the best treatment of most types of neck pain. This makes it difficult to develop good practice guidelines and often results in a 'trial and error' type of approach. We believe we can do better than this. By comparing the relative effectiveness of 3 common approaches to treatment, this study is the first step towards developing evidence-informed guidelines that clinicians can use to determine the best course of treatment for people with neck pain.

#### **Why am I being invited?**

You are being invited to participate because you are currently on the wait list of the pain clinic at either St. Joseph's or Parkwood Hospital in London. The information currently available indicates that you are experiencing chronic (>3 months) neck pain that is related to joints, muscles, ligaments or nerves about your neck. Further, you are between the ages of 18 and 65. If you agree to participate, you will be asked additional questions by the study coordinator and will undergo some routine clinical tests to make sure that you are eligible for this study and that all procedures are safe for you.

#### **What will I be asked to do?**

At your first visit, you will be subject to a standardized clinical assessment similar to what you would undergo at a routine doctor or physiotherapy visit. You will also be

asked to complete a series of questionnaires that will provide information about you (your age, sex, employment status), your condition (cause, duration, symptoms) and your emotions and understanding about your neck pain. The study coordinator will also review any documentation you have relating to diagnostic imaging procedures (e.g. X-ray, MRI, CT) you may have already undergone. If you consent, the study coordinator will also take a picture of you from the side and from the back for the purposes of evaluating your posture. You may wear a tank top or short-sleeved t-shirt for this analysis, as long as your shoulder can be exposed. Following this you will be scheduled to undergo a comparative medial branch block procedure, in which a trained physician injects a short-acting anesthetic into pre-determined joints of your neck under the guidance of a specialized X-ray. Your response to this diagnostic procedure will determine whether you are eligible to proceed to the next part of the study. A negative result (no significant pain relief) will mean you are not eligible, while a positive result (pain relief for the duration of the anesthetic) will mean you are eligible to continue. If you continue, you will then be assigned to one of 3 different types of treatment in a random fashion, described in the next section. Even if you don't respond to the medial branch block procedure, your data to that point will be retained in anonymous fashion to help us better understand who responds and who doesn't respond to this procedure.

Treatments that you were on prior to the study may be continued at the same rate (dose and frequency). You will be asked to return to the pain clinic at regular intervals (1 month, 3 months and 6 months following your first visit) in order to determine how you responded to the treatments. In the event that you are unable to physically come to the clinic for one of those visits, the follow-up questionnaires can be mailed to you. After the 6 month follow-up, your participation in this study will be complete.

An outline of each visit is as follows:

- **Visit 1** (approximately 1 hour): First pass eligibility screen including specifics of you, your condition, and your general health. A standardized clinical exam that includes active range motion (mobility) of your neck, the presence and number of tender points in your neck muscles using a pressure measurement device, and the response of your symptoms to compression and traction of your neck. Self-report forms will ask you more detailed information about your symptoms (intensity, frequency), your related disability, the things you do to help manage your symptoms, and the emotional impact of your condition. A second visit will then be scheduled within the next week for you to undergo the diagnostic facet block procedure as described above.
- **Visit 2 & 3** You will undergo the diagnostic facet block procedure. You will be requested to keep a record of how your neck symptoms have responded to the block by providing a rating of 0 (no pain) to 10 (extreme pain) once an hour for the following 6 hours.

- **Visit 4** (assuming good response to diagnostic block) will occur within 1-2 weeks of Visit 1, exact interval dependent on the treatment group to which you've been assigned. At this visit you will receive the treatment as described in the next section. Note that depending on your assigned treatment, you may need to attend up to 3 times to receive your full treatment.
- **Visit 5** (1 month following the start of the study, approximately 1 hour): You will undergo the same clinical examination and complete the same self-report forms as those on the first day with the exception of the injections and eligibility screening which you will not go through again. An additional form will ask you about how your current neck symptoms compare with those you had at the start of the study.
- **Visit 6** (3 months following the start of the study, approximately 1 hour): The same procedures as those done on Visit 3.
- **Visit 7** (6 months following the start of the study, approximately 1 hour): The same procedures done on Visits 3 and 4.

Of the evaluations being done, most are considered routine parts of clinical care that would be used regardless of whether or not you were in a research study. The exceptions here are that the sensitivity of your muscles to pressure will be quantified using a specialized pressure gauge rather than by the doctor's fingers, and some of the self-report measures of emotional impact are not routinely used in most clinics.

### **What are the treatments and how do they differ from standard care for chronic neck pain?**

Each of the different treatments being investigated are currently used as treatment options for people with chronic neck pain such as yours. The criteria for choosing one treatment over another are currently not well understood, and in fact this is part of why this line of research is being conducted. You will be randomized to receive one of the following common treatments for neck pain:

1. Intra-articular facet joint block under fluoroscopy. This treatment involves carefully injecting an anti-inflammatory (steroid) directly into selected joints of your neck. This is done under the guidance of a fluoroscope (specialized x-ray) to make sure the steroid ends up in the right place. No more than two joints per side will receive the medication. Two different types of steroid will be used in this study, the one you receive will be chosen at random and you will not know which of the two you received until the study is complete. They are betamethasone and dexamethasone, both of which are commonly used for this application and present low risk of complication. The procedure itself is fairly quick, requiring only minutes to complete, but the prep time before and monitoring afterwards will require about 45 minutes of your time in total.

2. Intramuscular lidocaine injection. This treatment involves carefully injecting a small concentration of a local pain-reliever (lidocaine) directly into the muscles around your neck. The doctor will determine where the injections should be placed by palpating (pressing on) your muscles to find the most tender spots. The injections will occur weekly for 3 weeks in total (3 sets of injections). Each session will require about 20 minutes of your time.
3. Evidence-based home exercise program. This treatment will require you to perform a set of exercises for your neck and arms at an intensity that is challenging but comfortable for you. All 3 groups will be performing the exercises. They have been compiled by a physiotherapist with expertise in treating chronic neck pain. The exercises should be performed daily, and each session will take about 20 minutes of your time.

There is a 50% chance that you will be randomized to the first group, and a 25% chance of being randomized to groups 2 or 3. Tell the physician or study coordinator if you know you cannot receive any one of the agents described above (e.g. if you are allergic to any one of them).

#### **How many people will participate in this study?**

We will enroll approximately 44 people to participate in this study.

#### **Will I be reimbursed for my participation?**

Your parking at the clinic will be covered for all visits associated with this study. No additional reimbursement will be offered. Reimbursement for parking costs may not be immediately available, in which case it will be mailed to you at the earliest opportunity.

#### **What are the risks of participating?**

This study will include the use of a needle for injections into the joints of your neck and an x-ray to guide the needle. This is a common approach for diagnosis and treatment in people with neck pain, and they will be administered by a trained physician with considerable experience in working with people with chronic neck pain. However, being an invasive procedure, injections are not without risk, and we want to be sure you are fully aware of these before consenting to participate. Side effects of the injection are generally minor and short-lasting. These include: lightheadedness, facial flushing, headache, local rash, insomnia, ringing in the ears, blurry vision, increased heart rate or blood pressure, allergic reaction, increased blood glucose (particularly if you are diabetic), fainting, increased pain, bruising or bleeding. More serious side effects, while very rare, have been reported, and these include: seizures, punctured lung, infection, nerve injury, spinal cord injury, stroke or death. Every effort will be taken to minimize

the likelihood of these risks, including use of a nurse and trained x-ray technician to support the interventional physician. The x-rays used in this study expose you to no more radiation than that of a routine chest x-ray. It has been estimated that exposure to this type of radiation might relate to a 1 in 100,000 to 1 in 1,000,000 chance of developing cancer later in your life. While exposure to x-rays has not been definitively linked to problems with fetuses, as a precaution you will not be allowed to participate in this study if you are pregnant or planning to become pregnant within the next 6 months.

### **What are the possible benefits of participating?**

You may or may not benefit directly from participation in this study. You will receive treatment that may include injections, home exercises, or some combination thereof. You may or may not experience some degree of improvement in your condition regardless of what treatment group you are in. In the event that, upon completion of the study, one treatment is shown to lead to significantly better improvement compared to the other 2, you will be offered the chance to receive the superior treatment if you weren't already in that group. It is up to you whether you wish to receive it. Your position on the wait list to see a pain doctor will not be affected by whether you choose to participate or not participate in this study. The potential risks and benefits of study participation compared to standard care are unknown.

### **Can I receive other treatments while participating in this study?**

We are requesting that you not initiate any *new* treatments for the first 3 months of your involvement in this study unless you are specifically requested to do so from your insurance company or doctor. This includes physiotherapy, chiropractic, massage therapy, acupuncture, naturopathic remedies, or new medications, but excludes psychological counseling, which you are free to initiate at any time at your own expense should you feel you require it. We also request that you not engage in any new formalized exercise programs such as yoga, tai-chi, aerobics or aquatic (pool) exercise for the first 3 months. If you know you are scheduled, or are on a waiting list, to undergo surgery of any kind within the next 6 months, please tell the study coordinator so that you can be evaluated for suitability to participate in this study. You may continue to take the same medications, at the same dose and frequency that you were taking prior to your involvement.

The purpose of this request is so that we are better able to determine the effect of the treatments under study without the influence of additional treatments. However, this is only a request. If you do decide to start a new treatment or exercise program you will still be allowed to continue in the study, although we will ask you to provide some information on the type, frequency and intensity (dose) of the new treatment. Since it is likely that people in this study have experienced neck pain for a long time (years) and have already tried several treatments, we don't anticipate any risks involved with refraining from adding new conservative therapies for a 3-month period.

**Who will have access to my information?**

We will not retain any information that could identify you or connect you to your responses after the final follow-up period. A unique randomly-generated 6-digit ID number will appear on all forms belonging to you for the sole purpose of connecting all of the data you provide. All of the responses you provide will be completely anonymized after you have completed the study. The lead researcher at Western University, Dr. David Walton, will collect all of the data provided by all participants and along with the other researchers on this project, will analyze and interpret the anonymous data in one large group. Data forms will be secured in a locked cabinet in Elborn College on the campus of Western University when not being used. Part of the data collected in this study will be used by Swati Mehta, a PhD student at Western University working under the supervision of Dr. Walton, as part of her thesis research.

Your specific information will not be shared with anyone outside of this research team, including your healthcare provider or legal counsel (yours or any others), without your express written consent to do so. Only group averages will ever be published. Note however that this means that after the study is complete it will be impossible to identify your data for the purposes of withdrawing it from the study should you so desire at some point in the future.

**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. If you choose to withdraw from the study, you may request to have your data to that point removed, at any time up until the end of the study. Withdrawal from the study or refusal to participate is your decision, and may be done without the requirement of explanation on your part. Withdrawal will in no way affect your current or future relationship or the care you receive from this or any other medical clinic.

**What if I want more information?**

You may contact the lead researcher, Dr. David Walton, at Western University (London, Canada) if you require any further clarification. His contact information can be found below. You may also contact the hospital contact Dr. Eldon Loh at either St. Joseph's or Parkwood Hospitals. If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute at XXXXXX. You are encouraged to keep this letter of information for your own records.

We thank you in advance for considering participation in this study.



Sincerely,

David Walton BScPT, PhD  
Lead Researcher

Eldon Loh  
Co-investigator

Funding for this study has been received from the Lawson Health Research Institute's Internal Research Fund. No funding has been received from the manufacturers of any of the treatments (medications) used in this study. The researchers declare no conflict of interest in the conduct or results of this study.

June 28, 2013

**Consent form****Facet vs. Trigger point injections or exercise for management of chronic neck pain: A randomized controlled trial**

Principal Investigator: Dr. David M. Walton PT PhD

I have read the letter of information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

---

 Participant name (print)

---

 Participant signature

Date

---

 Person obtaining consent (print)

---

 Signature of person obtaining consent

Date

**Consent for Photography****Facet vs. Trigger point injections or exercise for management of chronic neck pain: A randomized controlled trial**

Principal Investigator: Dr. David M. Walton PT PhD

I consent to having my picture taken using a digital camera for the sole purposes of evaluating my standing posture for this study. I am aware that this will require me to remove my shirt or wear a tank top that exposes my shoulders and back of my neck.

I do not consent to having my picture taken.

---

 Participant signature (if consenting)

Date

# Curriculum Vitae

## Education

PhD in Health and Rehabilitation Science, Health Promotion University of Western Ontario, London, ON	2012 – Current
Certificate in University Teaching University of Western Ontario, London, ON	2016
Masters of Arts in Counselling Psychology Yorkville University, Fredericton, NB	2012
Bachelor of Science in Biology and Psychology University of Western Ontario, London, ON	2006

## Teaching Experience

### Guest Lecturer

- Pain and Quality of Life: Rehabilitation Sciences 3061B: Foundations of Rehabilitation Sciences, *University of Western Ontario, London, ON* March 2016
- Psychological Inflexibility, Perfectionism, and Anxiety as Risk Factors for Chronic Pain Disability  
*University of Western Ontario Physical Medicine and Rehabilitation Grand Rounds. London, ON* Feb 2016
- Psychological distress among chronic pain individuals.  
*University of Western Ontario Physical Medicine and Rehabilitation Grand Rounds. London, ON* Jan 2016
- Pain after spinal cord injury.  
*Glenrose Rehabilitation Hospital Grand Rounds. Edmonton, AB* Nov 2015
- Psychological distress between individuals from a tertiary chronic pain clinic compared to a specialist rheumatoid arthritis clinic.  
*University of Western Ontario Interdisciplinary Pain Grand Rounds. London, ON* May 2015

### Teaching Assistant

- Physical Therapy 9539a: Therapeutic Modalities. Graduate Level Course. *University of Western Ontario, London, ON* Sept 2012 – Dec 2012

### Undergraduate Independent Study Project Co-Supervisor

- Alex Ng. University of Western Ontario, London, ON Sept 2010 – Apr 2011
- Katherine Cheung. University of Western Ontario, London, ON Sept 2010 – Apr 2011

## Research Experience

**Research Associate** (Supervisor: R. Teasell)  
Parkwood Institute, London, ON

May 2012 – current

## Academic Awards

Award	Granting Agency	Amount	Date
Canadian Institutes of Health Research Frederick Banting and Charles Best Canada Doctoral Graduate Scholarship	Canadian Institutes of Health Research	\$35,000	May 2016-Apr 2017
Western Graduate Research Scholarship	University of Western Ontario	\$10,000	Sept 2016-Aug 2017
Canadian Institutes of Health Research Frederick Banting and Charles Best Canada Doctoral Graduate Scholarship	Canadian Institutes of Health Research	\$35,000	May 2015-Apr 2016
Western Graduate Research Scholarship	University of Western Ontario	\$10,000	Sept 2015-Aug 2016
Canadian Institutes of Health Research Frederick Banting and Charles Best Canada Doctoral Graduate Scholarship	Canadian Institutes of Health Research	\$35,000	May 2014-Apr 2015
Western Graduate Research Scholarship	University of Western Ontario	\$10,000	Sept 2014-Aug 2015
Jonathan Lomas Knowledge Translation Doctoral Research Award	Canadian Institutes of Health Research	\$5,000	May 2014-Apr 2015
Ontario Graduate Scholarship ( <i>declined</i> )	University of Western Ontario	\$15,000	Sept 2014-Aug 2015
Ontario Graduate Scholarship with Distinction	University of Western Ontario	\$16,500	Sept 2013-Aug 2014
Western Graduate Research Scholarship	University of Western Ontario	\$10,000	Sept 2013-Aug 2014
Western Graduate Research Scholarship	University of Western Ontario	\$19,000	Sept 2012-Aug 2013
University of Western Ontario Entrance Scholarship	University of Western Ontario	\$800	Sept 2000-Aug 2001

## Research Funding

Investigators	Role	Granting Agency	Title	Total Amount	Date
Walton DM, Loh E, <b>Mehta S</b>	Co-PI	Lawson Health Research Institute	Facet versus trigger point injection for management of chronic muscular neck pain: A randomized clinical trial and creation of a clinical prediction algorithm	\$14,915	2013-2014

## Academic Reviewer

- Journal Ad hoc Peer Reviewer for Pain Research and Management (2016)
- Journal Ad hoc Peer Reviewer for Rehabilitation Psychology (2016)
- Journal Ad hoc Peer Reviewer for Disability and Rehabilitation (2011 – 2016)
- Visual Arts Graduate Program Reviewer, University of Western Ontario (2015)
- Journal Ad hoc Peer Reviewer for European Journal of Neurology (2015)
- Journal Ad hoc Peer Reviewer for Topics of Spinal Cord Injury Rehabilitation (2012 – 2015)
- Journal Ad hoc Peer Reviewer for Archives of Physical Medicine and Rehabilitation (2014)
- Journal Ad hoc Peer Reviewer for Health and Quality of Life Outcomes (2013 – 2014)
- External Grant Reviewer, Rick Hansen Institute (2012)

## Committee Member

- **Planning Committee Member**, National Spinal Cord Injury Conference. (2016 – present).
- **Early Career Officer**, American Congress of Rehabilitation Medicine Spinal Cord Injury Interdisciplinary Special Interest Group (2016-present)
- **Committee Member**, Secondary Complications and Aging Task Force of the American Congress of Rehabilitation Medicine Spinal Cord Injury Interdisciplinary Special Interest Group (2015-present)
- **Committee Member**, Health and Rehabilitation Sciences Graduate Research Conference, London, Ontario (2015-2016)
- **Steering Committee**, Clinical Practice Guidelines for Neuropathic Pain Post SCI. London, Ontario. (2013 – present)
- **Planning Committee**, Continuing Medical Education: Meta-Analysis of Botulinum Toxin A Detrusor Injections in the Treatment of Neurogenic Detrusor Overactivity After Spinal Cord Injury. (2013)
- **Organizing Committee Member**, Aging, Rehabilitation, and Geriatrics Care/Faculty of Health Science Symposium, London, Ontario. (2010, 2012-2013)

## Professional Memberships

- Trainee Member, International Association for the Study of Pain (2015-present)
- Trainee Member, Spine (2015-present)
- Trainee Member, Canadian Pain Society (2014-present)
- Student Member, Archives of Physical Medicine and Rehabilitation (2012-present)
- Professional Member, Canadian Counselling and Psychotherapy Association (2012-present)

## Publications

### Published Peer Reviewed Articles

1. Walton D, Kwok T, **Mehta S**, Loh E, Smith A, Elliott J, Kamper S, Kasch H, Sterling M. Cluster Analysis of an International Pressure Pain Threshold Database Identifies 4 Meaningful Subgroups of Adults with Mechanical Neck Pain. *Clinical Journal of Pain*. 2016: doi: 10.1097/AJP.0000000000000421 (*in press*).

### Published Abstracts

1. **Mehta S**, Loh E, Nielson W, Walton, D. Does current stage of pain effect mood and coping among individuals with chronic neck pain? *Pain Research and Management* (accepted).
2. **Mehta S**, Loh E, Walton D. Identification and characterization of unique subgroups of chronic cervical pain individuals based on their coping style. *Archives of Physical Medicine and Rehabilitation* 2015;96(10):e66.

### Conference Presentations

1. **Mehta S**, Loh E, Walton D. Identification and characterization of unique subgroups of chronic cervical pain individuals based on their coping style. *American Congress of Rehabilitation Medicine*, Dallas Texas, October 25-30, 2015.
2. **Mehta S**, Bellingham G, Frewen P, Walton D. Psychopathological model of the effect of corticosteroids on pain among people with chronic pain and psychological comorbidity. *9th Congress of the European Pain Federation*, Vienna, Austria, September 2-5, 2015.
3. **Mehta S**, Loh E, Walton D. Differences in mood and coping among individuals with chronic cervical pain based on current pain stage of change. *9th Congress of the European Pain Federation*, Vienna, Austria, September 2-5, 2015.
4. **Mehta S**, Loh E, Walton D. Predicting Successful Response to Medial Branch Blocks. *International Spine Intervention Society 23<sup>rd</sup> Meeting*, Las Vegas, Nevada, July 26-August 1, 2015, poster 9.
5. **Mehta S**, Loh E, Nielson W, Walton, D. Does current stage of pain effect mood and coping among individuals with chronic neck pain? Canadian Pain Society Scientific Meeting, Vancouver, British Columbia, May 24-27, 2016