Perceptions of Community-Dwelling Patients on the Impact of the Discontinuation of OxyContin® on their Pain Management:

A Mixed Methods Study

by

Sara Ibrahim

A thesis
presented to the University of Waterloo
in fulfillment of the
thesis requirement for the degree of
Master of Science
in
Pharmacy

Waterloo, Ontario, Canada, 2014

Author’s Declaration

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

Abstract

Chronic pain is considered a major health problem in older adults. OxyContin®, one of the most commonly used medications for treating pain in Canada, was recently discontinued, and delisted from the Ontario Drug Formulary due to high rates of abuse associated with its use. A tamper-resistant formulation was developed by the manufacturing company to replace it. Inadequacies in the available body of literature reporting on the discontinuation process prompted this study of patient perceptions on the impact of the discontinuation of OxyContin® on personal pain control. A qualitative descriptive study was carried out to provide evidence on patients' lived-experiences, placing particular focus on identifying any flaws within the medical infrastructure through sharing discontinuation experiences and investigating the efficacy of alternative pain medications. Chronic pain patients 45 years or older were recruited from three sites and interviewed using a semi-structured guide. Interviews were conducted with physicians to obtain their perceptions on discontinuation to develop a more comprehensive understanding of the experience from both patient and professional levels. Findings of the current study provided preliminary data illuminating several aspects of patients' pain and medical care through the discontinuation process. The emergent themes represented both convergences and divergences between patients and their clinicians. For example, areas of divergence included the motive for discontinuation, which was condemned by most patients, but supported by all physicians. Another discrepancy was reflected in the perceived impact of discontinuance on pain control, with the majority of patients reported experiencing a negative impact while most physicians described it as being insignificant within their practice. On the other hand, perceptions of patients and physicians on their experiences overlapped giving rise to a prominent theme of the need to optimize current pain management practices. Further research is warranted to build upon the foundation generated by this study to improve understanding of shortcomings in pain management and to optimize care for patients.

Table of Contents

Author's Declaration ii

Abstract iii

Chapter 1: Background and Literature Review 1

1.1. Pain: Definition and Types 1

1.2. Age and Pain Prevalence 2

1.3. Assessment of pain 4

1.4. Pain Management in the older patients 6

1.4.1. Non-pharmacologic management of pain 6

1.4.2. Pharmacological management of pain 7

1.4.2.1. Non-opioid Analgesics 7

1.4.2.2 Opioid Analgesics 7

1.5. Controlled-Release Oxycodone (OxyContin®) 9

1.5.1. Pharmacokinetics and pharmacodynamics of Oxycodone 10

1.5.2. Balancing safety and efficacy: OxyContin® for managing chronic pain 11

1.5.3. Discontinuation of OxyContin® 12

Chapter 2: Study Rationale and Objectives 16

2.1. Study Purpose 16

2.2. Objectives of the Proposed Research 19

2.2.1. Primary Objectives 19

2.2.2. Secondary Objective 19

Chapter 3: Methods 20

3.1. Research Methodologies: Quantitative, Qualitative and Mixed 20

3.2. Study Design: Mixed Methods 22

3.2.1. Typologies of Mixed Methods designs 23

3.2.2. Concurrent Nested Design 25

3.2.3. Qualitative Description 27

3.2.4. Constructivist Interpretive Paradigm 29

3.3. Recruitment Process 29

3.3.1. Study Sample 33

Table of Contents

3.4. Data Collection 35
3.4.1. One-on-one Semi-structured Interviews 35
3.4.1.1. Interviews with Patients 35
3.4.1.2. Interviews with Physicians 39
3.4.2. Questionnaires 40
3.4.2.1. Pain Treatment Satisfaction Scale (PTSS) 41
3.4.2.2. The Brief Pain Inventory (BPI) 42
3.5. Data Analysis 42
3.5.1. Descriptive Statistical Analysis 43
3.5.2. Discourse Analysis 44
3.5.2.1. Coding 47
3.5.2.2. Memo-writing 48
Chapter 4: Findings **52**
4.1. Introduction 52
4.2. Participant Characteristics 52
Table 1 General Patient Characteristics 53
4.2.1. Findings from Patient Questionnaires 54
Table 2: Findings from the Brief Pain Inventory (BPI) 55
4.3. Findings from patient interviews 56
Theme 1: Disagreement with the motive for discontinuation 57
Theme 2: Discontinuation negatively impacted pain control 66
Theme 3: Discontinuation had no impact on pain control 73
Theme 4: Learning to live with pain 76
Theme 5: Identification of flaws within the discontinuation process 79
Theme 6: Choosing to get off OxyContin® permanently 83
Theme 7: Need for optimizing patient care 87
4.4. Findings from physician interviews 92

Table of Contents

Theme 1: Support for the motive for discontinuation 92

Theme 2: Discontinuation insignificantly impacted pain control 93

Theme 3: Existence of adequate guidelines for opioid use 96

Theme 4: Disapproval of the introduction of generics 98

Theme 5: Need for optimizing pain management practices 100

Chapter 5: Discussion and Conclusion 106

5.1 Motive for discontinuation of OxyContin®: For or Opposed? 109

5.2. Differently perceived impact of discontinuation on pain control 112

5.3. Accepting pain and learning to live with it 113

5.4. Discontinuation experiences revealed flaws within process 114

5.5. Comfort levels of administering and prescribing OxyContin® 118

5.6. Need for optimizing current patient care 120

5.7. Study Strengths, Limitations and Future Directions 124

5.8. Conclusion 127

References 129

Appendices 142

Chapter 1: Background and Literature Review

1.1. Pain: Definition and Types

The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (International Association for the Study of Pain., 2012). This definition explains that pain could either be physical damage caused by an injury or emotional and psychological suffering. Margo McCaffery's definition reflects the extremely subjective and individualized nature of pain; "Pain is whatever the experiencing person says it is, existing whenever he/she says it does" (McCaffery M., 1968).

Pain is broadly categorized as mild, moderate, or severe, depending on its intensity. Pain is classified temporally as acute or chronic. Acute pain is usually temporary (less than 3-6 months) and caused by an injury or infection, whereas chronic pain occurs over a prolonged period of time (more than 3-6 months) and is not necessarily associated with a recognizable illness (AGS Panel on Persistent Pain in Older Persons, 2002). Chronic pain, also known as persistent pain, could be either malignant or non-malignant. Moreover, pain is classified according to pathophysiology into three classes; nociceptive, neuropathic, and mixed pain (AGS Panel on Persistent Pain in Older Persons, 2002). Nociceptive pain mainly results from the stimulation of pain receptors, as in the case of inflammatory arthritis and ischemic disorders (McCaffery M. and Pasero C., 1999). It is further subdivided into somatic or visceral pain (AGS Panel on Persistent Pain in Older Persons, 2002;McCaffery M., 1968). Neuropathic pain involves damage of pain receptors causing abnormal processing and is either centrally generated such as post-stroke pain or peripherally generated such as pain associated with diabetic neuropathy (McCaffery M. and Pasero C., 1999). Mixed pain, as its name implies, describes pain resulting

from mixed or unknown mechanisms, such as recurrent headaches (AGS Panel on Persistent Pain in Older Persons, 2002).

1.2. Age and Pain Prevalence

The rapid aging of the worldwide population gives rise to numerous health and financial concerns. Predictions show that the population of individuals aged over 60 years will be 1.2 billion by 2025 and will be approximately two billion elderly people worldwide in 2050 (Andrade et al., 2011). In addition, the World Health Organization's (WHO) 2012 Report on Aging estimates that by the year 2050, 400 million people worldwide will be over 80 years of age (World Health Organization, 2012). Statistics Canada estimates that five million Canadians were 65 years or older in 2011 and projects that by the year 2051, one in four Canadians will be over the age of 65 (Statistics Canada, 2014).

In Canada, the impact of aging projections on health-related issues is a primary and frequent concern. One important reason is the well-developed association between increasing age and increasing rates of morbidity. Secondly, there is significant evidence that the rate of aging in the Canadian population exceeds the capacity of the current healthcare organization in many provinces including Ontario (Busby and Robson, 2013). While pain is a widespread health problem among all age groups, it is especially prevalent in older adults, being one of the most common complaints of the elderly regardless of its cause (Elliott et al., 1999). Multiple studies have consistently demonstrated that the likelihood of experiencing pain increases with age (Blyth et al., 2001;Costantini et al., 2002;Elliott et al., 1999;Reitsma et al., 2011;Smith et al., 2001). Pain prevalence is twofold higher in adults aged over 60 years compared to younger adults (Crook et al., 1984). Given that global and Canadian estimates demonstrate an aging population,

and since old age is associated with a higher probability of experiencing pain, pain prevalence will likely continue to increase in our society over the foreseeable future.

A recent prospective study examining the prevalence of chronic pain in the Canadian population over a 14-year period (1994 to 2007) reported that 15.1% to 18.9% of Canadians experience chronic pain, but is most commonly experienced within the older population, where 23.9% to 31.3% of the elderly suffer it (Reitsma et al., 2012). Moulin et al. (2002) surveyed 2012 adults using random digit dial and reported chronic pain in 22% of individuals aged 18 to 34 years, 29% of individuals 35 to 45 years, and 39% of individuals aged 55 years and older (Moulin et al., 2002). Similarly, Boulanger et al. (2007) reported the prevalence of chronic pain to be 17% in those aged 18 to 34 years, 25% in those aged 35 to 54 years, and 33% in those aged 55 years and older (Boulanger et al., 2007). The prevalence of chronic pain in females was higher than males in all reviewed studies (Boulanger et al., 2007;Moulin et al., 2002;Reitsma et al., 2012;Tripp et al., 2006). Another study conducted to estimate the prevalence of chronic pain in Canada demonstrated a higher prevalence among the 46 to 66+ age groups in both women (23.4% to 31.5%) and men (22% to 22.8%) (Schopflocher et al., 2011). Similarly, in the United States of America (U.S.A.), it was estimated that approximately 68 million persons suffer chronic pain each year, of which 17.5 million are elderly (Code and Bonica, 2001). Clearly, these statistics demonstrate that chronic pain is alarmingly prevalent in North America, presenting the highest burden in older individuals. In turn, this emphasizes the urgent need for more effective pain assessment and pain management strategies.

Old age is not the only risk factor for chronic pain. Other illnesses such as cardiovascular disease, cancer, cognitive impairment, depression, and osteoporosis expose individuals to different types of pain, taking into consideration the higher prevalence of those diseases in the

older age group. Therefore, the increased likelihood of co-morbidities in the older population triggers concerns about the associated burden of pain.

While pain is a treatable condition (Freedman, 2002) and is becoming better comprehended by both clinicians and patients, under-recognition and consequently, under-treatment are potential contributors to high rates of inadequately managed pain (Pitkala et al., 2002). It has been shown that patients tend to underreport their pain to their healthcare providers because they fear being linked to medication non-compliance (Scharff and Turk, 1998). Other barriers to treatment include concerns that usually accompany long-term use of painkillers such as fear of addiction, adverse events, and tolerance (McCaffery M. and Pasero C., 1999). Multiple approaches for pain assessment and management are used in practice, and will be discussed in the sections that follow.

1.3. Assessment of Pain

The clinical challenge of evaluating and managing pain places an increasing burden on the healthcare system as a whole. Pain is not only differently perceived among different individuals but it is also multidimensional, affecting many physical, psychological, and social aspects for each patient. Furthermore, it can be difficult to identify the source of pain in patients presenting with multiple comorbidities. Improvement in these areas is a current research focus.

Pain is a subjective condition with no objective biological markers to indicate its presence in an individual (American Geriatrics Society, 1998). Pain management guidelines and handbooks confirm that patient self-report counts as a consistent and reliable indicator of the presence of pain and its intensity, and that assessment tools based on self-report are considered the most accurate for all patients regardless of age group (Agency for Health Care Policy and Research, 1992;American Pain Society Subcommittee on Quality Assurance Standards,

1990;Turk and Melzack, 2011). Additionally, the Registered Nurses Association of Ontario's learning package for assessment and management of pain in the elderly describes self-report as the "gold standard" of pain assessment in cognitively intact patients who are able to communicate their pain verbally to clinicians (Registered Nurses' Association of Ontario, 2007).

Several valid self-report pain tools are available and have been widely utilized in clinical practice. These include the Visual Analogue Scale (VAS), Numeric Rating Scale (NRS), Verbal Descriptor Scale (VDS), and Pictorial Pain Scales (Herr et al., 1998;Williamson and Hoggart, 2005). Typically, these tools allow patients to quantify the intensity of their pain on numeric scales from 0 to 10 with 0 representing no pain and 10 representing the most pain experienced or via choosing from a list of adjectives words that best describe their pain intensity, e.g. "no pain", "mild pain", "severe pain", "the most intense pain imaginable". Alternatively, pictorial pain scales (Faces Pain Scale and the Wong-Baker Faces Pain Scale) are used mainly to assess pain in cognitively impaired patients where a clinician simply chooses from a series of faces the facial expression that best matches the patients when experiencing pain.

Pain interviews and questionnaires are alternate multidimensional and more comprehensive tools to assess pain. Rather than one-dimensional pain scales that quantify a patient's pain intensity only, pain interviews enable the collection of more detailed information from patients about their pain such as its onset, duration, intensity, location, frequency, impact of pain on function, quality of life and daily activities, treatment and response to treatment, and patient expectations (Bruckenthal, 2008). Similarly, several commonly used pain questionnaires that allow thorough assessment of pain include the short form McGill Pain Questionnaire (Melzack, 1987) and the Brief Pain Inventory (Cleeland and Ryan, 1994). The ultimate goal of

such comprehensive assessments is to provide an individualized treatment plan for each patient, ideally resulting in decreased pain and increased functionality and quality of life.

1.4. Pain Management in Adults

Accurate pain assessment provides the groundwork for adequate pain management in patients with chronic pain. The assessment strategies mentioned above should be modified and tailored to fit each patient's needs accordingly. Despite challenges in assessment, medication use, or pain reporting that may complicate pain treatment, pain can be adequately managed in adults using an array of clinical and behavioral strategies. The multiple non-pharmacologic and pharmacologic modalities to treat chronic pain will be discussed next.

1.4.1. Non-Pharmacologic Management of Pain

A wide range of non-pharmacologic pain management strategies have been shown to work alone or in combination with other pharmacological interventions (Ferrell et al., 2009). Physical and psychological non-pharmacologic treatment modalities that were shown to reduce pain and enhance pain management in adults include regular physical exercise (Ferrell et al., 1997;Frost et al., 1998;Koes et al., 1995;Moffett et al., 1999), patient education programs (Burton et al., 1999;Ferrell et al., 1993;LeFort et al., 1998;Little et al., 2001), and cognitive and behavioral strategies (Henschke et al., 2010;Hoffman et al., 2007;Morley et al., 1999). Despite the lack of solid scientific evidence supporting the efficacy of complementary and alternative medicine approaches such as spiritual healing, homeopathy, and naturopathy, many patients often seek such strategies in hopes of attaining adequate pain relief (Weiner and Ernst, 2004). However, it is noteworthy that there are inconsistencies among studies regarding the

effectiveness of such non-pharmacologic approaches to pain, warranting additional research to provide definitive data.

1.4.2. Pharmacological Management of Pain

A variety of pharmacological therapies including analgesics, opioids, and adjuvant therapies are available for treating chronic pain. The most commonly used medications have been studied and compared for their efficacy and safety in controlling pain of diverse causes in different age groups. Numerous guidelines have been developed to ensure safe prescribing and use of different painkillers, including guidelines for special populations such as children and older adults. Classes of pain medications that are commonly used in practice will be discussed briefly in the next section.

1.4.2.1. Non-opioid Analgesics

Acetaminophen (also known as paracetamol; brand name: Tylenol) is a non-prescription analgesic and antipyretic that is indicated for pain relief. Its exact mechanism of action is not fully understood, however it is thought to be responsible for reducing pain by increasing the pain threshold in an individual through inhibition of prostaglandin (biological chemical that promotes pain and fever) production (Ogbru O., 2014a). Acetaminophen is among the most commonly used medications for mild to moderate pain, especially osteoarthritis and low back pain, where it is recommended as first-line therapy (Freedman, 2002;Schneider, 2005). The Canadian Chronic Pain Study II demonstrated that acetaminophen was administered by 18% of chronic pain patients across various Canadian provinces (Boulanger et al., 2007).

Non-steroidal anti-inflammatory drugs (NSAIDs) were prescribed to 43% of chronic pain patients (Boulanger et al., 2007). NSAIDs (e.g. aspirin) act by inhibiting the Cyclooxygenase enzymes; COX-1 and COX-2, which produce prostaglandins throughout the body and thus

reduces pain (Ogbru O., 2014b). Unlike acetaminophen, which lacks anti-inflammatory properties, NSAIDs are effective for treating chronic inflammatory pain, such as that associated with rheumatoid arthritis (Wienecke and Gotzsche, 2004). However, prolonged administration of high doses of NSAIDs in older adults should be avoided due to the high frequency of gastric bleeding (Ofman et al., 2002) and other adverse events associated with their use (Gloth III, 1996).

1.4.2.2. Opioid Analgesics

Opioids are narcotic painkillers that could be derived naturally from the opium poppy plant and/or produced synthetically in pharmaceutical companies to induce opium-like properties (i.e. relief pain by acting on the central nervous system) (National Institute on Drug Abuse, 2011). Opioids bind to opioid receptors in the body and inhibit transfer of pain signals to the brain, resulting in relief of pain sensations (National Institute on Drug Abuse, 2011). According to the WHO's Pain Relief Ladder, opioid analgesics are recommended as drugs of choice for treating moderate to severe pain (World Health Organization, 2013).

Opioids were shown to be the most frequently prescribed pain medications for treating chronic non-cancer pain in studies from Canada and the U.S.A. (Boulanger et al., 2007;Turk et al., 2011). In Canada, 83% of patients suffering from moderate to severe chronic non-cancer pain were administered opioids in 2004 (Boulanger et al., 2007). Among the reasons for common use of opioids in clinical care is their appropriateness for treating both acute and chronic pain, as well as the different classes (nociceptive and neuropathic) and types (malignant and nonmalignant) of pain (Chau et al., 2008). Opioids are available in either immediate-release or controlled-release formulations and in multiple routes of administration including oral, rectal, transdermal, intravenous, intramuscular, subcutaneous, and sublingual (Mercadante, 1999).

The appropriateness of controlled-release opioids for long-term therapy is strongly supported in the literature (Ferrell et al., 2009;Fukshansky et al., 2005;Glare et al., 2004). Long-acting formulations were shown to play an important role in optimally managing chronic pain due to the various advantages they offer. For example, the provision of consistent pain relief by releasing the medication over a prolonged period of 12-24 hours is a significant benefit that bypasses fluctuations in pain intensity and avoids breakthrough pain that otherwise may occur with short-acting painkillers (McCarberg and Barkin, 2001). In addition, many patients find long-acting formulations to be more convenient as it avoids nighttime dosing, which is among the potential causes of non-compliance and pain-induced sleep disturbances (Sloan and Babul, 2006).

The role of opioids for treatment of chronic pain has noticeably expanded in recent years, with multiple studies demonstrating a significant increase in the use of opioids over the past 20 years (Joranson et al., 2000;Novak et al., 2004;Zerzan et al., 2006). In Canada, opioids are among the most commonly prescribed medications (Dhalla et al., 2009). However, despite growing evidence and supporting guidelines of opioid efficacy, many physicians hesitate to prescribe opioids due to concerns regarding the side effects and addiction potentially associated with their use (see opioid efficacy and safety section below), which could create a barrier to optimum pain management (Ong, 2008;Schneider, 2005). Although the likelihood of opioid abuse has always been a clinical concern (Freedman, 2002), appropriately used opioids have been shown to be safe and effective with no evidence of drug misuse (Portenoy and Foley, 1986).

1.5. Controlled-Release Oxycodone (OxyContin®)

OxyContin® is a controlled-release formulation of oxycodone; a semi-synthetic potent opioid analgesic drug that was shown to be useful in the treatment of moderate to severe pain (Levy, 1996). Oral controlled-release oxycodone is reported to achieve analgesia comparable to that attained with immediate-release oxycodone with the benefit of less frequent dosing, thus enhancing patient compliance (Stambaugh et al., 2001) and maintaining adequate pain control (Salzman et al., 1999;Stambaugh et al., 2001). In Canada, OxyContin® is manufactured by Purdue Pharma. Tablets are supplied in 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg and 160 mg tablet strengths for oral administration (Purdue Pharma, 2009).

OxyContin® was approved by the USA Food and Drug Administration (FDA) in 1995 (Pan et al., 2007) and was indicated for treating moderate to severe pain of different causes when continuous, around-the-clock analgesia was required (Pan et al., 2007;Purdue Pharma, 2009). OxyContin® is not intended for use as a PRN (pro re rata; as needed) medication (Purdue Pharma, 2009). It was introduced in the Canadian market in 1996 (Canadian Center on Substance Abuse, 2011) and was added to the Ontario provincial drug formulary in 2000 (Dhalla et al., 2009), notably becoming the most popular prescription pain medication since its introduction (Canadian Agency for Drugs and Technologies in Health, 2011).

OxyContin® has been promoted as a drug that could change the lives of individuals suffering from chronic pain and was publicized as a "miracle pill" for chronic analgesia, with little risk of addiction (Jayawant and Balkrishnan, 2005;Lipman and Jackson, 2000;Van Zee, 2009). In the U.S.A., the drug has been highly profitable, accounting for 90% of Purdue Pharma's business by 2001 (Inciardi and Goode, 2003). Similarly, Canadian sales dramatically increased from just a few million dollars in 1998 to $243 million in 2010 (CBC News, 2012).

1.5.1. Pharmacokinetics and Pharmacodynamics of Oxycodone

OxyContin® tablets are intended to be taken intact orally for optimal systemic drug-distribution in a controlled manner. During improper administration by crushing, chewing, or dissolving tablets, the controlled delivery mechanism is eliminated, resulting in the rapid release and absorption of a potentially lethal dose of the parent drug oxycodone (Purdue Pharma, 2009).When OxyContin® is properly administered; oxycodone is absorbed in a bi-phasic manner. The first phase accounts for rapid release and absorption (t1/2 = 0.6 hours) of approximately 38% of the total dose when gastrointestinal secretions degrade the coating of the pill (Mandema et al., 1996). In the second phase, oxycodone is slowly released in the bloodstream (t1/2 = 6.9 hours) accounting for the remaining 62% of the dose (Mandema et al., 1996).

Oxycodone has a very high oral bioavailability ranging between 60 and 87% (Purdue Pharma, 2009). Oxycodone is metabolized by the liver; primarily to noroxycodone via CYP3A mediated N-demethylation and secondarily to oxymorphone via CYP2D6 mediated O-demethylation (Purdue Pharma, 2009). Excretion of oxycodone and its metabolites occurs in the kidney (Purdue Pharma, 2009). Due to the rapid release of oxycodone in the first phase of absorption, the onset of analgesic action occurs within one hour following oral administration of OxyContin® (Purdue Pharma, 2009).

1.5.2. Safety and Efficacy

The tolerability profile of an analgesic opioid is an extremely important consideration in the attainment of effective chronic pain management and it may significantly impact patients' and physicians' decisions regarding treatment compliance (Afilalo et al., 2010). The adverse events commonly associated with opioids include respiratory and central nervous system depression, constipation, gastro-intestinal symptoms, and physical dependence (Afilalo et al.,

2010;Hartung et al., 2007). Consistent and significant findings were derived from reviewing prior literature on the efficacy and tolerability of OxyContin®. Multiple studies reported that the side effects associated with OxyContin® were similar to those typically associated with other opioids, providing supporting evidence for its comparable efficacy and tolerability for treating pain of different etiologies (Afilalo et al., 2010;Hartung et al., 2007;Ong, 2008;Pan et al., 2007;Stambaugh et al., 2001). OxyContin® was shown to be slightly safer than extended-release morphine, which has a well-established tolerability profile (Hartung et al., 2007). It is important to clarify that study findings demonstrated a similar abuse potential of OxyContin® compared to other orally administered opioids, but it had a slight safety advantage in terms of adverse events. This differed from Purdue Pharma claims upon introduction of the medication and marketing to healthcare providers, as will be discussed in the next section.

1.5.3. Discontinuation of OxyContin®

OxyContin® was placed in schedule II of the 1970 Controlled Substances Act, which warned prescribers and users that its effectiveness in treating chronic pain was accompanied by a risk of addiction (Cicero et al., 2005;Jayawant and Balkrishnan, 2005). Initially, the package insert indicated that OxyContin® might have a lower abuse potential as compared to other oxycodone medications (Cicero et al., 2005). In July 2001, following prevalent reports of abuse associated with OxyContin®, the FDA mandated the company to strengthen the drug's warnings and to include a "black box" warning concerning abuse (Cicero et al., 2005;Jayawant and Balkrishnan, 2005) to alert healthcare providers of the higher-than-claimed addictive risks of the drug. However, the FDA soon discovered that the "black box" warning may have potentiated the realization of substance abusers that snorting or injecting the powdered medication was a simple mechanism to obtain the euphoric effect they sought (Jayawant and Balkrishnan, 2005). As a

result, the popularity of OxyContin® not only increased among pain patients, but among nonmedical users as well. Eventually, OxyContin® became one of the most highly abused medications in Canada (CBC News, 2012;Ong, 2008) and the U.S.A. (Cicero et al., 2005;Jayawant and Balkrishnan, 2005;Van Zee, 2009).

In March 2012, Canada's premier investigative news program, the Fifth Estate reported "Since OxyContin was introduced in 1996, Canada has recorded the second-highest number of prescription opioid painkiller addictions and the worlds' second-highest death rate from overdoses." (CBC News, 2012). In Ontario, the number of prescriptions for oxycodone medications increased by an alarming 900% between 1991 and 2009 (Artuso A, 2012;Dhalla et al., 2009;Ontario Ministry of Health and Long Term Care, 2012). In 2009, Dhalla et al. conducted a retrospective database case series evaluating trends in opioid prescribing patterns and related mortality following the introduction of OxyContin® to the Ontario Drug Formulary (Dhalla et al., 2009). They reported that the amount of OxyContin® dispensed per prescription increased by 24% between 2001 and 2007 as opposed to an increase of 3% in the amount of long-acting morphine dispensed per prescription during the same period (Dhalla et al., 2009). Furthermore, the annual number of oxycodone-related deaths increased by 416% between 1999 and 2004, demonstrating a five-fold rise in mortality related to the use of oxycodone following the addition of OxyContin® to the formulary (Dhalla et al., 2009).

The misuse and abuse of OxyContin® has been associated with excessive marketing of the drug by Purdue Pharma in both the U.S.A. and Canada (Lexchin and Kohler, 2011;Van Zee, 2009). It has been reported that the company provided physicians with fraudulent information about the drug's abuse potential, encouraging them to increase prescriptions to patients. The impact of generous prescription of OxyContin® was viewed to have caused a public health

tragedy in both countries, and called for regulatory processes to better control the promotion of drugs with abuse potential in the future (Lexchin and Kohler, 2011).

In the U.S.A., this misrepresentation resulted in the May 10, 2007 conviction of three company executives, along with an affiliate of Purdue Pharma, of misleading marketing of OxyContin® (claiming it has less addictive properties as compared to other opioids, when it has similar addictive properties) and a fine of $634 million (Dhalla et al., 2009;Van Zee, 2009). As a result, Purdue Pharma discontinued production of OxyContin®, replacing it with a tamper-resistant formulation of controlled-release oxycodone in April 2010 in hopes of combating the medication abuse issue (Schneider et al., 2010). In February 2012, OxyContin® was discontinued and dropped from provincial health plans in Ontario, Saskatchewan, and Atlantic Canada (CBC News, 2012). In March 2012, the new controlled-release formulation, OxyNEO®, was introduced in the Canadian market (Ontario Ministry of Health and Long Term Care, 2012) after being approved by Health Canada (Cupp M, 2012).

Surprisingly, very little is known about the effect of introducing OxyNEO® and the limited information available is only from the American experience. For example, data collected from July 2009 to March 2012 in the U.S.A. illustrated a decrease in the abuse of OxyContin® but a marked increase in the use of other opioid medications and heroin (whose use nearly doubled) (Cicero et al., 2012). The statistics indicated the persistence and perhaps worsening of the abuse problem following the introduction of the abuse-deterrent formulation of Oxycodone. It is readily apparent that the sole focus of follow-up investigations is on the effect of discontinuation on addiction rather than on pain control. There is a lack of information on the benefits and/or risks of OxyNEO® in the management of chronic pain. Given that OxyNEO® was a reformulation of OxyContin®, slight differences in the physical and biological effects of

the pill are possible, which could affect pain relief. Clearly, it was the fate of non-medical users of the drug that raised concerns, not chronic pain patients. A general sense of neutrality dominated the atmosphere amongst policy makers, media channels, and pharmaceutical representatives regarding legitimate users of OxyContin® since the debate generally focused on risks and consequences of addiction.

Following the expiration of Purdue Pharma's patent on OxyContin® in November 2012, Health Canada approved applications from six pharmaceutical companies to produce generic versions of OxyContin®; Sandoz Inc., Teva Canada Ltd., Cobalt Pharmaceuticals, Apotex Inc., PharmaScience Inc., and Laboratoire Riva Inc. (Kirkup K., 2012b). The FDA defines a generic drug as "identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use" (U.S.Food and Drug Administration, 2009). Generic drugs are chemically equivalent products sold at much lower prices than the branded medications given the lower development costs. The fact that patients can readily access knockoff versions of OxyContin® following Health Canada's approval of generic introduction was criticized by many in the healthcare infrastructure, as they believe that the harms outweighed the benefits of the medication in the OxyContin® experience (Kirkup K., 2012a)

Chapter 2: Study Rational and Objectives

2.1 Study Purpose

There were no specific leads to follow in conducting this study in terms of the impact of discontinuing OxyContin® on pain management in Canada. My passion for areas such as adult well-being and pain management, my absolute curiosity, and my interest in investigating patient perceptions on the matter initiated the current study. Poorly managed pain is well-documented within our society, so it was essential to explore the lived experiences of pain sufferers following the discontinuation. The absence of preconceived notions concerning positive or negative effects of this provincial action on patients set the ground for a study exploring this equivocal area.

One of the driving forces behind this project was the lack of information regarding the number of persons with poorly managed pain compared to the number of persons who abuse opioid analgesics. It was reported by the American Pain Society that approximately 50 million individuals suffer from chronic pain, 25 million individuals experience acute pain, and only one in four individuals receive adequate treatment for their pain (Heidrich, 2001). In contrast, it was reported in the National Survey on Drug Use and Health in 2004 that 3.1 million individuals are OxyContin® abusers (nonmedical users) (National Survey on Drug Use and Health, 2004). These numbers reflect the size of the problem of chronic pain and triggered an immediate concern about pain patients and the issues related to their inadequately treated pain. Recent Canadian figures of pain from two telephone surveys administered to a representative sample of adults across Canada reported a chronic pain prevalence of 18.9% Canada-wide (i.e. one in five Canadian adults) and 16.6% in Ontario (Schopflocher et al., 2011). Data on the prevalence of

OxyContin® abuse in Canada is not available (Canadian Center on Substance Abuse, 2011;Skinner BJ, 2012).

The discontinuation of OxyContin® immediately raised questions and concerns about the fate of chronic pain patients following discontinuation. These concerns were captured from clinicians' opinions to health reporters about the impact it might have on both pain and addiction (legitimate users are also subject to becoming medically addicted to an opioid and could endure withdrawal similarly to abusers if the opioid was not tapered down correctly) (Kirkey S., 2012;Ogilvie M., 2012). Suffering from withdrawal symptoms typically associated with discontinuing opioids was a major concern, especially since the severity of such symptoms could be intolerable unless the opioid is tapered down in a specific manner. Another concern was the accessibility of OxyNEO® by patients following discontinuation. Both OxyContin® and OxyNEO® were removed from the Ontario Drug Benefit (ODB) program in hopes of combating addiction in Ontario by tightening prescribing criteria. However, OxyNEO® was made available for switching patients who are under the ODB program for an additional year. Following that, OxyNEO® was no longer covered and could be accessed through the Exceptional Access Program (EAP) only. No information about the ease/difficulty of the EAP process or coverage of OxyNEO® for patients not under the ODB program was available. Therefore, highlighting those concerns and listening to patients' stories was warranted. An in-depth description of patients' experiences of discontinuing OxyContin® would provide information for developing necessary education and interventions for assisting chronic pain patients through such experiences. The aim is to ensure successful discontinuation of chronic pain medications, which would only be achievable after fully understanding any difficulties encountered by patients going through the discontinuance of OxyContin® (the first drug delisted due to its addictive properties in Ontario).

The absence of definite answers to those concerns necessitated conducting a patient-focused project to address this topic. Therefore, this project primarily focused on exploring an existing gap; the perceived impact of discontinuation on pain control. An additional gap in pain research is patients' perceptions on treatment, which is an area that is surprisingly not commonly investigated despite its significance in enhancing pain management. Therefore, patients were given the chance to provide feedback on their alternative pain medications through this project. As previously stated, to date there is a paucity of that reflect on patients' opinions regarding the discontinuation of OxyContin®. Were patients comfortable with switching to an alternative pain medication or did they have particular concerns and worries regarding the change? Did they believe their previously controlled pain (with OxyContin®) has continued to be controlled or has it become poorly managed with the alternative therapeutics? Did they think they received appropriate information from their healthcare providers to guide them through the transition phase? Were they 'satisfied' with how their current medication treats their pain? It was important to find out answers to these questions in order to develop an overall impression of the impact of this discontinuation as perceived by patients with chronic pain.

Another crucial aspect of this investigation of the impact of discontinuation was to obtain the perceptions of the patients' primary healthcare providers. The inclusion of clinician opinions enhances comprehension of the consequences on chronic pain. The lack of data on physicians' experiences with the discontinuation mandated an in-depth inquiry to highlight patient-physician interactions throughout the process. Did they have full understanding of the alternative options available for chronic pain patients? What was their viewpoint on the discontinuation? What were their patients' questions and concerns following discontinuation? Were their expectations about pain control and the availability of adequate treatment optimistic or concerned?

Address of the questions under study will enable clinicians to better understand patients' perceptions of the implications of the discontinuation on their pain management, and through sharing experiences, may improve patient care. Parties benefitting from the insights of patients and professionals include clinicians, policy makers, and pharmaceutical companies. Identification of the difficulties patients experienced by the discontinuation, comprehension of clinicians' concerns, and highlighting communication issues between physicians and patients can inform all parties involved with future interventions to provide better health services to patients.

The general public may benefit from this research that provides imperative data about how the recent discontinuation of one of the most commonly used pain treatments has affected chronic pain patients and their healthcare providers. This project is among the first to investigate the discontinuation with the aim to report comprehensive qualitative data to supplement existing quantitative data (e.g. prevalence studies, pain management surveys). It was important to approach affected patients using an information-seeking qualitative methodology to give them a voice. This enhances understanding of concerns that should be considered when discontinuing future medications. This study will offer a starting point that can be used to evaluate experiences of patients from different communities, provinces, or settings such as long-term care facilities.

2.2 Objectives of the Proposed Research

2.2.1 Primary Objective

1) To obtain patients' perceptions about the discontinuation process and their pain management following the discontinuation of OxyContin®.

2.2.2 Secondary Objective

1) To explore healthcare providers' personal perceptions and their experiences with their chronic pain patients following the discontinuation of OxyContin®.

Chapter 3: Methods

In this section, I will elaborate on the research methods I followed in the project. I begin with discussing briefly the different research methodologies and explaining the nature of my study design by providing an overview about the chosen methodology. Then, I will discuss the procedural details for the study: recruitment, data collection (including any challenges encountered), and data analysis. Finally, I will conclude by providing details on documenting my research journey, discussing techniques that transitioned me between the data collection and data analysis throughout the process.

3.1 Research Methodologies: Quantitative, Qualitative, and Mixed

The three methodological approaches used in the research community are quantitative, qualitative, and mixed models. To distinguish between research methodologies, it is crucial to develop a complete understanding of what each approach entails. As Creswell (2003) suggested, the three elements contributing to defining a methodology are specific claims for developing knowledge, strategies of inquiry employed, and methods for data collection (Creswell, 2013). In quantitative inquiries, a researcher utilizes post positivist claims (assuming a particular "truth" exists and seeks that truth) and employs experimental and/or survey-based strategies in order to test objective theories deductively by means of stipulated instruments. In contrast, qualitative inquiries focus on inductively capturing meanings and lived experiences of individuals. Therefore, a researcher makes claims based on constructivism (assuming that there is no "truth" and conducts the study with no pre-conceived notions of particular theories) and employs strategies including grounded theory, narratives, and phenomenology to obtain data by way of open-ended questions and observations. Qualitative research is multi-dimensional, and this is

reflected by the absence of an essential definition of process. Unlike quantitative studies that rely on a set range of objective methodologies for data collection and analysis with certain steps of application and which typically seek "numerical data", qualitative studies utilize an array of subjective methodologies that are quite different from one another (for example, interviews versus observations for collecting data and grounded theory versus phenomenology for analyzing data). Qualitative inquiries have no fixed sequence of procedures but instead rely on customized designs that typically seek the "meaning" of what is being said and/or done by participants in a study, and the interpretation of findings is based on the researcher's choice of the methodologies that best fit the purpose of the inquiry. The mixed methods approach combines the collection of both quantitative and qualitative data relying on either a simultaneous strategy or a sequential one. In mixed models, obtaining both numerical data and text data abides by an assumption that this provides a more complete understanding of the research problem.

Generally, quantitative methods have long been the dominant paradigm in health research (Tariq S. and Woodman J, 2013). Studying social behavior and human interactions relied profoundly on objective measures with a strict worldview of "positivism". However, health researchers have gradually accepted qualitative methods over the years and adoption of such methods has become more common with recognition of their significance. Emergence of qualitative methods with a worldview associated with variants of "constructivism" created a notable shift in health research as a result. Mixed methods research makes use of the positivist perspective of quantitative methods as well as the interpretive framework of qualitative methods. Although both notions might seem extremely divergent, ideally they overlap, generating a more comprehensive description of the topic. The merge aids in synergizing strengths and counterbalancing weaknesses of both methods, since qualitative methods explore areas that

cannot be tackled by quantitative measures and vice versa. Therefore, mixed methods demonstrate promising potential in health research, especially in complex health issues (such as chronic medical conditions) which demand coverage of both areas. The rising interest in merging both methods was shown in a review of health services research conducted within England by O'Cathain and colleagues (2007) when the incidence of mixed methods studies increased from 15% between 1996 and 1998 to 30% in the early 2000s (O'Cathain et al., 2007).

3.2 Study Design: Mixed Methods

The purpose of this study was to describe the experiences of chronic pain patients following the discontinuation of OxyContin®. A mixed methods approach was used to explore that phenomenon in depth. Mixed methods research is defined by Clark et al. (2008) as a "design for collecting, analyzing, and mixing both quantitative and qualitative data in a study in order to understand a research problem." (Clark VLP et al., 2008). Although it has .been well-established that chronic pain is a serious problem within our society, very little is known about patient perceptions on pain medications in general, and more particularly their lived-experiences of discontinuing a chronic pain medication. As a result, a qualitative descriptive methodology was primarily employed in this study to allow for exploration of patients' experiences through discontinuation, their thoughts prior to and after discontinuation, their perceptions on alternative pain treatment options, and the impact of discontinuation on their pain control. While qualitative description compromised the major portion of the inquiry, a quantitative component assessing multiple dimensions including pain intensity, patient satisfaction levels with treatment, and influence of pain on several quality of life (QOL) aspects compromised the secondary portion. The simultaneous use of qualitative and quantitative methods enables a researcher to address the

questions under study more comprehensively by employing the method each question precisely entails (Creswell, 2013;Greene, 2007;Tashakkori and Teddlie, 2010).

A mixed methods design is specifically appropriate for broad and complex topics of interest with numerous components. This is because the combination of both qualitative and quantitative methods captures multifaceted aspects in social and behavioral research that a single method alone might explore insufficiently. A good example of such complex topics is pain, and this is due to its high subjectivity and the various life aspects that influence it or get influenced by it. For describing patient perceptions on the impact of OxyContin's discontinuation, in-depth qualitative data was primarily needed. Quantitative data of patients' pain levels, treatment satisfaction levels, and QOL domains complemented the descriptive piece by numerically presenting highly relevant information, which further strengthens inquiry. Comparing and contrasting both types of data allows better and fuller understanding of the phenomenon under study by generating richer insights into the research question. Therefore, a mixed methods approach seems well-suited to the objectives of this study. The classification of mixed methods designs and the typology for this study are discussed in the next section.

3.2.1 Typologies of Mixed Methods Designs

Greene and colleagues (2007) derived five distinct purposes for mixing methods in research from work done in 1989: Triangulation, Complementarity, Development, Initiation, and Expansion (Greene et al., 1989;Greene, 2007). Complementarity best serves the purpose for the proposed study design. Complementarity refers to the use of multiple methods in parallel to explore different facets of the same phenomenon. Complementary design is becoming more commonly used among investigators in the research community as the advantages of mixed

methods are increasingly acknowledged over time. In fact, complementarity is one of the most common reasons for mixing methods in practice (Greene, 2007).

Furthermore, scholars have categorized mixed methods designs into many different typologies. By incorporating the Greene et al. (1989) purposes and taking the sequence of data collection into consideration, Creswell (2002) classified mixed methods into three different typologies; Triangulation, Explanatory, and Exploratory (Cresswell, 2002). While Triangulation is the collection of both data sets in a simultaneous manner, Explanatory and Exploratory typologies are sequential. In explanatory design, quantitative data (concerned with explaining and confirming a hypothesis) is gathered first and then qualitative data is collected to build on and further elucidate the quantitative results. On the other hand, exploratory design involves first collecting qualitative data (concerned with exploring and generating a hypothesis) followed by obtaining quantitative data to confirm findings. Illustrating some degree of controversy in classification, three different designs were adopted from the published work of Greene et al. (1989) by McMillan & Shumacher (2001); Complementary, Developmental, and Expansion (McMillan J.H. and Schumacher S., 2001). Complementary design proceeds in a simultaneous manner resembling triangulation, while Developmental and Expansion designs are sequential. However, those sequential designs differ from Creswell's sequential designs in that there is no pre-determined sequence of the qualitative and quantitative components.

Greene & Caracelli (1997) revised the designs based on purposes of Greene et al. (1989) and categorized mixed methods designs into two main typologies constituting seven designs; Component designs (Triangulation, Complementary, and Expansion) and Integrated designs (Iterative, Nested, Holistic, and Transformative) (Greene and Caracelli, 1997). In 2003, Creswell and colleagues conducted an in-depth review of the existing typologies, developed collective

criteria (based on purpose, sequence and theoretical perspective), and proposed six types of mixed methods designs; Sequential Explanatory, Sequential Exploratory, Sequential Transformative, Concurrent Triangulation, Concurrent Nested, and Concurrent Transformative (Tashakkori and Teddlie, 2010).

Clearly, there have been several points of agreement and controversy among researchers regarding classification of mixed methods designs (Tashakkori and Teddlie, 2010). Currently, a clear "divergence in nomenclature" exists as different researchers label the same designs differently (e.g. concurrent, simultaneous, or parallel and nested or embedded) (Tashakkori and Teddlie, 2010). However, there is basic agreement that mixed methods design involves obtaining qualitative and quantitative data, either sequentially or simultaneously, and integrates data in one or more phases of the research process (Creswell, 2013;Tashakkori and Teddlie, 2010).

3.2.2 Concurrent Nested Design

Based on the classification of Creswell et al. (2003), this study made use of the Concurrent Nested design. Creswell (2013) recently referred to this design as "The Embedded Design" in his latest version of the book "Research Design: Qualitative, Quantitative, and Mixed Methods approaches" (Creswell, 2013). Despite the absence of a uniform conceptualization of mixed methods designs among scholars, it is apparent that the existent divergences are minor. There is a general understanding that by saying Concurrent Nested, Concurrent Embedded, Simultaneous Nested, Simultaneous Embedded, Parallel Nested, Parallel Embedded, or simply Embedded design, we are referring to the same typology of mixed methods designs.

In the Concurrent Nested design, the researcher collects both qualitative and quantitative data in one phase of the study, merges both forms of data to comprehensively analyze the research problem, and finally integrates the yielded data in the interpretation of findings.

However, the Nested design differs from Triangulation in that collection and analysis of both data sets is carried out within a traditional qualitative or quantitative research design. Therefore, one component takes primacy over the other, with the secondary component adhering to methodological procedures associated with the guiding method. This contrasts with Triangulation, which gives equal weighting to both qualitative and quantitative components to address a single principal question. The Concurrent Nested design permitted the use both types of data, thus broadening and expanding the means to address the primary objective of this study.

The study purpose directed my choice of design and I believe that the Concurrent Nested was a good fit for this study. Some may argue that I could have used the Concurrent Triangulation design instead. However, the nested design grants superiority to one component (either qualitative or quantitative) over the other and it is obvious that the quantitative component is playing a supportive role in this study. With a richer application of the qualitative design being the main goal in mind, the quantitative data obtained from the questionnaires was only meant to complement data obtained from interviews in the proposed study by characterizing the study sample in terms of their pain intensities, treatment, and opinions about the medical care they receive. The quantitative component was included to address secondary research questions within the predominantly qualitative study, and therefore does not directly explore patient perceptions on the discontinuation. For instance, information such as current pain intensity, variations in pain levels overtime, satisfaction levels with alternative medications, side effects experienced, and extent of current interference of pain with several QOL aspects was primarily covered in the utilized questionnaires. The high relevance of each piece of information to the perceived impact of discontinuation on patients' pain management (the primary objective in this case) demanded mixing methods to benefit from complementarity, especially given the complete

absence of data on the topic. As previously mentioned, the qualitative method specifically used in this study was "Qualitative Description" which I will discuss in the following section.

3.2.3 Qualitative Description

As its name implies, the aim of Qualitative Description is to provide a rich description of an experience or event in the participant's own language. The key here is staying close to the actual data and translating meanings using the participant's own words rather than interpreting findings through theoretical lenses. Qualitative Description is a particularly useful methodology for studying phenomena that have not been fully described, such as discontinuation of chronic pain medications. It is noteworthy to clarify that Qualitative Description involves interpretation (since no description is free of interpretation), nevertheless a low-inference type of interpretation (Neergaard et al., 2009;Sandelowski, 2000). This is because the researcher is tasked with the meaning-making process (i.e. analyzing data to identify patterns and themes), and cannot possibly detach himself/herself completely from the data as if they do not exist. Regardless of how a researcher describes the informant's discourse, "descriptions always depend on the perceptions, inclinations, sensitivities, and sensibilities of the describer." (Sandelowski, 2000).

Even though Qualitative Description neither seeks the development of a theory like Grounded Theory, nor provides a highly interpretive description of an experience like Phenomenology, qualitative descriptive studies may have shadings from other qualitative approaches based on the chosen techniques (Sandelowski, 2000). This means that a Qualitative Descriptive study might have the feel of or be inspired by other approaches. This is because description could overlap with different approaches that aim to explore theories and describe such theories in the study findings. The final outcome of Qualitative Description, however, has to be the presentation of a straight description of an experience rooted in the participant's

perception and expressed in their everyday language (Neergaard et al., 2009;Sandelowski, 2000;Sullivan-Bolyai et al., 2005). The intended audience should be kept in mind to re-present the findings comprehensively in the most relevant fashion (Sandelowski, 2000).

Qualitative Description was shown to be a successful method for inquiry in health services research (Neergaard et al., 2009;Sandelowski, 2000;Sullivan-Bolyai et al., 2005). A Qualitative Descriptive study enables the lived experiences of patients, clinicians, and whoever can relate to the field to be the main focus, and highlights their perceptions on health services and the organization as a whole. Therefore, it demonstrates promising potential for improving health outcomes, particularly in vulnerable populations (Sullivan-Bolyai, 2005). Among its other strengths, Qualitative Description saves time and does not require formal theoretical education in qualitative research methods, which made it an appropriate choice for this study given the limited time and resources. Moreover, Qualitative Description is a good candidate for mixed methods inquiries since it bonds well with quantitative procedures (Sandelowski, 2000;Sullivan-Bolyai et al., 2005), further justifying its use for the purpose of this study.

Discourse analysis is an analytic strategy that can be easily associated with Qualitative Description. This is an inductive procedure in which the verbal data from interviews and visual data from observations are coded and sorted to identify patterns and themes, hence describing specific meanings reflected by the voiced experiences. Like most qualitative analytical procedures, discourse analysis is a non-linear process which involves swinging back and forth between the different stages of interpretation, making necessary modifications to embrace new insights about the data at hand (Sandelowski, 2000). Discourse analysis will be described in more detail in the data analysis section.

3.2.4 Constructivist-Interpretive Paradigm

It is important to comprehend that, as a researcher, I was working from a constructivist interpretive paradigm since the primary design in this study is rigorously qualitative. Unlike positivism, which seeks the "truth" with expectation of correspondence between what is being said and constructing that "truth", constructivism believes that there is no particular theory that we are after, rather theories unfolding through shared stories of lived-experiences. In his book, "Qualitative Methods for Family Studies and Human Development," Daly (2007) described constructivism as follows; "In this paradigm, language and reality are no longer separate realms. Reality is as it is constructed through our language and stories. There is no reality out there, only an unfolding reality that is created through our verbal constructions of it." (Daly, 2007). Using qualitative principles, Denzin and Lincoln (2011) explained this interpretive framework in the Sage Handbook of Qualitative Research, "The Constructivist Paradigm assumes a relativist ontology (there are multiple realities), a subjectivist epistemology (knower and respondent co-create understandings), and a naturalistic set of methodological procedures. Terms like credibility, transferability, dependability, and confirmability replace the usual positivist criteria of internal and external validity, reliability, and objectivity." (Denzin and Lincoln, 2011).

3.3 The Recruitment Process

The research question that was explored in this study was, "What is the impact of the discontinuation of OxyContin® on pain management in community-dwelling older adults?" Chronic pain outpatients 45 years or older were recruited to address the question under study. I was specifically interested in this age group because it has been reported in multiple studies that the prevalence of pain is highest among this population (Boulanger et al., 2007;Fejer and Leboeuf-Yde, 2012;Moulin et al., 2002;National Centers for Health Statistics, 2006;Nickel and

Raspe, 2001;Rustoen et al., 2005). I was therefore curious to learn how this high risk group of chronic pain patients was affected by OxyContin's discontinuation.

Subjects were enrolled by means of recruitment posters (See Appendix A). In addition, flyers were handed out to chronic pain patients by their physicians or other clinic staff. The exact criteria for inclusion were clearly stated in the posters and flyers to target eligible participants only. Also, the posters and flyers included brief information on the research topic and study purpose and listed all expectations from volunteers (i.e. what will be asked of study participants in terms of time commitment and methods of data collection employed). Contact information; telephone number, and e-mail address, were included on the poster to directly volunteer for the study and/or for further inquiry.

Screening of volunteers was carried out to ensure recruitment of only those who qualify for the study. According to the eligibility criteria, volunteers were required to be 45 years or older, residing in the community, suffering from malignant or non-malignant chronic pain (employing the common definition of chronic pain; suffering from pain for more than three to six consecutive months), English-speaking, show no signs of cognitive impairment, and have been administered OxyContin® for at least six months before February 2012. First, a simple eligibility checklist (See Appendix B) was utilized for telephone screening, and individuals who failed to meet the criteria were screened out. Next, mild cognitive impairment was ruled out by administering a valid, commonly-used 3-minute screening test for cognitive function; the Mini-Cog. I met potential participants in an agreed upon location and conducted the Mini-Cog test as the final step of the screening process. Only those who were negative for dementia (according to the Mini-Cog scoring criteria) were included in the study. This was necessary to confirm self-reporting and identify individuals who might be suffering from early stages of cognitive

impairment. At completion of screening, basic demographic data were gathered from patients who qualified for participation to describe the study sample.

This type of recruiting is known as "Purposeful Sampling" (also called "Purposive Sampling" or "Judgment Sampling") that involves targeting of individuals who are wealthy with information required to fulfil the project's purpose and to clarify the questions under study (Patton M.Q., 2002). The reason information-rich cases were targeted in this study was to allow the capture of maximal information about the matters of central importance to the investigated topic. Obviously, the scarcity of information on the perceived impact of discontinuing OxyContin® mandated inclusion of directly affected individuals, which together would generate a well-rounded picture of the subject.

Among the different strategies of purposeful sampling, the selection of participants for this study falls in the Criterion sampling category. As indicated by its name, this type enables the in-depth study of a particular group based on a pre-determined criterion of importance, thus provides the advantage of a focused strategy as per the inclusion criteria. This particular strategy would be useful to identify subjects that meet the sampling criteria and thus is likely to target information rich cases only.

"Purposeful sampling" is considered to be the dominant sampling strategy in qualitative research. The use of recruitment posters is common in qualitative studies similar in design to the current study. For example, a pilot study testing the validity of the Canadian Sexual Health Indicators Survey recruited self-selected volunteers by following a purposive sampling technique (Public Health Agency of Canada, 2012). Posters were displayed in shopping malls, universities, colleges, drop-in centers, employment centers, and other locations accessible by young individuals (Public Health Agency of Canada, 2012). Likewise, Hilton and Smith investigated

public views of the swine flu pandemic and recruited their sample by placing posters and flyers in different community settings including shops and universities (Hilton and Smith, 2010).

Even though I solely relied on posters and flyers initially, recruitment went at a much slower pace than planned. This was due to low response rates to posters which possibly resulted from patients not noticing the posters at clinics, patients not considering recruitment timeline and postponing participation, posters failing to capture patients who were between appointments, patients not interested in participating despite eligibility, and potentially other reasons. Moreover, clinic staff were forgetting to hand out flyers to patients and some patients' non-compliance to scheduled appointments also contributed to delayed recruitment. This necessitated certain adjustments to speed up the recruitment process in order to fit the project timeline.

Firstly, I requested physicians to start informing chronic pain patients who presented to the clinic about the study. Furthermore, nurses and other medical staff contacted a list of potential participants inquiring about their interest to volunteer for the study. Secondly, I personally made weekly trips to clinics which aided recruitment and data collection in multiple ways; my presence acted like a constant reminder to physicians and other staff about the study, I was able to recruit and interview some patients who resided in far-away locations on spot (since making additional trips to the clinic was inconvenient for them and not accommodating for it would have otherwise created a barrier to their recruitment), and I enriched my observations of the settings which enabled me to develop personal insights on substantial matters like patient-professional interactions and professional-professional interactions, a chronic pain patient's life and suffering, as well as the overall practice atmosphere. Finally, in order to overcome the non-compliance issue, I followed up with reminder calls or voice messages to patients confirming

appointment timings. Recruitment and data collection accelerated notably after implementing those alterations.

As mentioned earlier, the secondary objective of this study was to explore perceptions of healthcare providers about the impact of OxyContin's discontinuation. Practicing healthcare professionals formulate a solid understanding of chronic pain and pain management within the healthcare system by incorporating their own perspectives. Professionals have influential authority necessary for causing change and stimulating improvements in the healthcare organization. Thus, it seemed fairly reasonable to include their points of view in the study.

Toward the end of patient interview phases, I had a clear vision about specific areas that require involving professionals' perceptions to expand on already gained knowledge. I created a focus group guide covering topics such as: personal perceptions on details of discontinuation, therapeutic decisions, patient experiences, and future vision (See Appendix C). A request for ethics clearance of a modification to an ongoing application was submitted for the focus group guide and received approval. I carried on with a second phase of recruitment for enrolling physicians. There were no specific inclusion/exclusion criteria. After gathering their names and contact information from participants, I contacted physicians to explain the study details and inquired if they were willing to participate. All physicians agreed to participate; however, they were hesitant about the possibility of organizing focus groups. It was for that reason that I was open to individual interviews instead if needed.

3.3.1 Study Sample

Recruitment took place from May 2013 to October 2013. Subjects were recruited from a client base of patients who had been assessed and received treatment for chronic pain at one of the collaborating recruitment sites. Three recruitment sites were included in the current study;

Huron Hospital Family Practice Clinic (Exeter, Ontario), St. Joseph's Health Care Pain Clinic (London, Ontario), and Huron Community Family Health Team (Seaforth, Ontario). Huron Family Practice Clinic and Huron Community Family Health Team include most, if not all, of the patients in Exeter and Seaforth, respectively, since each clinic is the only family practice in the corresponding area. In contrast, St. Joseph's Pain Clinic is one of the largest ambulatory pain specialty clinics in the region of Southwestern Ontario. The choice of multiple sites for recruitment allowed for inclusion of a diverse sample of community-dwelling older adults with chronic pain due to different etiologies. I initially targeted a sample size of 20 patient participants while acknowledging that this number was subject to change based on the theoretical saturation of categories.

In qualitative research, sample size is usually determined once theoretical saturation is attained. When participants' data is no longer revealing new patterns concerning the study questions, a researcher reaches saturation point. This is considered an indicator to stop gathering more data. Hence, the recognition that categories are saturated relies heavily on the researcher's judgment (Daly, 2007). However, there have been disagreements about the definition of saturation and how to determine when it is reached. Scholars argue that some researchers proclaim saturation early during the process without proving such claims. Some researchers have questioned the legitimacy of theoretical saturation and suggested the term "theoretical sufficiency" instead (Charmaz, 2006). After reviewing different standpoints, I assumed the common perspective on saturation (i.e. no new themes emerging from data). Factors, other than theoretical saturation, such as limited resources, nature of investigated topic, and established research also play a role in sampling.

3.4 Data Collection

Data collection took place from July 2013 to October 2013. As expected with the current study design, data collection overlapped with data analysis and they were carried out simultaneously. This is because the initial steps of analysis must be done while a researcher is still gathering data from participants. This will be discussed in more detail in the data analysis section. For the sake of clarity, I will discuss each of the two processes separately. I start with the data collection methods of choice in the current study.

3.4.1. One-on-one Semi-structured Interviews

3.4.1.1. Interviews with Patients

After educating myself on the different types of interviews in qualitative research, I decided that an interview guide best serves the purpose of the proposed study because it provides the interviewer with sufficient flexibility without allowing the respondent to lead the interview and deflect to irrelevant subjects. There is capacity for the interviewer to maintain focus while also having the ability to listen to the participant (Daly, 2007). This allows for the researcher to co-facilitate data creation without getting off topic. Therefore, a guide is a checklist that helps the interviewer remain to the point yet provides the luxury of freely discovering individualized perspectives and experiences that could emerge along the interview with each respondent.

During the interview, I noticed that a participant sometimes diverted to a topic that was not listed clearly on the guide but that ultimately led to derivation of useful information for the study. A semi-structure gave me the privilege of branching to such opportunistic topics asking further questions that illuminated that particular area. I found this to be particularly advantageous in the current study given the very personal and subjective nature of pain. Naturally, different

chronic pain patients are likely to have different experiences and opinions about their medications, medical care, pain relief, etc. My questions evolved based upon each participant's experience. For example, some participants went into finer details about their pain history than others. Thus, it was my responsibility to appropriately direct participants in order to keep the interviews as focused as possible.

The interview guide covered three main topics for discussion; the discontinuation process, pain relief, and current pain medication. I intended to ask focused questions targeting detailed information from patients about their perceptions in those three areas. The structure of the interview served as an opportunity for patients to share their opinions on their lives with chronic pain, OxyContin® and its discontinuation, the transition phase, impact on pain control, and alternative medications. Some of the interview questions included: How did you learn about OxyContin's discontinuation? What was the information you received from your healthcare providers prior to and following discontinuation? How did discontinuing OxyContin® impact your pain control? What was the pain medication you got switched to and how do you think it worked for your pain? For full semi-structured interview guide, see Appendix D.

Interviews were approximately 40-60 minutes in length for the majority of participants. It was carried on a one-to-one basis in private rooms in clinics or in the patient's residence, depending on their personal preference. However, for safety purposes, I asked a research team member to accompany me whenever possible to interviews scheduled in patients' homes. I noticed that meeting in private locations while employing the one-on-one approach helped participants feel comfortable disclosing their honest opinions on the topic. Always trying to accommodate for participants' preferences by interviewing them at the comfort of their own homes reflected confidentiality and created a less formal atmosphere, which they seemed to

appreciate. Moreover, I sometimes felt that long drives to and from participants' houses gave me interesting opportunities to reflect on certain categories. This will be elaborated on later.

Appointments began with participants reviewing the information-consent letter (See Appendix E), which outlines the purpose and objectives of the study, the participant's ability to withdraw from the study at any time, and affirms clearance from the Office of Research Ethics at the University of Waterloo/ University of Western Ontario. Next, they completed the consent form attached to the information letter. The consent form indicated the specific conditions which required permission before proceeding with data collection; consent for audio-recording of interviews, obtaining relevant medical information from professionals, and use of anonymous quotations in future research and/or publications. All participants agreed to these conditions and signed the associated documents.

Before starting the interviews, patients completed the two questionnaires as was mentioned in the information-consent letter. The time required to complete both questionnaires ranged between 15 and 40 minutes among individuals. I was sometimes asked to clarify certain questions for patients. Upon completion of questionnaires, I proceeded with interviewing participants immediately. The interviews started with reminding patients that any verbatim quotations that will be used in future work or publications will be anonymous, thus encouraging them to express their opinions openly. Furthermore, I assured participants that there were no 'right' answers to the questions that were being asked. I also explained that I would avoid using their names during the interview, and asked that they refer to their healthcare providers without using any names as well (for example; my pharmacist, my pain doctor, my family doctor, etc.). Patients seemed comfortable with the interview questions, which facilitated the flow of conversation.

The observations that I had during interviews were few, but knowing their importance in qualitative research kept me watchful for any visual data. I carefully observed patients' body language including hand motions, facial expressions, seating positions, etc. I also paid attention to a participant's tone changes, which sometimes reflected particular emotions. For example, while I interviewed the seventh patient (B3), she raised her voice in anger several times to communicate how frustrated she was with the government and pharmaceutical companies for not making particular medications available for use. Another participant (B4) got emotional while talking about her pain experience, and I noticed her voice quivering (trying to hold back tears) as she mentioned particular moments that obviously represented great suffering for her. I documented these observations in my research journal (or the research computer), which consequently enabled me to reflect on each participant.

As previously mentioned, interviews were audio recorded to facilitate accurate collection and transcription of data. When needed, I took down any emergent questions that I wished to probe into later on during the interview. This is especially beneficial in case of participants who respond with very short answers that are unlikely to yield significant information. I listened attentively throughout the interview and seized any opportunity for follow-up questions, which is a specifically preferred technique with the interview guide approach. In fact, it happened on many occasions that a patient's response generated my next question. At the end of the interview session, I thanked the participants for sharing their experiences and answered any further questions they had about the study. A number of patients expressed their interest in receiving a copy of the study results upon completion. Each participant was provided with a $10 gift card in appreciation of his/her time.

3.4.1.2. Interviews with Physicians

Originally, I had planned to collect data from physicians through focus group discussions. After enrolling physicians, I hoped that they would share their opinions and experiences associated with the discontinuation by participating in active discussions on the impact of discontinuation on pain management as intended. The idea of bringing professionals at different levels of the healthcare hierarchy (i.e. general practitioners (GPs) and specialists) around the same table and engaging them in a debate to create opportunity for group expansion on key concepts appealed to me.

However, all trials for organizing focus groups did not succeed. Several challenges including tight and busy schedules, different weekdays at clinics, transportation barriers, relatively distant meeting locations, and external commitments made it impossible for doctors to agree on specific dates and locations for group discussions. Such inconvenience with focus groups called for gathering information by means of one-on-one interviews with physicians. Therefore, using the focus group guide, I conducted in-person interviews tailored to each physician's needs in terms of time and location. This modification certainly extended the course of data collection resulting in further delay in project execution.

The duration of interviews varied slightly between physicians, never exceeding 30 minutes. Physicians reviewed an information-consent letter (See Appendix F) explaining study objectives and signed it before starting the interview. Comparing physicians to patients, the difference in comfort level during the interview was significant in my opinion. Conversing with physicians pressured me because I constantly felt they were in a hurry, and that I had to utilize the limited time I have with them most efficiently. However, I realized this is due to their busy schedules and understandingly accepted the time they could contribute.

3.4.2. Questionnaires

As stated earlier, patients were asked at the beginning of the session to complete two questionnaires; the Patient Treatment Satisfaction Scale (PTSS) (See Appendix G) and the Brief Pain Inventory (BPI) (See Appendix H). Questionnaire responses provided a "one-point-in-time" insight into patients' quantifiable measures such as pain intensity, satisfaction with current pain medication, and effect of pain on their quality of life. As mentioned earlier, this snapshot aids in better characterizing the current study sample by highlighting highly relevant data such as that investigated in the chosen questionnaires. For example, although patients discussed their treatment in the interviews, the exact number of patients who are satisfied with a particular medication or the percentage of patients who are not satisfied with specific issues of their medical care provides a more solid image of the population being interviewed, and thus compliments qualitative data in that sense.

Among the domains investigated in the current study and that fall under the word "Impact" is pain relief. With no doubt, patients' current pain medications play the primary role in the pain control they are currently experiencing. The aim was to explore patients' satisfaction with their alternative pain medication, which is particularly important as it will provide information characteristic of a group of patients' personal evaluation of their treatment appropriateness as well as the medical care they receive from their healthcare providers. Also, physicians and pharmacists can find the obtained information useful to help them better understand issues from the patients' perspectives. Hence, such findings can consequently open a venue for improvement in chronic pain management.

There are several valid tools that assess patients' health status in general and others that assess patients' satisfaction with their medications such as the Treatment Satisfaction

Questionnaire for Medication (TSQM). However, those tools are not expected to be precisely and explicitly indicative of satisfaction with pain medication. This is even reflected in the questions included in such questionnaires where they seem to be very broad and unspecific to a single condition. Therefore, the PTSS was chosen for this study because it is a tool that is specific to pain medication, includes questions that are relevant to the topic of interest, and would be easily comprehended by the study sample according to their concerns and issues. Significantly, patient satisfaction with a particular medication has become a reliable indicator of patient adherence to clinician instructions (Evans et al., 2004) and patient compliance is as crucial with chronic pain as it is with any other chronic condition. Therefore, this represented another benefit of evaluating patients' levels of satisfaction with their current pain medications. The quality of life (QOL) of chronic pain sufferers is of particular concern (Von Korff et al., 1988) and the BPI was shown to be a useful tool for assessing it (Daut et al., 1983). Details of the content of both questionnaires (PTSS and BPI) will be briefly presented in the next sections.

3.4.2.1 Pain Treatment Satisfaction Scale (PTSS)

The PTSS is a validated assessment tool used to evaluate patient satisfaction with their pain treatment. Based on interviews with patients, physicians and nurses, the PTSS was developed in 2004 to serve as a tool for measuring treatment satisfaction with regard to pain medication particularly (Evans et al., 2004). Upon psychometric evaluation, it demonstrated good reliability and clinical validity (Evans et al., 2004). Unlike other pain scales, the PTSS was developed to fully address the multidimensional nature of patient satisfaction (Evans et al., 2004). This questionnaire relies on questions of the 5-point Likert-scale type. The PTSS constitutes 39 items assembled in five domains; information about pain and its treatment (five items); medical care (eight items); impact of current pain medication (eight items); side effects of

current pain medication (12 items); satisfaction with current pain medication that was divided into two subscales: medication characteristics (three items) and efficacy (three items) (Evans et al., 2004).

3.4.2.2 The Brief Pain Inventory (BPI)

The BPI is a valid tool that was primarily developed to assess pain in cancer patients, but was shown to be an appropriate measure of pain due to different etiologies, including non-malignant pain (Keller et al., 2004;Tan et al., 2004). The first version was called "Wisconsin Brief Pain Questionnaire" and was developed by Daut and colleagues in 1982 (Daut et al., 1983). The long form, the Brief Pain Inventory, was developed in 1989 by modifying the content of the original version according to patient preferences. However, this tool was too lengthy for clinical use and a shorter version of the BPI was developed as a result. The use of a 24-hour patient recall period is the major difference between the longer and shorter versions of the BPI. The short form is what is clinically used and what is referred to when the BPI is cited in research. The BPI includes four pain severity items, front and back body diagrams for specifying the location of pain, a question about percentage of pain relief attained by medication, and seven pain interference items. Patients are asked to rate their pain intensity currently and in the last 24 hours at its worst, least, and average on 0-10 numeric scales. Patients also rate the extent of pain interference with seven QOL domains; general activity, mood, walking ability, work, relations with others, sleep, and enjoyment of life.

3.5. Data Analysis

Once the interviews were completed, they were transcribed, proof-read for any spelling errors, and sent to the participants for review. Transcripts and questionnaires were labelled using

codes (for participants) and securely locked in my office cabinets till the analysis process. Labels facilitated handling the collected data while maintaining participants' anonymity. I spent quite a long time on transcribing interviews, which was surprising to me. The time-period dedicated to this process alone undeniably exceeded my expectations. However, my feelings of frustration disappeared when I did more research and realized that I am very well within the typical boundaries of producing high-quality transcripts. Potter's words were reassuring for me, "It is hard to give a standard figure for how long it takes because much depends on the quality of the recording and the type of interaction; nevertheless; a ratio of one hour of tape to 20 hours of transcription time is not unreasonable." (Potter and Wetherell, 2004). Despite how demanding the process was, transcribing certainly benefited me in several ways. Most importantly, I became closer to the data and familiarized myself with the participants' characters and perceptions. Similarly, after interviewing all physicians, I went through the same process of transcribing conversations and labelling them for analysis. A member of the research team helped with transcribing physician interviews.

3.5.1. Descriptive Statistical Analysis

Quantitative data from questionnaires was analyzed by using "Qualtrics," which is an online survey software. Accessibility of this service to students was granted via the University of Waterloo. This is a simple and commonly used method for describing a data set in terms of numbers or visual graphs. For example, information such as the mean level of satisfaction with current pain medications and average daily pain intensity among patients can be obtained. My experience of using the software for the first time was relatively smooth. Basically, I created the two questionnaires on the website, by typing in all of the questions. Next, I transferred the participants' answers by taking the survey and inserting each participant's responses. I finally

exported the results and graphs presented by the software to a Word document. With such conclusions made on data derived from participants' questionnaires, a better understanding of patients' current impressions about their pain and pain treatment is consequently attained.

3.5.2. Discourse Analysis

Discourse analysis is a method of careful analysis of the language being used. This enables an understanding of the underlying meanings within a text as well as the thoughts and beliefs that emerge from it. A key element in this technique is to pay attention to language in the sense of capturing what is being directly said as well as meanings between the lines, "Language is telling – not simply of acts and facts, but also of views and values, and feelings, priorities, and involvements." (Charmaz, 2006). Discourse analysis is therefore intended to capture the participant's specific language. Therefore, during the interview, the interviewer might need to clarify the participant's specific terms to grasp the intended meaning accurately (Starks and Trinidad, 2007).

In 'Discourse in Educational and Social Research', MacLure (2003) comments, "...analyzing texts involves much more than attending to whatever is 'in' those texts...The point...is not to get the text to lay bare its meanings (or its prejudices), but to trace some of the threads that connect the text to others." This statement explains the aim of discourse analysis, which is to search for recurring themes and patterns that can be correlated in participants' responses, thus enabling the drawing of a conclusion regarding the phenomenon under study(MacLure, 2003).

Discourse analysis is very different from traditional quantitative analytic strategies in that there is no pre-determined way of doing it since the material that will be analyzed cannot be predicted prior to conducting the study. This is not to indicate that discourse analysis is a random

process with no outlined standards, rather a process that is highly dependent on strategies that emerge upon handling the collected data. This is well elucidated by Potter and Wetherell (1988) in 'Discourse and Social Psychology': "... it is not a case of stating first you do this and then you do that. The skills required are developed as one tries to make sense of transcripts and identify the organizational features of documents." (Potter & Wetherell, 2004).

As Starks and Trinidad (2007) explained, discourse analysis basically relies on a "decontextualization" and "recontextualization" process (Starks and Trinidad, 2007). In decontextualization, the data is sorted and "units of meaning" are manually coded by the person who is analyzing data (Starks & Trinidad, 2007). In recontextualization, these codes are observed for emerging correlations and themes that develop from the text (Starks & Trinidad, 2007). Variation in technique implementation stems from diverse understandings of performing those two essential steps (Starks and Trinidad, 2007). After reviewing the literature, there is a clear definition of the methodology and thus a straightforward answer to the question "What is discourse analysis?" However, there is no definite set of steps that are pre-determined for carrying out those phases. A standard answer to the question "What are the steps of conducting discourse analysis?" is absent as a result. Simply, it is impossible to predict the procedural sequence and decide on specific sorting, coding, and categorizing techniques in advance. Unlike quantitative inquiries, the methods followed in a qualitative study normally evolve and change during implementing the study, explaining the broad strategies used by researchers in this area.

I can specifically speak to this because my initial attempt to analyze the transcripts started with employing an incidence-by-incidence coding approach. I immediately changed my coding technique to line-by-line after realizing that I was not grasping much from the data. This is particularly typical with all qualitative analytic methodologies including grounded theory,

phenomenology, etc. Researchers are introduced to multiple techniques in all essential phases involved in a qualitative inquiry. Examples include different types of data collection (interviews, focus groups, observations), different types of data analysis (grounded theory, phenomenology, ethnography, discourse), and each analytic methodology constitutes different types of coding (word-by-word, line-by-line, incident-by-incident), and reflexivity involves different types of memo-writing (clustering, free-writing). This reflects the multi-dimensional nature of qualitative research. Researchers design studies using the most appropriate techniques depending on study purpose, resources, collected data, etc. In addition to this, a researcher needs to develop a degree of sensitivity to make warranted changes in design along the course of implementing the study.

Generally, the strategies proposed by Miles and Huberman (1994) describe the analysis process followed in qualitative inquiries in a fairly comprehensive fashion (Miles and Huberman, 1994). At this point, it is well established that the general stages of analysis are agreed upon among researchers but the techniques are independently chosen by each researcher to best suit each individual study. The general stages are listed below followed by a discussion of the techniques employed in this study. Importantly, the stages are not numbered, stressing the non-linearity of the analysis process. Ideally, all stages are re-visited randomly throughout the process to exhaust the data and interpret it as accurately as possible.

Stages of qualitative data analysis:

- Coding of data collected from interviews, focus groups, observations, etc.
- Memo-writing to capture reflections on the collected data.
- Sorting of data to explore distinct patterns and themes.
- Constantly comparing and contrasting data sets for similarities and/or differences.
- Categorizing themes into focused theoretical categories.

- Placing findings in the existing pool of literature.

It is interesting to know that all of these stages are entailed in the majority of qualitative methodologies. Yet, methodologies vary greatly due to the depth and complexity required at each stage, the conceptual frameworks adopted, etc. For instance, the process I employed resembled analysis in grounded theory to some extent but diverged in terms of grappling with the emerging theories. The focus was put on the language being used to communicate participants' meanings rather than categories that are grounded within a core theory. Therefore, although the coding and sorting stages might be similar to those followed in other methodologies, categorizing themes and reporting findings are unique to each methodology.

3.5.2.1. Coding

Coding is considered the first step in the analytic process. It is the process that helps a researcher move from the phrases simply being stated by participants to making analytic interpretations. Charmaz (2006) explained coding, "Qualitative codes take segments of data apart, name them in concise terms, and propose an analytic handle to develop abstract ideas for interpreting each segment of data." (Charmaz, 2006). I adopted a two-step coding technique starting with initial coding followed by focused coding. Among the different types of initial coding, line-by-line coding proved to be the most suitable for this study. One significant advantage of this technique is that it "frees you from becoming so immersed in your respondents' worldviews that you accept them without question. Then you fail to look at your data critically and analytically." (Charmaz, 2006). Line-by-line coding helped me remain open and close to the data, capture nuances in it, and refocus future interviews.

For each transcript, I started coding by assigning an initial code (usually four or five words long) to each line of the transcript. Every code portrayed the meaning of that line and

illuminated the key notion of that particular data segment. Questions about these codes began to crystallize in my head as I progressed in the process, which is consistent in studies with an interpretive emphasis on emergence. Next, I moved to focused coding which involves "using the most significant and/or frequent earlier codes to sift through large amounts of data." (Charmaz, 2006). I reviewed the transcripts repeatedly and decided the specific initial codes that should be categorized to best represent the data at hand. It is important to clarify, though, that focused coding is a non-linear process. I continuously returned to earlier data, expanded on certain themes, and explored topics that appeared implicit initially.

Following sorting data and synthesizing theoretical categories, I finalized the associations between all categories and revealed fundamental participant insights. Themes were constantly refined along the analysis process to best represent the obtained data. Unlike grounded theory, no core concept is being generated in this case. All categories are considered of equivalent significance to the phenomenon being studied, thus collectively contributing to a deep understanding of it.

3.5.2.2. *Memo-writing*

The principle of reflexivity is emphasized in Charmaz's (2006) text as an important concept for qualitative analysis as it allows researchers to compare and contrast connections within and between data sets. Stated by Charmaz (2006) "Memo-writing forces you to stop other activities; engage a category, let your mind rove freely in, around, and from the category; and write whatever comes to you." (Charmaz, 2006) It is this standard that is deemed of great importance in the current study. However, reflexive writing is not limited to the data analysis phase in qualitative research. I found that it to be very helpful since the early stages of data collection in the study. Coming from a solid quantitative background, I had my personal

concerns about designing and conducting a qualitative study. Yet, writing memos over the course of the project cleared my doubts and benefited me in numerous ways.

Memo-writing serves as an effective way of tracking a researcher's thoughts and emergent directions. It offers the researcher a venue to converse with himself making connections between different codes and categories. Besides capturing relationships between categories, it also captured my thoughts, feelings, and reactions regarding the research process. Reflecting in that way was an ongoing process during data collection and data analysis. It enabled me to focus codes and categorize data by making comparisons between participants.

I was comfortable with freewriting; a specific method of memo-writing (Charmaz, 2006). This technique entails jotting down whatever comes to one's mind such as observations, interpretations, thoughts, and feelings. Doing so encouraged me to free my mind completely and approach my data sets with no preconceived notions of my own. This, of course, is crucial to avoid the "crises of representation" which occurs if a researcher falsely represents a study participant based on his/her personal biases on the topic of study (Pinn, 2001). I also wrote memos about specific codes to build my categories and identify discrepancies within them and in comparison to other categories. Below are excerpts from reflections I wrote in my research journal. On the day of my first scheduled interview, I felt uncertain about my capability of handling this process for the first time. I quickly wrote to myself what later on appeared to be a contradictory debate between the confident quantitative researcher and the novice qualitative researcher:

> "Ok, how do I know I'm asking all the right questions? Hey, this is qualitative research, remember? There's no such thing as asking a "right question", any piece of information obtained from a participant's responses could give rise to meanings that describe the

phenomenon I am trying to explore. I need to get rid of this solid quantitative mindset for now. But, what if I fail to get the participant interested? What if I get nothing from them? This is purposeful sampling based on voluntary participation, they wouldn't have participated in the first place if it doesn't concern or interest them. I'll be fine. Alright, there we go."

I believe reflecting was at its peak during analysis. I wrote whenever I sensed a wave of frustration and uncertainty, which happened many times. Mostly, my reflections are momentary feelings and thoughts, nevertheless in other times I document recurrent ones that occur to me whenever I handle the transcripts. One of those dominant feelings is represented in this memo:

"It's weird...whenever I grab a transcript and scan through it, I can't push that strange feeling away. It's as if I know that person very well, it's as if we developed a solid relationship in the transcript. Each participant allowed me into sensitive areas of their lives; their suffering, their families, their past, their future. It's as if they readily opened up to me. I feel responsible for getting their voices through. I am just trying to wave off any personal feelings for their stories. I constantly keep reminding myself that I am a researcher, not a friend. What makes it extremely difficult is that I've seen those participants in their weakest statuses. How can you watch someone in pain and force yourself not to react to it, simply feel and act neutral? Witnessing some cry, witnessing others become that vulnerable in front of me just confirms that feeling of an existing bond between me and each one of them. It's weird."

As illustrated, I relied on two types of memos during the phases of data collection and data analysis. First are field notes which mainly constituted my emergent ideas before, during or

after the interview sessions. These could simply be observations of settings or participants, questions prompted during interviews, and off-record opinions expressed by participants themselves during a casual conversation with me. The second type is reflexive memos in which I documented my thoughts throughout the analysis process. It is those reflexive notes that facilitated interpretation; the sense-making process. By creating memos, I was able to track the progression of my thought process, thus transforming raw data into findings.

Chapter 4: Findings

4.1 Introduction

The following chapter represents the data gathered and analyzed in this study. The interviews and questionnaire responses provided by the participants who took part in this study yielded a rich description of their experiences and opinions. Perceptions of chronic pain patients were the primary focus in the current study and therefore, the interview captured all aspects that were directly and/or indirectly relevant to the discontinuation. As noted in the methods section, these included opinions on the discontinuation of OxyContin® starting with reason for discontinuance, reactions and concerns, transition phase, information obtained from professionals, pain control prior to and post discontinuance, alternative pain medications and informational and/or medical needs. The findings of this qualitative inquiry take the form of themes as previously explained in the data analysis section.

4.2 Participant Characteristics

Ultimately, I recruited thirteen patients (twelve females and one male) who were all suffering from non-malignant pain. Their characteristics are summarized in Table 1. Six patients were enrolled from St. Joseph's Pain Clinic, four from the Exeter Family Health Team, and three from the Seaforth Family Health Team. The ratio of females to males was surprising to me and triggered my interest to conduct further research on prevalence of pain in both genders. The average age of included patients was 58 years (46 to 78 years). All thirteen patients readily provided their physician's names and contact information for enrollment in study. In total, there were eight physicians from all three locations (three pain specialists and five family physicians). I successfully enrolled all physicians upon contacting them. However, one family physician withdrew immediately before the appointment for personal reasons, which left one patient from

the study sample unrepresented by their physician. Therefore, my final study sample constituted thirteen patients and seven physicians.

Table 1: General patient characteristics

Patient	Age	Gender	Source of pain	OxyContin® use	Care provider
A1	49	Female	Diabetic neuropathy	≈ 7 years	Family physician
A2	51	Female	Chronic rotator cuff tears	≈ 8 years	Family physician
A3	68	Female	Spinal stenosis	≈ 11 years	Family physician
A4	52	Female	Occupational injury causing chronic back and leg pain	≈ 10 years	Pain specialist
B1	53	Female	Complex regional pain syndrome (lower back pain)	≈ 6 years	Pain specialist
B2	60	Female	Failed back syndrome	≈ 2 years	Pain specialist
B3	58	Female	Abdominal wall pain	≈ 7 years	Pain specialist
B4	52	Female	Fibromyalgia, osteoarthritis, restless leg syndrome	≈ 10 years	Pain specialist
B5	51	Male	Chronic rotator cuff tendinitis (shoulder pain)	≈ 5 years	Pain specialist
B6	46	Female	Severe painful sensory neuropathy	≈ 2 years	Pain specialist
C1	77	Female	Chronic low back pain	≈ 8 years	Family physician
C2	78	Female	Osteoarthritis	≈ 4 years	Family physician
C3	63	Female	Car accident causing chronic pain	≈ 8 years	Family physician

4.2.1 Findings from Patient Questionnaires

Analysis of the responses to the Brief Pain Inventory questionnaire that was administered to all patients captured a snapshot of the patients' pain and how it interferes with their quality of life (Table 2). Eighty three percent of patients reported their back as the region where they feel most pain. Patients rated their pain at the time of the interview at a mean value of 5.58 (0 – 9) (n=12). Similarly, they evaluated their average pain at 5.23, although with a wide range of minimum to maximum pain intensity, demonstrating that some patients receive adequate relief while others do not. This was confirmed from their responses to the question of the percentage of pain relief achieved in the past 24 hours; where they reported an average of 53.8% relief (10 – 90%). Furthermore, patients' pain interfered most with sleep, normal work, and enjoyment of life over the past 24 hours. However, all other QOL domains were negatively influenced by pain as well, with most showing maximum pain interference. Appetite was the only domain where no interference was reported by some patients.

Findings from the PTSS were also representative of patients' satisfaction with different aspects of their pain and patient care. The majority of patients (61.5%) reported receiving sufficient information on causes of their pain and treatment options. Alternatively, most patients required more information on their pain medications (53.8%) and possible side effects (76.9%). None of the patients wanted to receive less or no information on any aspect. About their medical care, 92.3% felt they can easily ask questions to their clinicians, 84.6% agreed that medical staff do their best to keep them from worrying, and 76.9% confirmed their doctors' willingness to prescribe the medication of desire.

Table 2: Findings from the Brief Pain Inventory (BPI)

Patient	Average pain score (0-10)	QOL domains with highest pain interference	Pain medications used post discontinuation of OxyContin®
A1	2	Walking ability, appetite	OxyNEO, Gabapentin, Toradol, Tylenol
A2	4	Normal work, enjoyment of life	OxyNEO
A3	5	Normal work, enjoyment of life	Gabapentin, Tylenol
A4	8	Enjoyment of life	Percocet
B1	6	Sleep	OxyNEO, Percocet, Fentanyl Patch
B2	3	General activity, walking ability	OxyNEO
B3	6	General activity, sleep	OxyNEO
B4	7	Ability to concentrate, normal work, sleep	OxyNEO
B5	7	Sleep	OxyNEO
B6	8	Mood, normal work, sleep, ability to concentrate, enjoyment of life	OxyNEO, Lidocaine infusion
C1	5	Walking ability, normal work, sleep, enjoyment of life	OxyNEO, Fentanyl, Tylenol, Gabapentin
C2	1	Sleep	Hydromorphone
C3	6	Mood, normal work, sleep, ability to concentrate	OxyNEO

With regard to current pain medications, there seemed to be an equal split between patients' opinions. For example, five patients agreed that their medication allows them to concentrate better while five disagreed, and six patients agreed that their medication permits more participation in leisure activities while five disagreed. However, the majority (61.5%) agreed that their medication positively affects their physical health and helps improve their outlook on life. It was also found that 66% of patients were either dissatisfied or very dissatisfied with their current medications, 25% were either satisfied or very satisfied, while 8% were neutral. Moreover, 61% indicated that their level of pain relief does not meet their expectations and 67% felt that their current medication could be more effective in controlling pain. Data from both questionnaires helped characterize the study sample allowing us to better understand their pain along with different medical matters associated with it.

4.3 Findings from Patient Interviews

Seven major overarching themes emerged and developed in this study through constant comparisons made between data sets. Each overarching theme constitutes subthemes that fall into that particular category of meaning. The themes identified during the data analysis phase captured the essence of patients' discontinuation experiences by illustrating an in-depth description of those experiences. Each theme will be presented individually with supporting verbatim quotes extrapolated from participants' transcripts.

The seven predominant themes are: 1) Disagreement with the motive for discontinuation, 2) Discontinuation negatively impacted pain control, 3) Discontinuation had no impact on pain control, 4) Learning to live with pain, 5) Identification of flaws within the discontinuation process through shared experiences, 6) Choose to get off OxyContin® permanently, and 7) Need for optimizing patient care. These themes serve the purpose of filling a significant gap in pain

management research by providing supportive information on the discontinuation of OxyContin®.

Several other notions emerged from the interviews, however not frequently enough to develop into distinct themes. Such concepts included learning inaccurate information about medications, recalling bad experiences with healthcare providers, patient directly contacting authorized parties, and self-medicating according to personal needs. The appearance of an uncommon concept reflects a participant's personal judgment of a matter and/or incident which cannot be eventually claimed as a theme among all participants. All study findings will be presented in detail in the succeeding sections.

Theme 1: Disagreement with the motive for discontinuation

To gain a better understanding of how patients perceived the impact of discontinuing OxyContin® on their pain control, I asked them about their immediate reactions after they learned about the removal of the drug from the market. A very apparent theme arose from the expressed frustration in disagreeing with the discontinuation action altogether. Knowing that the reason for pulling off OxyContin® was the addiction rates associated with its use, patients fiercely disagreed with the purpose for discontinuance. In the majority of interviews, patients pronounced the need for taking up other solutions to address the addiction problem. In addition, it was repeatedly suggested by patients that authorized parties including the government, pharmaceutical companies, and policy makers should consider enforcing more strict regulations to address the abuse of medications with abuse potential. Some recommendations were even proposed by a number of patients to reduce addiction based on their beliefs of what has led to this epidemic.

The theme of disagreement with the motive for discontinuation comprised the following sub-themes: *criticizing authorities for discontinuing effective medication, anticipating persistence of the addiction problem, feeling irrationally deprived of pain medication, addressing one issue by creating another, blaming prescribers for misuse and abuse of OxyContin®, assuming GPs' incapability of prescribing opioids, government considering addicts not patients, decision-makers not attending to patient needs, and suggesting alternative solutions for addiction.*

A key notion which came across frequently was the feeling of being punished for abusers' actions. Patients commonly criticized and wronged the authorized parties for discontinuing OxyContin® while expressing thoughts of being overseen as individuals who chronically benefitted from and depended on that medication. This was clearly illustrated in the following opinions shared by participants:

> "Ok, I understand why OxyContin® got cut, because the kids could snort it, needle it, chew it, whatever. But what about people like me? I'm not addicted. I take it when I need it…People that have chronic pain should still be able to have it…Yes I understand the abuse that it went through, and I understand why they changed it, but it doesn't help people like us, like me." [A1]

> "I guess my point today in even wanting to do this is to let people know that not everybody abuses this drug and it's sad that the people who have chronic pain, have to suffer because of the people that don't know how to use it." [A2]

> "That kinda got me mad, cause I thought well you know, um, they're taking it off the market because of people abusing it…It's not fair to us, you know. Like, I mean cause

you know, like like we depend, I I mean my myself I've been on it for years and I mean, you know, to take that away from me, um, because of people that ab..that, excuse me but junkies or whatever, I mean that's not fair…I think the government was wrong to to, uh, pull them off the market, you know, because of people abusing them, no like they weren't looking at the people that need them…But I think it's really unfair that people that really do need them can't get them." [B1]

"I was upset, I was like Oh there goes the government again changing something instead of doing something…No they just go and pat the pharmaceuticals on the back and say oh yea, let's do try to do this… I was just upset that this was just something, a change that, wasn't for the benefit of the, of the patient." [B3]

In multiple cases, patients openly provided a justification for their disapproval of the discontinuation. From their standpoints, their perceptions were based on rational explanations that they did not hesitate to discuss during the interviews. For instance, the topic of addiction was naturally brought up in most, if not all, conversations. Given the fact that discontinuing OxyContin® was decided upon in an attempt to address and hopefully reduce the rates of addiction in Ontario, and with a tamper-proof formulation being introduced to substitute OxyContin®, it was expected for patients to critically discuss the anticipated consequence of this change. Mostly, patients strongly believed that the discontinuation will not fulfill its purpose and they predicted persistence of the abuse problem. The two main explanations backing up their predictions were that addicts would turn to abusing other medications instead or succeed in overcoming the tamper-resistant mechanism of the new formulation and/or possibly accessing the medication from other Canadian provinces where it is still made available. The following quotes illustrate some participants' perceptions regarding this:

"I don't see how it helped and apparently now, the OxyNEO®, they found a way to, to bypass whatever breakdown is of that drug, you know. So I don't know. Like are they gonna take it off the market and have people in pain?...because if you're a drug addict, you're gonna find a way, to do, to get that high, that whatever high they're searching for…next week they're gonna think of something new, there's gonna be this hydromorph, whatever it's called, that's gonna be the new epidemic…doesn't matter what they put out there, people are gonna abuse it if they can get a hold of it. So to decorate your drawer, put it in different package to me, was just a waste of tax payers' money." [A2]

"I understand about the street drugs, but in my opinion, they'll find a way to try to snort up, melt it down, do whatever. I'm sorry these kids are way smarter than I am and my generation. So they'll find a way. So what good is that?...it's just disappointed with the government, pharmaceuticals…it was a big joke to change it…cause why change something, these people that use drugs off the street just know what to do with it, with any drug." [B3]

An additional point that was tackled by a fewer number of patients (since not all patients were aware of it) was the approval and introduction of generic forms of the drug shortly after discontinuation. Some patients were clearly not supportive of the introduction of generics and felt that such an action defeated the purpose of the whole discontinuation. In fact, they felt that OxyContin should have been kept in the market, being a medication that was perceived by the majority as the most effective in controlling pain rather than allowing generics. This obviously elevated their feelings of disappointment and, according to them, further proved their claims about the persistence of the abuse problem when pharmaceutical companies make other drugs

with addictive properties accessible to and affordable by the public. For example, the following was stated by one participant conveying an amount of confusion and frustration:

> "I don't understand that part, it's the same pill but it's a generic brand, so it's like you eat cheerios, or you eat no name cheerios. So you got OxyNEOs, no name OxyNEOs, only the same way, but because it doesn't have that company's name on it, it's gonna be cheaper." [A1]

It appeared that some patients felt they were not heard by authorized parties. It was also recognized while talking about the motive for discontinuing OxyContin® that, in some cases, patients perceived their needs were not attended to by the decision-makers. This could have been a consequence of the complete media focus on addiction and the anticipated outcomes associated with it. As a result, patients felt neglected and not reasonably considered by the government in terms of assessing and deciding upon the discontinuation.

> "It's that nobody really wants to listen to the patient. The government doesn't wanna listen to them. They always think of what they know best, but they don't listen to the patient…the Canadian government just doesn't care." [B3]

As previously mentioned, some patients strongly believed that the addiction problem will continue to exist following the discontinuation. In fact, they thought that the correct way of approaching this problem was to get at its roots and eliminate the causes rather than the tool of addiction (i.e. OxyContin®). A central opinion that was often mentioned among patients who disagreed with the rationale behind pulling off OxyContin® was that of irresponsible prescribing. Prescribers got a share of blame from patients who thought that handing out narcotic

medications unprofessionally and/or easily probably contributed to the abuse problem in the first place. Over-prescribing was a major perception that was brought to the table by those patients.

> "Doctors can't give it out just for the hell of giving it out, like you know, if somebody goes to the ER and they've broken their arms or something and, or they smashed something and they, you know, pain killer, fine give them Tylenol 3s whatever, but not Oxys." [A1]

> "I think it's ridiculous that the government is, taking OxyContin® off the market if they're, the doctor, I believe should be, know their patient before they prescribe this to someone. And leave the rest of us alone now we're doing well and actually have a life, you know, somewhat of a life." [A2]

Furthermore, one participant actually believed that her condition, which was as a result of a car accident, could have been controlled by means of a less potent non-addictive painkiller. She felt that the doctor unnecessarily prescribed OxyContin® for her pain and she had been physically dependent on it since then. She stated the following in support of the perception of wrong prescribing:

> "Yes, there is pain that needs it and it doesn't matter if it's at that point, does it matter if it's addictive? No. But, in other cases like mine and surgeries and so many cases, they're throwing this drug at them and, they shouldn't be, you know, there is other answers for some of these people…they're just giving it out too easy, that's how I feel." [C3]

Not only did patients hold over-prescribing to be responsible for the abuse problem, some even expressed an extent of uncertainty in the GP's capability of prescribing narcotics. For example, one participant stated the following revealing her belief that pain specialists are more

capable of handling and prescribing narcotics with a clear assumption that family doctors are not trained to do so:

> "Why don't they just stop giving it to the people that are abusing it? I mean, and the people that are not abusing it, I mean, the doctors know who they are…just stop doctors that are, like like family doctors from giving it out, like you know? Stop them from, uh, prescribing it…Why would a family doctor be giving out OxyContin®, I mean, I had to go through the pain clinic and that, I mean, why would they even be handing that out? They shouldn't be." [B1]

Another participant, who finds that her current dose of OxyNEO® is insufficient for managing her pain, mentioned that her physician was very conscious about the dosage prescribed. She felt that the doctor should have further increased the dose as her tolerance to the medication developed but being a GP, was not capable of doing so.

> "Now when I'm just with a normal family doctor, because there's such a hassle for a family doctor, I don't think, she doesn't understand or she isn't comfortable with increasing it…I don't think it's helping me." [B4]

Normally, it would be expected of an individual to offer an alternative solution to an existing problem if they critically attacked one that has been employed. It was quite apparent that patients were willing to propose different solutions that, unlike discontinuing the medication, made more sense to them. Their perceived ideas revolved around alternative ways to help address the problem of drug abuse directly without compromising pain relief. The above mentioned opinion of limiting the role of prescribing OxyContin® to specialists was among the suggested thoughts. However, several other ideas were discussed by patients during the

interviews. Some participants introduced the notion of enforcing stricter criteria and surveillance techniques to detect and prevent potential abuse of the drug.

> "Monitor me. I don't care. I'm taking my meds as I'm supposed to. I'm not abusing them." [A2]

> "I think that perhaps something like OxyContin would have its place, um, if the pain was extremely severe, and I think that it's, I would hope that it could be used under controlled circumstances maybe, because it is, I think it is a very good pain reliever." [C2]

One participant used the story of a friend's daughter as an example to illustrate that abuse possibly results from readily prescribing OxyContin®, sometimes to the wrong candidates. She explained that the 20-year old girl was put on OxyContin® after a car accident and eventually got addicted to it. Expressing her perception of a poor judgment of the whole situation on the physician's behalf, she felt that he failed in prescribing the appropriate medication for optimum patient care in that particular case and in sufficiently considering the consequences of prescribing such an addictive medication to the young girl. She also emphasized the importance of individualizing healthcare services by paying attention to elements like a patient's personality and medical history.

> "The doctor should have looked at this young girl and thought, now what are the chances of her abusing these drugs? You know what I mean, like, did he know her personally? Did he know is she, does she have an addictive personality like there's, there's other scenarios to check out instead of a doctor going, well I know what'll cure ya…I think there's different approaches and avenues that they could take rather than just screw with the whole medication and cut the people off that need it." [A2]

She also alluded to the importance of involving other family members when prescribing OxyContin® to teenagers and young adults. She felt that this could reduce chances of diversion by providing necessary personal information about the young patient to the doctor, and thus taking part in the decision-making process.

> "If my daughter was gonna be put on OxyContin® and my doctor or her doctor didn't call me in to discuss this like, for me to talk to him maybe, and say, you know, what's your daughter like because I want, I was interested on trying her on I think it'll really help. Involve the family when it comes to younger people that, they're either gonna go, Oh no don't you dare cause this is you know, he likes his beer or this is just gonna trigger something else or oh he's a great kid, uh yeah, as long as it's short term." [A2]

Among the various ideas that were identified by participants as potential solutions for addiction, one participant suggested a distinctive perception on reducing the risk for addiction when using medications like OxyContin®.

> "You know what? I think people need a mandatory break from it, after so many years, you know what I mean, like it because, um, they get on those you need to say after like three years, you have to take a holiday from it and you go on this, to give yourself, cause they say take a holiday from it and then go back on it, but you gotta switch off and take this, like it should come with a sister drug." [B4]

Patients tended to allude to the perception of disagreeing with the motive of discontinuation and actively engaged in proposing alternative ways to address addiction without placing any burdens on the chronic pain community. Based on the variability in how patients perceived the impact of discontinuation, it was apparent that the participants who opposed this

provincial action were those who were negatively affected by it in terms of pain control. The notion of feeling disadvantaged by the discontinuance of OxyContin® drove their opinions and triggered their thinking of different solutions and associated outcomes.

Theme 2: Discontinuation negatively impacted pain control

Eight of the thirteen patients were dissatisfied with the medication change and indicated being unfavorably affected by the discontinuation. While patients recalled details of their experiences and discussed their current pain relief in comparison to that attained prior discontinuation, giving rise to the theme of 'Discontinuation negatively impacted pain control.' This theme constituted many subthemes, with each representing patients' perceptions on one particular subcategory that illustrates an undesirable influence on their pain and pain control. Therefore, all subthemes in this category are indicative of unpleasant experiences during and after the discontinuation of OxyContin® according to the group of unsatisfied patients.

The subthemes overarched by this theme are: *attaining most satisfactory pain relief with OxyContin®, rating pain relief at lower level than prior discontinuation, associating poorer relief to alternative medication, currently receiving unsatisfactory pain control, going through trial-error phase, experiencing withdrawal symptoms upon discontinuation, increased pain limiting cognition and functionality, re-training self to manage new medications, and cost being barrier to accessing alternative medications.*

It has been repeatedly shown in the existent literature that OxyContin® proved to be both, an effective and safe painkiller (Afilalo et al., 2010;Ong, 2008;Pan et al., 2007;Stambaugh et al., 2001){Hartung, 2007 73 /id. This notion was supported by the majority of participants in this study, including those who voluntarily chose to get off OxyContin® and any opioid

medications (will be discussed in another section). All thirteen participants confirmed the success of OxyContin® in managing their pain. The following quotes exemplify this idea:

> "I wouldn't be doing what I do if I, without it, I wouldn't be able to manage or cope if I didn't take it, um, the OxyContin®. I know that. I would be in too much pain, and I wouldn't, life would be just miserable." [B2]

> "The OxyContin®, it really helped...that's actually the first time that I could say with the OxyContin®, that I was actually didn't feel pain. So I just thought that this is a miracle drug, like thank you God because the pain was actually gone." [A2]

> "I think it did help a lot, um, I don't know how I would have made it through, um, you know, the initial years I don't know how I would have made it through without it." [B4]

> "Oh it was perfect, worked perfectly for my pain." [B1]

All eight patients were switched from OxyContin® to its new formulation, OxyNEO®, and all eight indicated receiving lower pain relief than that attained with OxyContin® prior to its discontinuation. Patients claimed the non-equivalency of the formulations with OxyNEO® being the less effective one.

> "I just found it just wasn't working for me…I went to the doctor and I talked to him and I said, look, I don't think this is working so…he just never filled out no more, no more prescriptions for me, cause if it's not working, why take it?...Um…I found the OxyContin worked so much faster where the other, I don't know, it just didn't, it just didn't cut the pain. I don't know why the difference was, if they were the same pill and that, but it just wouldn't, I didn't find like I was getting the relief out of it like I did the others." [A4]

> "I don't feel it's, it works near as good as the OxyContin®…I do have some relief with it but it's just not as quick, and it's not as strong as, the Oxy like, OxyNEO® isn't as strong as the OxyContin®…I think I could take like probably six a day of them to equal the three a day that I'm taking, uh, like from the OxyContin® to the OxyNEO®, I could probably take six of those a day to be equal to the 20 milligrams of OxyContin® I used to take." [A2]

> "It didn't work as well, it really did not work as well, at all, it just really didn't…I always felt, uh, sick to my stomach." [B1]

> "Well, she put me on the OxyNEO®, and, the pain was a little worse. It didn't give me the same as OxyContin®…I still had to take either, uh, Aleve, or…Tylenol." [C1]

Some patients even revealed being unable to obtain comparable pain relief despite trying more than one medication since OxyContin's discontinuation. Different aspects of patients' decisions to either continue administering a medication or change it were discussed. Some chose to continue administering OxyNEO® despite the unsatisfactory relief it provided based on their opinions. Reasons included reluctance to try other medications, believing no better options exist, and having tried previous medications that proved ineffective. Others discontinued OxyNEO® and currently rely on another medication that still fails to provide the satisfactory relief they are seeking. All eight patients made constant comparisons to the pain control previously attained with OxyContin® while giving their insights about all other medications administered following discontinuation, and perceived it was unmatched to date. The following excerpt illustrates a patient's evaluation of her pain control (currently administering fentanyl patches) at different stages using different medications:

"Alright, so if I ask you to rate your pain control, um, like how many percentage of your pain was managed when you were on OxyContin®, and then compare it to now, what would you say about that?" [SI]

'Oh, I may still think, I'd still say the OxyContin® was better…I'd say the OxyContin® managed my pain about 90%." [B1]

"And now you think it's [looks at questionnaire response] 70 I guess?" [SI]

"Yea, between 70 to 80, yea." [B1]

"And what was that percentage with OxyNEO®?" [SI]

"[laughs sarcastically] I'd say about 60%, yea it didn't work that well at all." [B1]

The impact of the discontinuance that was perceived to be negative by most participants was not confined to pain control. Some patients discussed undesirable changes in their daily life activities after making the switch from OxyContin® to OxyNEO®, which in turn helped clarify the adverse influence of less controlled pain on their lives. For example, one participant compared both formulations and explained that aspect in detail introducing the drawback of over-analyzing every action when experiencing poorly controlled pain:

"With the OxyContin®, I could at least have a bit of my life back. With the OxyNEO®, it's, I'm, I'm never without pain…With the OxyContin®, um, I didn't have to, uhh, pinpoint everything I'm going to do, I could actually make a move without analyzing what I have to do. With the OxyNEO®, I have to, I'm back to kinda square one, where uh, Ok I wanna sweep my kitchen floor now…how bad is it? Does it need done?...That's my main concern from them discontinuing OxyContin® is, it puts you, it put me back to

where everything in my life I have to analyze before I do it and anybody with chronic pain knows what I mean, because just to get up and pour a cup of coffee, something that simple, uh, for me isn't." [A2]

With regard to functionality, patients commonly alluded to the notion of increased pain limiting cognition and the ability to perform daily activities. The following was stated by one participant describing differences in functionality associated with levels of pain control attained with both formulations:

"If I got up in the morning and the pain was bad, I could take an OxyContin®, wait an hour, by that time I've had my breakfast, my insulin, my pills, pack up the truck and go fishing for the day, and have maybe, an hour before I was leaving, the pain would say hey I'm here, not bad but I'm still here, where the whole time it's like, it's not there. I could still function. I could still do what I wanna do. The OxyNEOs, you can't." [A1]

Patients also emphasized the point of feeling threatened by the discontinuation, not only because of being deprived of their pain medication, but they also expressed their discomfort with the trial-error phases they had to go through as a result. Fearing the unknown in terms of potential effectiveness of different medications that substitute OxyContin® as well as hesitancy to try more medications and evaluate them was reflected in some of the patients' responses. For example, the following participants stated:

"We have to like go to things like fentanyl patch or, or be guinea pigs and have to try these other new medications that, that come out, just to see if we can get something that help, uh, take care of our pain." [B1]

> "They felt, well let's try this one, let's try that one…I have several different pains going on in my whole body…so I think that's why they're just trying to see if, one is better than the other or, if they can accommodate two different pains into one pill…I'm just tired of medication after medication. I, I don't like taking it." [A4]

Chronic pain patients administering opioid medications for extended durations have concerns about withdrawal. Their awareness of the drug's addictive properties and the building of drug tolerance increased their understanding of the potential withdrawal symptoms that could be experienced upon discontinuation. Therefore, patients were asked whether they had gone through withdrawal upon discontinuing OxyContin®. Some patients experienced uncomfortable adverse effects while switching to other medications and associated those effects to withdrawal symptoms from getting off OxyContin®. For example, one participant stated:

> "I was thinking, are they gonna work for me? Am I gonna go through withdrawal? Well, um, and I did feel like I, I did feel like I went through withdrawal, because I mean they're not the same medication, I mean, I I think I didn't feel well when I first started taking the OxyNeo, like I, I really didn't feel that good." [B1]

An interesting concept highlighted by some of the negatively impacted participants while re-visiting their experiences was that of re-training themselves to manage different dosages, formulations, or new medications. Patients clearly expressed their preferences of complying with the medication regimen they get optimal benefit from, reflecting an apparent discomfort with having to re-adapt to changes in that regimen. Patients appeared unwilling to experience and/or re-experience that process with alternative pain medications or formulations of the same medication. For example, one participant who obtained lower pain control from OxyNEO® as

opposed to very satisfactory control from OxyContin® seemed discouraged to try other medications. When asked whether she would consider switching from OxyNEO® to seek more effective pain control, she stated:

> "I'm just not willing to, uh, maybe it's just my mindset, I'm just not willing to go on a new pill and it do nothing…Right now, I know what I'm dealing with, I I you know, I know what I have to do during the day with the OxyNEO® now. You have to retrain yourself for it, kinda thing. So, I'm not going down that road again." [A2]

Another issue that contributed to some patients' bad experiences with the discontinuation was that of the medication coverage. Unlike OxyContin®, the government announced at the introduction of OxyNEO that it would not be covered under the ODB program. Therefore, unless patients had drug plans covering medication expenses, they would have to pay for OxyNEO® and tolerate the extra expense of a chronic medication. Despite this not being a problem for most participants, two patients identified cost being a barrier to administering OxyNEO®.

> "What good are they gonna do me? They cost me my food money to get a pain killer, that might or might not work for me, or might work too much for me, and not enough living…I couldn't afford it." [A1]

> "I was very upset. That's what I was. People who worked and had insurance companies that would pay for it can continue it, we are the lower part of, the income scale…My option is OxyNEO®, but I have to pay for it. I have no idea how much it is, and if I have to pay for my occupational therapy, if I have to pay for my, what's its name, to come and do my exercises, if I have to pay for, I mean…this country that pays for your medication is not telling the truth." [C1]

Theme 3: Discontinuation had no impact on pain control

While the majority of participants communicated their perceptions on the discontinuation being of negative impact on their pain control from various aspects, others expressed a different opinion about the way discontinuation affected their pain. Five participants were indifferent to the change in pain relief with their new medication after the discontinuation. Since all five patients attained a comparable amount of relief, this raised the theme of 'Discontinuation had no impact on pain control.' Three of the five patients did and still receive satisfactory pain control while the remaining two were not at a satisfactory level of relief with OxyContin® which continued to be the case. This theme encompassed the following subthemes: *rating pain relief at equivalent level to prior discontinuation, continued receiving satisfactory pain control, continued receiving unsatisfactory pain control, identifying some medication differences, and discontinuation impacting aspects other than pain control.*

It is important to note that participants were asked specific questions during the interviews that were intended to unfold any differences and/or similarities in pain control prior to and after discontinuation. This was necessary to enable the capture of the impact of changing medications on pain control rather than just exploring how the current medication manages pain, which would not be constructive under the current study objectives. Patients were asked to compare the pain relief they obtained from OxyContin® prior to discontinuation to that attained with the alternative medication(s).

Three patients who maintained optimal pain management through the discontinuation perceived no differences in drug effects. Two patients were prescribed OxyNEO® and one was prescribed Hydromorphone as substitutes for OxyContin®. They clearly indicated experiencing a smooth transition phase between medications and had no complaints about the switch. For

example, one participant replied to the general question, "What do you think the overall impact of OxyContin's discontinuation was on you and how has it affected your pain control":

> "It hasn't affected it at all. In other words, I wouldn't know, uh, whether I am, by the way I feel, I can't tell, I wouldn't be able to tell whether I am still taking OxyContin®, if I was in a blind taste test, not taste test but uh, blind medication administration test I suppose, uh, I wouldn't know there are it would be OxyContin® or Hydromorph, not at all, absolutely not, not a tenuous little bit." [C2]

As mentioned earlier, two patients were previously receiving non-optimal control from OxyContin® and continued to receive an equivalent effect from OxyNEO®. In case of these patients, the lack of impact characterized a continuation of poorly controlled pain. One of them associated the unsatisfactory relief to tolerance from an extended duration of being on the same dose of OxyContin® and her doctor's unwillingness to increase the dosage. However, she stated that OxyContin® optimally controlled her pain initially and proved to be the most effective among all other painkillers she administered. When asked to compare how both medications controlled her pain, she stated:

> "I didn't notice any difference, really nothing…I've been at the same dose for years and years and years, so I don't know if, I don't feel, it isn't helping me, and hasn't helped me in a long time, and because it's not doing anything for me, because I know because I was on it enough years before, that you do have to increase the doses now and then for it to make a difference in you, right?" [B4]

The other patient was in the process of tapering down OxyContin® when it was discontinued. Her aim was to get off the drug completely and not rely on it for pain relief

anymore. At the time of discontinuation, she was already receiving the lowest dose of the medication (10 mg). Following discontinuation, she was switched to the same dose of OxyNEO® and could not identify a different effect on her already poorly managed pain.

> "It was done and I didn't even know, because my husband, I should explain, my husband because I was on so many drugs…he took over and, uh, sorted them out for me and have them ready for me, so I didn't know when I started the OxyNEO®…It wasn't really controlling my pain because 10 milligrams of anything does not…because 10 milligrams of them do, do not kill any pain after being on it for so long." [C3]

Since most of the participants were switched to OxyNEO®, it was the main painkiller whose effectiveness was being evaluated by patients, especially in comparison to OxyContin®. Although the group of patients who obtained lower pain control with OxyNEO® focused on the drug's effectiveness along those lines, other patients whose pain management was not negatively (or positively) influenced by the discontinuation evaluated OxyNEO® differently. They received equivalent pain control, yet they still reported some noted differences between the two formulations. The subtheme of *discontinuation impacting aspects other than pain control* captured that perception. For example, it was frequently stated by some patients that OxyNEO® seemed to have a slower onset of action and the pill itself was more difficult to administer.

> "Like the one thing about it, at least before, I could just get it and take it, and put it on my tongue and swallow it, now with the, I've to build up a lot of saliva and swallow, it's just not convenient now with that big thick bloody layer on it." [B4]

> "With the OxyContin®…I remember I would take sometimes if I had no water available and it was time to take, I would just take them and swallow them, but with the

OxyNEO®, I make sure that I have got something to drink with it, so. That's, switching over, that would be the only, um, um, thing that's inconvenient, for me." [B2]

"Um, it's just the delay that I found, I keep, I, I understand it's the same medication but like I said it was, it just takes longer to get in the system and, um…sometimes it does get locked in your throat and stuff, and if you don't drink enough water, then it does swell up." [B5]

Theme 4: Learning to live with pain

Seven of the thirteen patients stated that their primary hopes for attaining optimally managed pain changed over time and were replaced with an understanding that they will continue to live with uncontrolled pain. It was further explained that this has somehow changed some of the patients' way of looking at pain medications and their evaluation of them. For instance, some patients indicated never expecting optimum relief from a medication but rather willing to tolerate some pain with the perception that this is as good as it can realistically get. With the majority of patients currently living with poorly managed pain, either as a result of the discontinuation or not, many emphasized the notion of learning to live with the condition and never anticipating a pain-free life. The subthemes included within this category are *accepting life with pain, limited alternatives, wishing for a miracle pill, and hoping to regain OxyContin®.*

Some patients said the following supporting the notions of getting used to the presence of pain and accepting to live with it:

"You just kind of suck it up and just kind of, Ok this is my life, this is how I deal with it…when there's so many people that are walking around otherwise with pain and, you

probably can't even tell that they have pain, because they just put up with it. Especially if you had it for a while." [B3]

"It's been so long, I just [laughs lightly], I can't remember how long it's been without pain. I deal with more pain than what most would, like, most would be, like just sitting here, I'm probably at a five, five six, without even moving around…I know I'm in pain but sometimes it's, you just put it in the back of your head, you know, it's there but you just kinda forget about it." [A4]

"I just found different ways to cope with it, and to, I guess accept that, it's here to stay, and um, you just have to kind of figure out a way to, um, to try manage it and try, still have a bit of a life too…I guess the change just has to come from you just trying I mean myself just trying to, um, find a way through it or work around it." [B4]

Despite the split of patients' opinions between a negative impact and no impact of OxyContin's discontinuance on pain control, most pointed out the need for making more pain medications available to chronic pain sufferers. The perception of running out of alternatives after having tried multiple medical and non-medical options was often mentioned by patients.

"I feel like the options are running out there, like, I don't know much about the medication but I feel like, I don't know, that if you take it all the time like it's, you're gonna run out and then what are you gonna use?" [A4]

"I have tried a gazillion other medications of all different things and nothing ever worked for me…I tried a lot of different things for my symptoms and nothing else worked for me, I mean that's why even being here, like I've tried a lot of different things they offer and they've just never worked and, even here they've told me, uh, we don't have

anything else for you. So, um, you know so there, there is nothing um, there is nothing else so it is what it is." [B4]

"There's nothing else out there, so I just deal with it." [A2]

"I even asked my doctor if, uh, there was anything else that could replace it with, you know, because I don't find that there's any relief…He just keeps saying that I'm at the max, of what he can give me." [B6]

Along with complaints about the deficiency of effective choices for treating chronic pain within current practice, patients commonly voiced their hopes for better alternatives to existing options. For some patients, especially those who perceived satisfactory relief with OxyContin®, being able to re-administer the medication appeared to represent the ideal scenario.

"I just wish they they would bring, uh, bring back the, uh, the OxyContin®…I had heard that they they they might bring back the, um, the OxyContin®…I said well if they bring them back, can I go back on, you know, cause they work…If they were to bring back the OxyContin®, I would love to go back to that." [B1]

"I just wish that they bring back the OxyContin®…If they say we're gonna bring back the original OxyContin®, then yea, uh, garbage my OxyNEO®, here have them, I don't want them, you know, heartbeat I would be back with OxyContin®." [A2]

"I just wish they'd left the OxyContin® alone, and let it stay on the market." [A1]

Others wished for a miracle pill that would help ease their pain and eventually put an end to their suffering. This reflected the general perception of not believing that an effective pain medication currently exists according to patients who are now living with uncontrolled pain.

"I just wish there was something out there that could help with my pain so I can, be a little bit more active without pain too…I would love it if there's something out there, I'm not asking to get rid of all the pain, I can tolerate some pain, but just a little bit more than, but nothing that's addictive." [C3]

"You know, I wish there was a magic pill out there that would help, you know, just one. I've always said that…if I could find a magic pill, one, I would be so happy, you know, because people shouldn't live like this." [B6]

Theme 5: Identification of flaws within the discontinuation process

While sharing their discontinuation experiences, all thirteen participants perceived the existence of several gaps within the medical care they received, including flaws in patient education, communication, and treatment. The need to address those flaws was identified as a significant element in improving current pain management practices. Patients discussed complaints about the medical services offered to them at the time of discontinuation, elaborated on their relationship with their healthcare providers, and provided details of their alternative treatment plans. In-depth descriptions of those aspects allowed for the identification of various flaws in the discontinuation process through their detailed experiences. Those comprised the following: *learning about discontinuation from media/internet, communication gap existing between professionals and patients, feeling unheard by healthcare providers, lack of pharmacist intervention, expecting more information at discontinuation, and not involving patients in decision making.*

One of the flaws in the medical care provided to patients was detected in manner some participants learned about the discontinuation and the resources used to obtain most of their

information. It was commonly mentioned by participants that they came to know about OxyContin's discontinuation from the news, radio, or internet. Moreover, some even stated that their doctors and/or pharmacists did not provide any information on the reasons for discontinuance or the range of alternative medications available. Also, details about differences between the discontinued and new formulation were not explained to some patients by their healthcare providers. This is demonstrated in the following excerpts:

> "No, no, nobody said anything. Well, I asked my doctor and only because I heard on the news, she didn't come to me and tell me this was gonna happen, it was all the news…I wanted to know why, and um, I have to think, because I was very concerned, um, because at the time when I listened, when I heard it on the news, they were, they wanted to take it right off the market, that's what I was concerned about…I was worried what's the next step…like there was a lot of thoughts, uh, like that that was going through my mind." [C3]

> "The OxyNEOs…the doctor didn't even know side effects of it, the pharmacist told me side effects of it, the doctor didn't know. It's like she, here's a prescription, but I don't know nothing about it." [A1]

> "I really wasn't aware that he have written, uh, for the Hydromorph, until um, uh, until I got them, the pres.. the scripts uh filled…I didn't think he had, he had given me anything, I thought I was going from OxyContin® to nothing…I thought he would have discussed it a little bit more, in other words, he didn't discuss it at all." [C2]

When asked to recollect their discontinuation experiences and their healthcare providers' interventions during the transition phase, patients grasped the opportunity to discuss general

details about the medical care they receive. Some patients tended to point out to communication gaps between themselves and their clinicians which appeared to be due to difficulty in accessing physicians at times. For example, one participant illustrated the inaccessibility of her doctor between appointments that she clarified when asked about communicating her concerns to professionals at the time of discontinuation:

> "Well I could call the pain clinic and uh, I can leave a message, and nine times out of ten she wouldn't call me back, but the nurse would." [B1]

It was also noted that many patients feel as though they are not being heard by their healthcare providers. Since switching from OxyContin® to another pain medication was not a positive change for all participants, some had complaints about their alternative medications. All patients indicated clearly communicating such information to their doctors whose reactions sometimes left the patient disappointed. The point of feeling unheard was raised by some participants as shown in the following statements:

> "The last time I went in about the Gabapentin, cause I'd had enough, upping it didn't work, side effects were horrible…I said I want off it, so she tried everything in the book to keep me on it, and up the dose again, and I'm like it don't work, why should I take a pill twice a day that doesn't work, it doesn't take away pain, I'm still in pain…I shouldn't have to argue about taking, not taking something that doesn't work, I don't need it." [A1]

> "A couple times we tried, uh, Gabapentin and I said it doesn't work but, they're bound it does…she was positive that, that uh, gabapentin will work. It don't work but she believed that that's the only best thing there is for my pain…I was even on Gabapentin once

before with another doctor and I told that doctor it didn't work but, they didn't seem to believe me, either one." [A3]

The lack of pharmacist intervention in patients' pain treatment plans was highlighted when patients discussed their relationships with their healthcare providers. Most participants indicated not getting any information about medications from their pharmacists unless they ask specific questions. This was also revealed when patients shared how they received new prescriptions for pain medications following discontinuation. For example, one participant stated the following about her drugstore:

"I don't know if it's because I've been going there for the same medications for so long, that there's never really a, you know, do you have any questions or anything like that, just well, here's your meds, you know…there's never, do you have any questions about them, or any concerns." [B3]

Furthermore, some patients directly sought information about their medications from resources like the internet instead of asking their pharmacists. Reasons for avoiding pharmacy services included preferring to communicate with their physician, dissatisfaction with offered services, and not believing a pharmacist could provide new information.

"There's no use to just or I don't feel there's any use asking the pharmacist um, either than if I want something, you know, different. But no that's, I usually go to my family doctor, I feel confident in what the physician has told me." [A3]

"The pharmacy that I was at, um, you you you couldn't talk to them there cause they had this, old man there and he was just terrible…if you try to ask him a question about

anything, all he would do is basically read you that, you know like when they they staple that pamphlet? He would basically just read that to you, that's all he would do." [B1]

The notion of not involving patients in the decision-making process in terms of prescribing medications emerged from some participants' experiences with the discontinuation of OxyContin®. Physicians sometimes switched patients onto different medications without discussing the available options in advance. According to some patients, this was viewed as the normal situation and they did not have specific concerns in that regard. The following was stated by one participant whose doctor prescribed hydromorphone for without her knowledge:

"Oh no not my choice at all, it was just that I, I found that that was, after I left his office he prescribed it yes, so I presume he did that in place of OxyContin®…but that was alright, I, I didn't ask him either." [C2]

Others felt surprised by the change and started seeking more information about the switch from healthcare providers upon receiving their new prescriptions.

"I just went to the pharmacist and he was like, all of a sudden, oh well now it's OxyNEO®. And like I said, there was no information given…I guess I was ups.. stunned and it was like, ok so how is this gonna affect me and, it was just, uh, well it should be the same, you shouldn't find any difference." [B3]

Theme 6: Choosing to get off OxyContin® permanently

Choosing to stop administering OxyContin® might not be directly related to the medication's discontinuance and its impact on pain control; however it was essential to explore the individual experiences on this notion in depth and to get a better understanding of patients'

fears associated with OxyContin's use. Despite treating pain efficaciously as was confirmed by all, the idea of getting off of OxyContin® was raised by some participants. This set the ground for further investigation into this matter with two goals in mind; grasping reasons for considering or taking such a decision and exploring the process of permanently discontinuing OxyContin® from patients who have achieved it. Encompassed in this theme are the following notions: *fearing life-time dependence on medication, addiction to OxyContin® triggering decision/desire, tolerating resulting withdrawal symptoms, bearing with worsening pain, and relying on distraction methods to ease pain.*

Feeling highly dependent on OxyContin®, both physically and psychologically, was a source of concern for some participants. Two participants made the decision of discontinuing OxyContin® on their own.

> "I realized that it was an addiction and I couldn't, I realized how I felt if I couldn't get to it…so I knew it was an addiction, and I knew I had to get off of them because that's not, my plan of life to live on addiction…so I decided that's it, I'm gonna do it on my own and I did." [A3]

> "I just experienced not being able to concentrate, I couldn't do just my typical every day to get dressed, and I was complaining about it, I was very moody, I was argumentative, I was just not who I was…after that I thought, well I've gotta get off of these pills, cause they're doing more damage than they are doing good…that was when I decided Ok, I have to do something to get off these drugs." [C3]

Other patients indicated desiring to discontinue OxyContin® at some point in their lives and disliked the idea of relying on a medication for life. For example, one participant stated:

"I have before actually tried to cut down on my own but then I just, I started to get the side effects so I, I couldn't do it." [B4]

The driving force for choosing to discontinue opioid medications is usually the fear of becoming dependent on them forever. Although this theme primarily emerged among participants who planned to (or successfully) permanently discontinue OxyContin®/ OxyNEO®, many patients shared the fear of addiction and expressed serious concerns about the consequences of getting off the medication such as experiencing withdrawal symptoms and suffering from intolerable pain. The following statements from participants reflect awareness of such dependence and fear of consequences associated with it:

"My biggest problem, my biggest fear I should say, is becoming addicted to a drug. I don't wanna be addicted to medications. I wanna use them for the sake of needing them." [A1]

"I know that if I stopped it tomorrow, I, any, like even the OxyContin® or the OxyNEO® or whatever, I know I would be in trouble. Absolutely, because I know there is that, um, physical dependency and psychological." [B2]

"I've been on them a long time so I imagine I would be pretty sick…but I, you know, heard people like seen them again on these TV shows, the vomiting, the the constipation and then the diarrhea, and the shakes, and the night terrors and, I'm like Oh my God, I hope I never have to experience that." [A2]

"I've been on it for years so, I mean obviously I knew I was, um, basically addicted to it, but I mean medically addicted to it, right? So I knew if I had to come off of it, it was gonna be, a tour to come off it." [B1]

The journey of discontinuing OxyContin® was described in detail by the two participants who went through it, however only one of them had already achieved getting off of it permanently while the other was in the last stage (reached the lowest dose) as she referred to it. Both patients had been administering OxyContin® regularly for over eight years and eventually took the decision of discontinuing it independently. A highlight of their individual journeys was the withdrawal symptoms they experienced. The hardship of the process is illustrated in the following excerpts:

> "The side effects, the side effects of them is awful, it's hell, the side effects of going off of those pills, they're it's hell, I don't know how else to explain that. um, I just feel like there is worms or or insects crawling out of my skin, and you're just jittery and, I was hitting, I was literally hitting my body, bruising myself because of this jumpy feeling that's going on in my body and, I was moody I was, irritable, I would cry, I, I wanted to scream in fact there was times I screamed." [C3]

> "To get off of it, I walked a lot, I cried a lot, I kicked my husband, I broke the mattress of the bed because I lay on bed and kicked the mattress in pain so bad in trying to get off of it. My skin always felt like there was bugs climbing around inside, all the time I was trying to get off of it…it was pretty wicked." [A3]

Going through withdrawal symptoms was not the only downside to discontinuing OxyContin®. Both patients indicated currently suffering from uncontrolled pain which diminished their ability to perform certain activities. Each patient handled the withdrawals and increased pain with the help of different distraction methods or by relying on other over-the-counter (OTC) and immediate-release medications.

"Now, I, when I'm in pain, I bitch a lot but so what…I just take some more extra strength Tylenol, because it does get some days though, I can't do a lot of things now that I could when I was on OxyNEO® and OxyContin®, I can't work in the garden anymore, I can't bend over and dig in the garden, I look pretty funny the way I do it yes, but you know, I can't do those things that I loved to do before, now even in crocheting and knitting, your shoulders burn so bad sometimes you can't even do that now but, it's, it'll get through this, I will." [A3]

"It's not totally getting rid of my pain, but that's because I'm on a low dosage, and I'm not willing to go on a higher dosage to control my pain, so therefore, I'm not satisfied with it at all, right?...I took the advice of my pain tolerance doctor, to not to concentrate on my pain, to more concentrate on other things that there was games on the computer I would play…I would get audio books and listen to them, and relax that way…I eat frozen grapes that, it's, I had to eat something intense, something really cold or something really hot…so that helped." [C3]

Theme 7: Need for optimizing patient care

Numerous issues were identified by participants as barriers to optimal pain management with chronic use of OxyContin®. Despite attaining satisfactory pain relief with the medication, as was stated by the majority of participants, some pointed out to several imperfections that accompany the use of the medication. Patients perceived that these issues had influenced their experiences with OxyContin® in an adverse manner. Basically, the nature of the drug provoked certain expectations from its long-term users regarding the current practices that are associated with its use. To enable a complete understanding of those areas where optimization of patient

care is needed, patients used their own experiences with the medication to highlight the existent issues from their points of view. This theme embraced a number of sub-themes that aided in illuminating areas for improvement: *professionals not clarifying addictive properties and/or long-term effects, professionals not educating patients on multiple matters, professionals inadequately integrating practices, and absence of regulatory program for re-assessing pain and medical needs.*

It was indicated by some patients that healthcare professionals are expected to play a key role in assuring the appropriate use of this medication, thus achieving optimum outcome. In fact, some suggestions for optimizing current practices in relation to OxyContin® (and similar medications in terms of properties and long-term effects) were discussed by some participants. Those notions were clearly derived from patients' own journeys which extended over years of regularly administering the medication. Some patients recalled being put on OxyContin® without receiving any information on the drug properties and its long-term effects in advance. For example, the following participant stated that such information would have been appreciated.

> "I didn't really know the long term, what the medication can do to me, like that would be, better to know, the long term of it. And it seems like he never gave that information. They give you information on what it'll do for you and stuff but not over the time of taking it, what it can do for ya, and that would be nice to know…I think they should let you know, a little bit more on the long term if you're on it for a long period of time. Like they don't say Ok in five years this isn't gonna work for you anymore, we're gonna have to give ya something stronger or, if you stay on this pill for a certain longer time, it's gonna wreck your liver or, you don't hear too much of the side effects that way, which I think we should all know about." [A4]

Another patient revealed a lack of trust in the medication-related information provided by her doctor at the discontinuation. This mistrust was induced when the doctor previously failed to inform the patient about OxyContin's properties before prescribing it to her.

> "I asked my doctor, and she just said it has nothing to do, I wouldn't feel any difference she said, but I didn't, I didn't trust her and it was probably the fear that I, only because she never told me right from the beginning that this was gonna be addictive, uhh, I didn't trust her when she said that so, I was still scared." [C3]

The lack of patient-focused individualized care was brought up by one participant, further clarifying the challenges encountered by being on chronic medications and hence supporting the need for optimizing current practices. The following excerpt illustrates the patient's perception on the importance of obtaining sufficient knowledge about a chronic medication which she feels would only be attainable through individualizing medical services.

> "I just think it's important that, um, that, as far as doctors go that doctors really listen, um, and um, hopefully react, um, to when a, when a person comes in with um, with whatever their, um, complaint is I think sometimes, um, people are too, um, generalized together and um, are put under set names of different things, and they're not looked at as individuals and dealt with that way…when you come to a doctor and you're so sick and you're desperate for answers, you really, you really do need an advocate for you, who does have the energy and the time to, just research a little bit, or take the time to become a little bit more informed about, um, I guess especially when it comes to, well I guess any drug, just taking a bit of time just to research a bit, before you jump in, um, long term on a medication without really understanding it a bit." [B4]

Being uncertain whether the benefits of a medication outweigh its drawbacks or vice versa was a point that occasionally came across in some participants' responses. Usually, patients did not solely decide on that based upon their personal experiences but they also relied to a great extent on their healthcare providers' perceptions on different matters. In such cases, poor integration of medical services among professionals in the same or different hierarchies of the healthcare infrastructure could only lead to the patient's increased confusion about the medication. Contradictory opinions among professionals were illustrated in the following quotes from two participants:

> "I'm very confused about the medication itself, I, I really am, I am, I know it does good but I'm, I'm confused really if it's um, I'm just confused about, um, if it, if it has in all these years done me a good thing or bad thing…every doctor has a different opinion about it, so um, you pick up different things, you know, so I really don't know." [B4]

> "I took a leaf, no but they told me a leaf was so bad for you, but my doctor still prescribes it…the doctors in London said it ruins your liver, that's all, that's all I know, if if somebody could tell me that, you know, if you took twenty a day it might do it but two or three a day won't and they say, my script for a leaf is called naproxen or something, yea, and it said um, I could take one or two twice a day, so my doctor doesn't think that it's gonna ruin my liver…I was in a lot of pain, and that was, before she sent me to, the knee doctor and she had me on Oxepam…it helps some, but down in London they said that the Oxepam causes falls…well, I don't know…so I can't say it was the medication…my doctor said she's never had anybody go down and had good results." [C1]

One participant expressed her opinion regarding the integration of both pharmacological and non-pharmacological methods for managing pain in her experience. She felt that her doctor did not make the right choice of time for incorporating physiotherapy in her pain treatment plan.

> "I think the physical therapy would have helped me if I wasn't doing it when I did it, cause it was too early. I think I needed to heal a little bit more, and if my doctor has not sent me at that point, and waited a little bit and then sent me and then used the therapy with cutting back on my OxyContin®, that would have been great. I really think that would have worked a lot better, because my therapist stopped me, because he says I can do no more for you he said." [C3]

Among the areas that were emphasized by some participants was the need for a regulatory program to aid in following-up chronic pain patients in order to enable attending to their changing medical needs along the therapeutic journey. Some patients were clearly against the chronic use of stable doses of medications like OxyContin® and felt that it should be periodically adjusted according to each patient's needs. This gave way to the perception of re-assessing pain on a regular basis and making necessary modifications in patients' treatment regimens. For example, one participant stated the following:

> "Why are doctors not, my doctor never came to me, she just wrote me out the prescription every month, you know. Why did she not? Isn't there a way that you can go through some kinda procedure and say do you still need that amount? She never asked, she just wrote it out to me. How many doctors are doing that?...There should be some kinda program that these people can go through Ok, I'm not in as much pain now as I was two years ago, let's start cutting back. Why did my doctor not do that?" [C3]

4.4 Findings from Physician Interviews

Seven physicians were interviewed from both general and specialized practices (four family physicians and three specialists) to provide feedback on the discontinuation of OxyContin®. The aim was to explore their individual experiences with the group of patients who were administered the medication to be able to highlight the major themes that emerged from their responses to represent the professional perception on the impact of discontinuance on pain control. Moreover, patients' responses outlined major points that needed to be addressed in physician interviews. This will be noted from the themes developed from physicians' interviews. Upon interviewing physicians, five prominent themes were identified: 1) Support for the motive for discontinuation, 2) Discontinuation insignificantly impacted pain control, 3) Existence of adequate guidelines for opioid use, 4) Disapproval of the introduction of generics, and 5) Need for optimizing pain management practices. Each theme will be separately described with supporting quotes in the following sections.

Theme 1: Support for the motive for discontinuation

All seven physicians communicated their approval of the discontinuation of OxyContin® and its removal from the Ontario Drug Formulary. Most of them also supported the government's decision not to fund the new formulation, OxyNEO®, and to restrict accessibility through the EAP. Based on their personal experience in practice, physicians believed that the high addiction potential associated with the use of OxyContin® exceeded that of other medications within the same therapeutic class and was therefore responsible for the elevated rates of abuse. There was general consensus among physicians that other pain medications would be equivalently effective to OxyContin®. This was illustrated in the following two statements:

"I think it was a good idea, to discontinue OxyContin®, um, mainly because especially in the area where I practice we saw a lot of abuse and misuse, and still do, um, and given that there are other, you know, effective alternatives in terms of pain management, I think it was a good decision." [MD4]

"The discontinuation of OxyContin® was absolutely essential, because it was perceived as having a very high, uh, uh, addictive component and street value, and we have many other drugs that are just as effective as OxyContin®." [MD2]

Theme 2: Discontinuation insignificantly impacted pain control

A notion that was frequently alluded to by all GPs and specialists was that discontinuation had minimal impact on pain control. All physicians perceived an insignificant (or no) influence on patients' ability to attain equivalent relief in comparison to prior discontinuation. Although the patient load between family doctors and pain specialists cannot be compared, doctors from both practices seemed to believe that the transitions were carried out efficiently and that they had sufficient flexibility with a range of other treatment options to choose from. Some physicians even seized the opportunity to switch patients to other opioid or non-opioid drugs due to their specific dislike of OxyContin®. When asked to share their perceptions on the discontinuation's impact on pain management, physicians stated:

"Negligible, because we have options and we can switch them to other drugs that are just as effective. There's the odd patient who will say it's the only thing that works and nothing else helps, uh, but most people we can find an alternative that works just as well." [MD2]

"I don't really think I had any problems at all with my patients going from OxyContin® to OxyNEO®." [MD6]

"It didn't seem like a big blip or anything in my practice, it just, patients were explained, they changed over and the pain was controlled, so it was not a big issue." [MD5]

In addition to supporting the theme of 'Discontinuation insignificantly impacted pain control' based upon experiences from their practice, two physicians brought up the perception of associating reported unsatisfactory outcomes to illegitimate use of the medication by patients. Both physicians explained their uncertainties for patients who had major problems with switching onto a different painkiller and they claimed that equivalent relief should be obtained with other medications, particularly OxyNEO®. Despite the existence of this dissatisfied group, both physicians believed that the majority of their patients had undergone the switch smoothly with no problems.

"I had a couple that, a couple of patients, that I was, you know, concerned that, there might be misuses of medication…but for patients that were on it, you know, for what I thought were legitimate reasons, um, yeah I mean a couple people were anxious about it, um, but I think they were pretty reasonable too, they understood there were other alternatives and that it wasn't gonna be a situation where they were gonna go from taking something to nothing." [MD4]

"My thought was that OxyNEO® really should have been the same as OxyContin® and, I I did have a certain suspicion back for my people that really didn't like OxyNEO®, how legitimately they're maybe using the medication...overall I think the impact for patients is

not that huge because we've been able to switch to other opioids for genuine patients, I don't think it was a large thing." [MD1]

One of the pain specialists provided a detailed categorization of chronic pain patients who were administering OxyContin® based upon her evaluation of the major differences in the individuals' reactions to discontinuation. As a pain specialist that sees the highest numbers of patients in the pain clinic, she derived her opinions from her observations within her practice. She divided her patients into three groups, with the first group of patients comprising the highest percentage of patients, which further supported the perception that discontinuation caused an insignificant impact on pain management. The following statement illustrates her breakdown of patients in terms of how the discontinuation had affected each subgroup depending on their expectations for pain control (or abuse):

"I'd say the patients, were in my mind sort of divided into three groups; those who, um, understood all the background, didn't want to be part of it, were happy to be get any medication that we felt would cover them instead of OxyNEO®, and they were, not that anxious, and confident that we would make that change. Then there was a group that were really terrified that this was gonna change their pain management completely, they might not get it, they would be in withdrawal and those had usually arrived at OxyContin® from many other trials and errors, and had probably been on it for four or five years, they knew exactly the dose they needed and nothing else worked, and that was probably a little smaller group, maybe 20 or 30%, then there was a very small group, and this was the group that we all hoped to eliminate, who knew that this medication could not be abused, would not be sellable, and that was maybe 5%." [MD3]

Theme 3: Existence of adequate guidelines for opioid use

Of the seven physicians, six doctors emphasized their belief that the existing guidelines for the use of opioids in Canada, and more specifically in Ontario are adequate and sufficient for physicians to prescribe them safely. There appeared to be a general perception among physicians that the use of opioids across different pain management practices will be optimized if doctors follow the regulations that are currently in place, by ensuring appropriate prescribing, safe and effective use of medications, as well as accurate conversions between opioids. However, some physicians referred to the lack of adherence to those guidelines as being the real issue. Nonetheless, a need to enforce stricter guidelines for regulating opioid prescribing was not suggested by any of the physicians or pain specialists interviewed. The following statements are representative of some of the physicians' thought s and perceptions on the current guidelines for opioid use:

> "I think we have the right regulations and the, uh, College of Physicians and Surgeons of Ontario, uh, provides, uh, guidelines and we have national opioid use guidelines as well. I think the guidelines are adequate. The challenge is getting prescribers to follow the guidelines." [MD2]

> "I think the Canadian guidelines for safe and effective opioid prescribing, if applied uniformly, will do a lot." [MD3]

> "I think there is enough regulations and I think physicians are educated and then they decide, you know, within their limits what they can prescribe or not." [MD5]

A number of physicians believed that the available recommendations were capable of helping a physician (whether specialized in pain or not) achieve successful conversions when

switching patients onto alternative pain medications without causing them to experience withdrawal symptoms. One GP stated that multiple resources, particularly the recently released guidelines by the College of Physicians, have assisted him in his practice in terms of safe prescribing and abuse prevention:

> "I think as a physician group, we are doing much better in our, within our personal group here at education and abuse prevention, uh, and as a doctor's college, I would say we're doing better as well. There now are many opportunities for education around chronic opiate prescribing and I think the biggest change that I've seen in the last year, is the publication of the college guidelines, to give us an understanding, you know, what are the numbers we should be looking for in chronic non-malignant pain management, so I think that's provided us with a lot of education, it tells us when to have a red flag for those patients, so that has been helpful for me." [MD7]

Another GP supported the narcotic database, which was put on track recently in Ontario and perceived that it is expected to enhance monitoring strategies for prescribing narcotics across the province.

> "I think the, you know, the narcotic monitoring database which was started in the past year I think or so, is excellent, I came, I did medical school in Nova Scotia and in Nova Scotia, they've had, um, uh for a long time…a narcotic database, so I think that Ontario is behind on that, um, so yeah absolutely…to me, it makes sense that, you know, if you're at a pharmacy in Toronto, that pharmacists should be able to find out if this patient has gotten, you know, narcotics anywhere else in the province, it only makes sense, so yeah I think it's good. [MD4]

Theme 4: Disapproval of the introduction of generics

One of the prominent themes that emerged from the patients' transcripts was that of limited alternatives to OxyContin®. Many patients did not feel that the medications they got switched to were controlling their pain as effectively. Therefore, it was necessary to explore the physicians' opinions on that matter. With regard to generics, some patients were unaware of their introduction in the market, others were uncomfortable trying generics or new drugs in general, and a few were willing to try them after discussing it with their healthcare providers. Physicians, on the other hand, openly indicated the adequacy of the existent pain medications and their competency in replacing OxyContin®. However, it was necessary to capture their views regarding not only the other opiates, but the introduced generics for OxyContin®. Production of generics to a particular brand is usually encouraged to facilitate patients' access to the medication by increasing supply and reducing cost. This is especially beneficial for patients who lack a drug plan that covers their medication expenses. This was not exactly the case with OxyContin® due to the abuse risk accompanying it, and instead a persistent theme of physician 'Disapproval of the introduction of generics' developed.

All but one GP were strongly against the introduction of generics and felt that it defeats the purpose of discontinuing OxyContin® in the first place. Physicians perceived that the release of generics will only result in the persistence of the addiction problem. None of the physicians has prescribed generics to their patients and six doctors discouraged using them in practice in favor of abuse prevention. The following quotes by physicians reflect that:

> "I think the generics probably just reintroduced it back onto the street again, um, I didn't switch any of my patients back to the generic version, they either stayed on OxyNEO® or

they went onto a different, um, opioid because I did have that concern at the back of my mind." [MD1]

"I'm actually very angry, what was the whole point then? What was the purpose of OxyNEO® then? Right? That makes me mad…so the whole exercise about taking it off the street is actually negated if they have a generic on the market, right?" [MD5]

"I have never used a generic controlled release and I would not recommend it…it's a mimic of, uh, of OxyContin®, and carries the same risks of substance abuse. So most pain specialists were against, the, release of generic controlled release oxycodone, and we discouraged the use, uh, and I don't use it." [MD2]

One specialist justified her disapproval of the generics by her belief that the harms occurring from this move would outweigh the benefits since this was the drug of choice for a high percentage of abusers across Canada, especially among the lower income population. While it could be beneficial for some patients who were legitimately using the medication, this consideration was viewed as being greatly outweighed by the negative consequences of abuse and addiction that would arise with the drug being re-introduced to the marketplace and at a lower and more affordable price.

"I wanted Health Canada to not, uh, participate, you know, not sanction that and just because, um, oxycodone, they say it's not more addictive but just the culture of people who are using it, oxycodone was the drug to use and it seems that, particularly among native populations and certain lower income groups, it was just like endemic, so I, I that's why I don't want the generics out there again…I don't support the generic version coming in, even for the small number that may feel more comfortable on it." [MD3]

Theme 5: Need to optimize pain management practices

Three specialists and one GP identified various challenges and proposed some ideas that would contribute to optimizing the current practices employed in pain management. They have arrived at these recommendations based on their practical experiences with the discontinuation of OxyContin®. All seven physicians made the case that switching to a different medication was successfully accomplished by the majority of their patients. However, some pointed out to a number of challenges they encountered through switching several patients to other pain medications. Although this notion did not emerge frequently enough given the small sample of physicians (and with most having a very small patient load that was on OxyContin® thereby diminishing their experiences of switching patients), it is important to identify such challenges to advise future improvements within the current practice in terms of discontinuation of chronic medications. One pain specialist described some of the impracticalities she came across while making the switch from OxyContin® to OxyNEO® for her patients:

> "We did have some significant issues for coverage, um, I had one patient in particular where I was trying to decrease the opioid she was on, and, in the whole process of the switch to OxyNEO®, getting the government to agree to cover a decreased dose of OxyNEO® was almost impossible, um, because they wouldn't give new authorizations for OxyNEO® so actually that was probably our biggest stumbling block…so unfortunately, basically either the patient had to pay for it themselves or you had to hold them at the stable dose, cause there was no way to get a change approved. I think the exceptional access program made it extremely difficult to access OxyNEO®." [MD1]

Another specialist pointed out the abruptness of the change and clarified certain issues with the short notice period that was allowed for doctors to switch patients to other pain medications. She associated this to an added pressure on the doctors to make optimum conversions for patients within a short time. Furthermore, this short notice eliminated the option of gradually weaning down OxyContin® as requested by a number of frustrated patients. However, she felt that the rationale behind suddenly discontinuing the medication was reasonable to control diversion.

> "I thought it was done quite abruptly without any warning, I guess they had to do that because if there'd been warning, it's organized and there would have been OxyContin® coming across the border and stuff…many of our patients only come every three months, so there was no way we could see all those patients and discuss with them, um, and the other thing was it was going to immediately convert to exceptional access so that, um, there was a little bit of a barrier, and then the 80 milligrams would not be available and also, um, so yeah time-wise, it wasn't enough time. I understand perhaps why they did it and I understand it was the company that set that timeline, not the provincial government or the pharmacies." [MD3]

With regard to switching patients to OxyNEO®, she encountered some difficulties with the EAP. She perceived that not only was there a delay in notifying professionals about the discontinuation, but also in processing the applications submitted for patients to start receiving OxyNEO®. Based on her past experiences with the program and a meeting with officials, she anticipated a 3-month period for processing applications and acted upon that by switching the majority of patients to other medications to avoid the wait time, which could potentially get

patients into withdrawals. The specialist stated the following indicating the inconveniences that were involved in the process:

> "I prepared my patients that it was going to take a while and uh, no I don't have a lot of confidence in that, I think they improved in the last few months in a lot of areas but not at that time, and I remember I was meeting with some provincial officials who knew this was coming…they were saying oh this was going to be really bad, and uh, they didn't, they were not allowed to add extra personnel or anything else, so, so for me I guess, I did not have trust that they could do it in a timely manner so I just knew I had to switch people over and make the application for those who really couldn't stand anything else and, and wait…it took me two or three months to keep dealing with uh back log around those requests for more information and initial refusals." [MD3]

After sharing those encounters, the specialist made several recommendations that she felt could have made the transition easier for OxyContin® ex-users. She proposed a strategy to help eliminate each challenge independently and hoped for future discontinuations of chronic medications to adopt such strategies.

> "I think the company Purdue could have worked with the provincial ODBP more closely…there should have been more websites to go to and maybe even speakers for the month just how to convert your patients and how to complete the forms, and uh, some sort of additional personnel that would process these applications, and they may have had to set aside other things but just try to process the applications." [MD3]

Emphasis was put on one area which was perceived to be a substantial subject for improvement by the participating specialists. All three specialists stressed on the need for

providing more training and/or education to family doctors and other GPs to enhance opioid prescribing in general practice. None denied the capability of a GP to prescribe medications like OxyContin® to patients. They all suggested that prescribing of opioids should not be limited to specialists; however, GPs were expected to become more comfortable with handling opioids and more knowledgeable about the guidelines for optimal pain management.

> "Family doctors probably need better training in pain management but they should have the ability to prescribe opioids and again, they need to prescribe within the prescribing guidelines, I think a specialist's role is appropriate to give them some guidance." [MD1]

> "Pain specialists are going to be more comfortable prescribing these drugs because they do it all the time, but family doctors are perfectly capable of prescribing these medications. If they're prescribed within guidelines, they're usually, uh, safe and can be, uh, effective, and uh we need more education of family doctors so that they will use these drugs when it's appropriate earlier so that they can be treated before they have to see a pain specialist." [MD2]

Some of the areas that necessitate more training for GPs according to one specialist's point of view were elaborated on in the following excerpt:

> "I can see that for a lot of doctors they wouldn't understand, still the concept of equi-analgesic opioid conversion. Opioid rotation is not well understood, so for a lot of doctors it would've provoked like, you know, what do I do? I don't know how to switch them to MS Contin or Hydromorph Contin, without putting them into withdrawal, so yes, some education, like this is what this equals [taps table], these are your three options for doing this, would've been helpful." [MD3]

Interestingly, it was believed that the problem did not just arise in practice but has actually originated from the medical school curriculum. She felt that GPs received no training to permit them to intervene in pain management. However, she claims that this has been recently adjusted. Among the errors due to lack of sufficient training, she discusses issues that had occurred to some patients with the conversion from OxyContin®. In response to the question regarding family doctors' capability of transitioning patients through the discontinuation as compared to specialists, she stated the following:

> "Doctors would do something like say oh, you're on OxyContin® 80 milligrams, let's just put you on Tramadol 300 milligrams and see how that works, well hopeless, you know, they would go into severe withdrawal…I don't think that was right, I think that they should've at least checked with a pain specialist every time they made that conversion…perhaps the pharmacist would've been more knowledgeable about whether that dose was appropriate…I mean family doctors in medical school and with their residency until recently the last two years, had zero training at all, and they would try to get out of their lack of knowledge by just saying, I don't prescribe opioids, I don't deal with chronic pain, you can't not deal with it." [MD3]

When asked to share their perceptions with regards to balancing the benefit of medications like OxyContin® versus their abuse potential, physicians proposed a number of strategies that could be adapted to help achieve that balance. The idea of a national database that could be accessible by all healthcare team members to monitor patients' use of opioids and to prevent "doctor shopping" was commonly discussed by physicians. For example, one specialist indicated the following approaches to address the need for better prescribing practices by exemplifying the regulation in a different Canadian province:

"I think that, um, Ontario specifically needs to be much better at its regulation, I came here from Alberta where the regulation of controlled substances is much better and more transparent, I think Ontario needs a system where the physicians, the, and the pharmacists, all can see if a patient is getting multiple prescriptions of so, where are they getting it from, we need to have that information much more accessible and I think patient just need to sign a consent saying if you're getting opioids, anyone who prescribes to you can look at your prescription records and see that, and I think that will go a long way toward helping some of the problems, I think they have to get it from one doctor, one dispenser, and we need to be able to see if they're doing red flag behaviors." [MD1]

Chapter 5: Discussion and Conclusion

The aim of this study was to explore the perceptions of chronic pain patients and their physicians on the impact of the discontinuation of the pain medication, OxyContin®, on patients' pain control. In this study, patients diagnosed with chronic non-malignant pain provided a detailed description of their discontinuation experiences. Targeted interviews were used to investigate the opinions of patients and their physicians about the ease or difficulty of the transition from OxyContin® to an alternative medication, the extent of pain relief attained by patients with the new protocol as compared with that attained prior to discontinuation, concerns that accompanied discontinuation, and barriers and suggestions concerning potential future discontinuation of chronic pain medications. The findings of the current study demonstrate considerable variation in patients' perceptions on the subject. In contrast, all physicians seemed to share similar opinions regarding the discontinuation. Despite the highlighted differences and/or similarities in insights among and between patients and their primary healthcare providers, an emergent need for optimizing patient care within current pain management practices was deduced from both groups through personal descriptions of their lived-experiences.

The main perceptions among participants were grasped by carefully analyzing transcripts, comparing and contrasting different data sets, and interpreting emergent findings following a constructivist approach starting early on in the process. The overarching themes derived from the in-depth information provided by the participating patients are: 1) Disagreement with the motive for discontinuation, 2) Discontinuation negatively impacted pain control, 3) Discontinuation had no impact on pain control, 4) Learning to live with pain, 5) Identification of flaws within the discontinuation process through shared experiences, 6) Choosing to get off OxyContin® permanently, and 7) Need for optimizing patient care. Since the study methodology does not aim

to develop a single theory that is alluded to by all themes, it is important to understand the significance of each of the seven themes in exploring the topic under study.

In response to the study question, "What is the impact of the discontinuation of OxyContin® on your pain control?" patients discussed numerous points directly and indirectly relevant to the question. Patients would not only describe the direct influence on their pain relief, but in addition, tend to draw attention to the indirect effects of discontinuation on pain relief. To further clarify this point, I provide the following example: For a chronic pain patient who perceives being negatively impacted by the discontinuance by receiving less adequate pain relief after switching to another medication, this direct influence of worse pain management has led to the indirect outcome of learning to live with pain. Therefore, the latter is still considered among the discontinuation influences on that patient's pain condition, although it might not appear to be a direct response to the study question. For associating necessary linkages and interpreting such diverse perceptions, which are greatly influenced by each patient's experience and attitude towards it, such complexities with the participants' lived-experiences must be considered. This is particularly important in the case of chronic pain patients, given the multidimensional and subjective nature of pain itself and how every patient differently perceived the change.

Patient perceptions that represent the direct impact of the discontinuation on their pain management are illustrated by the following two themes: 'Discontinuation negatively impacted pain control' and 'Discontinuation had no impact on pain control.' Perceptions that capture patients' reflections on the discontinuation process as a whole and allow for highlighting current challenges in such provincial actions are illustrated by the following two themes: disagreement with the motive for discontinuation and identifying flaws in pain management practices through shared experiences. The theme of 'Learning to live with pain' was included as it represents the

indirect impact of discontinuation on a number of participants, as was explained earlier. Moreover, it provides evidence for the presence of substantial barriers to adequate pain management among pain sufferers further supporting the category 'Need for optimizing patient care.' The theme of 'Choosing to get off OxyContin® permanently' was uniquely identified as a significant patient perception within the context of the current study. This theme was required to explore the experiences of patients who were voluntarily discontinuing OxyContin®, including the reasons behind that decision, regardless of whether it was triggered by the inaccessibility to OxyContin, and details of the experience. This was considered specifically important as it produced information on a subject that has not been sufficiently tackled in research, and other patients' previous consideration of stopping OxyContin® use necessitated exploring this theme in depth. In addition, this is anticipated to provide a better understanding of the impact of discontinuation on the patient population that might not have received alternative pain medications for any possible reason. Finally, patients' perceptions allowed for deducing the theme of 'Need for optimizing patient care' through the problem areas they put emphasis on while recalling their experiences with the discontinuation. It is important to note that although themes five and seven seem to overlap, they were not merged into one theme, as theme seven discussed the suggestions provided by patients to address the flaws highlighted in their discontinuation experiences under theme five. Therefore, the problem areas were grouped under theme five and the recommended approaches under theme seven, representing closely related but consequent points from patients' stories.

Interviews with physicians were more concise and strictly focused on a number of profession-related matters such as healthcare providers' personal opinions about discontinuance, availability and efficacy of alternative medications, and medical challenges encountered and

ways of bypassing them in the future. Five distinct themes were extracted from physicians' perceptions on discontinuation; 1) Support for the motive for discontinuation, 2) Discontinuation insignificantly impacted pain control, 3) Existence of adequate guidelines for opioid use, 4) Disapproval of the introduction of generics, and 5) Need for optimizing pain management practices. There was no variation in physicians' responses in concluding that the impact of discontinuation on pain control was insignificant and support for the necessity to withdraw OxyContin® from the market. Perceptions of patients and physicians interestingly overlapped in agreeing on the imperative need to optimize current practices employed in pain management. Several suggestions were made by participants in both groups to enhance patient care. The flaws pointed out by participants and the discussed areas for improvement have been addressed in the available body of literature. This chapter aims to evaluate these findings within the context of the available literature and to illuminate novel findings. In the following sections, I will ground the findings of the current study in earlier literature to identify a gap in research that is reflected by the scarcity of studies directly addressing the discontinuation of OxyContin®. This chapter will also discuss study strengths, limitations, and opportunities for future investigation.

5.1 Motive for discontinuation of OxyContin®: For or Opposed?

A point of disagreement between patients and physicians was their approval or disapproval of the reasons for discontinuing OxyContin® and their perceptions of whether phasing out the medication will fulfil its purpose of limiting diversion. Supporting the motive for discontinuation was a view shared by all physicians participating in this study. Specialists and GPs clearly applauded the change and indicated that it was a step in the right direction. However, specialists seemed more knowledgeable about non-medical users' diversion to other medications, which they associated with the unavailability of OxyContin®, possibly due to their exposure to a

much larger population of pain patients. Specialists communicated their doubts that targeting and restricting access to one problematic medication with abuse-potential, while leaving other opioids easily accessible is not likely to address addictions that have become a national epidemic. This was supported by many medical experts who were uneasy about the discontinuation, especially with Health Canada identifying lack of evidence on the ability of reformulated OxyContin® to reduce rates of prescription opioid abuse (Poynter, 2012; Kirkup, 2012). However, physicians agreed that the popularity of OxyContin® among non-medical users necessitated its discontinuation and confirmed the availability of equally effective pain medications for legitimate users.

While physicians were evaluating discontinuation from a professional view, patients' reflections were based on their personal experiences. It is important to note that it is very likely for their perceptions to be driven by how they were affected by discontinuation in terms of their pain control. The impression that the involved parties (i.e. Purdue Pharma and the government) made the wrong decision by discontinuing OxyContin® in an attempt to reduce the significantly high rates of diversion associated with its use was stressed by the majority of patients. Patients opposed the phasing out of OxyContin® for two main reasons; under-treatment of their pain and persistence of the abuse problem. Disagreement with the motive for discontinuation was not limited to the patients in the current study. It has been noted in several lay articles that were published at the time of discontinuation that the major outcome resulting from this change is not expected to prevent abuse {Kirkey S., 2012 92 /id}(Ogilvie M., 2012;Strachan Y., 2012;Weeks C., 2012). Several healthcare professionals and addiction experts voiced their concerns about the sudden discontinuance of OxyContin® eventually leading to diversion of addicts to other accessible substances of abuse like heroin (Kirkey S., 2012;Ogilvie M., 2012;Strachan Y.,

2012;Weeks C., 2012). According to these reports, phasing out the most commonly abused opioid in Canada was likely to trigger other consequences such as increased emergency visits of abusers due to withdrawal, pharmacy robberies, and elevated crime rates, especially in the First Nation's communities where the highest addiction rates occurred.

Such concerns were supported by findings reported on the American experience of discontinuing OxyContin® that took place in 2010 (Cicero et al., 2012). Data collected from July 2009 through March 2012 demonstrated that the rates of addiction to prescription drugs have not decreased with the introduction of the tamper-resistant formulation of OxyContin®. Although the abuse of OxyContin® was specifically reduced, the rates of abuse of other opioid medications and heroin were shown to increase significantly within the same period, suggesting that addicts replaced OxyContin® with these alternates. Findings from another recent observational cross-sectional study were similar, showing that higher rates of abuse of specific long-acting opioids coincided with the introduction of the tamper-resistant formula in the U.S.A. (Cassidy et al., 2014). A qualitative study conducted in the U.S.A. by Mars and colleagues used semi-structured interviews between 2010 and 2012 to illustrate the transition of abusers of OxyContin® to injecting heroin (Mars et al., 2014), which is considered to be of higher risk to overall public health than OxyContin® (Cicero et al., 2012).

The above mentioned expert opinions and study findings were focused on individuals who were using OxyContin® outside of its medical indications. Data regarding the fate of chronic pain patients following discontinuation is lacking from the available literature. Therefore, this study's findings on patient concerns about and reports of inadequately controlled pain, the primary reason for opposing discontinuation, are novel. All patients who were against discontinuing OxyContin® perceived obtaining less adequate pain relief from their alternative

medications. In contrast, patients who perceived obtaining equivalent pain relief did not oppose or support discontinuation but rather appeared neutral to the change. This backs up the deduced hypothesized correlation between patients' perceptions on the change and the way it has impacted their pain management.

5.2 Differently perceived impact of discontinuation on pain relief

The impact of the discontinuance of OxyContin® on pain control was perceived differently by patients in this study, with 61.5% reporting a negative impact and 38.5% reporting no impact. The established role of environmental and psychological factors in modifying a patient's perception of pain (McGrath, 1994) opens the possibility that patient perceptions of their post-discontinuation pain control could be affected by psychological influences that might have originated at the time of discontinuation. However, seeing that patients were interviewed nearly two years after the phase-out of OxyContin®, psychological factors were expected to minimally influence their current perceptions about the impact, increasing the likelihood of patients having conveyed their true perceptions about pain control and current treatments.

Eight of the thirteen patients perceived lower pain control and associated it with the discontinuation of OxyContin®. All eight switched to the new tamper-resistant formulation of the drug. Recently, a review of clinical evidence was carried out to validate patient objections to the tamper-resistant formulation substituting for OxyContin® in the U.S.A. (Argoff et al., 2013). Interestingly, the objections common to investigated patients were consistent with the complaints about OxyNEO® that were identified by patients in this study; "costs more," "not covered by insurance," "can't feel it working," and "causes adverse events" (Argoff et al., 2013). Argoff and colleagues (2013) found evidence validating patient tolerability objections related to the difficulty of swallowing the medication and efficacy objections related to a delayed onset of

action – both complaints indicated by patients in the present study. However, authors showed that validating objections related to cost and insurance coverage require direct involvement of the patient's insurer and pharmacist to inquire about plans and out-of-pocket costs respectively (Argoff et al., 2013). A gap in the literature researching clinical data on tamper-resistant formulations was evident through this review. Furthermore, no data was found regarding perceptions on discontinuation implying no or insignificant impact on patients' pain control which necessitates building on the currently scarce baseline data available on the topic.

5.3 Accepting pain and learning to live with it

The majority of patients appeared to be quite accepting of their pain, acknowledging its persistence, and getting on with their lives as normally as possible. Ward and colleagues (1993) found that some patients felt that pain was unavoidable and expressed clear perceptions of accepting to live with it by indicating their expectations that medications might not necessarily relieve pain as desired (Ward et al., 1993). Indeed, some patients expressed their low expectations of relief from treatment and appeared to be handling their medical conditions according to their personal preferences. For example, a number of patients mentioned relying on non-pharmacological approaches.

Acceptance of pain does not simply mean that a patient is experiencing a low level of pain (McCracken, 1998). This concept aligns well with some patients' claims in the present study, that understanding the persistent nature of their illness has contributed to their acceptance of experiencing pain over time, despite currently suffering from poorly managed pain. McCracken (1998) reported that positive patient outcomes such as less pain-related anxiety and avoidance, less depression, less physical and psychosocial disability, and more daily uptime appeared to be associated with greater acceptance of pain (McCracken, 1998). Similarly, a

prospective study investigating relations between acceptance of pain and patient functionality demonstrated that patients with greater acceptance of their pain condition reported less medication use, and better functioning on the emotional, social, and physical levels (McCracken and Eccleston, 2005). Such correlations encourage increasing medical services that are likely to aid patients in accepting their pain and learning to live with it, thus working towards increasing their diminished activity and quality of life aspects.

5.4 Discontinuation experiences revealed flaws within the process

No data currently exists to provide sufficient evidence of the negative consequences faced by patients who discontinued OxyContin® at the time of discontinuation. The current study provides novel information about specific details of patients' experiences including sources from which patients learned about discontinuation, perceived quality of communication with professionals, perceived role of different healthcare providers through discontinuation, assessing adequacy of the provided information, and perceived efficacy of alternative medications prescribed to them. Investigating such patient-focused details in depth revealed the presence of various flaws within the process itself and raised concerns regarding the readiness for such abrupt phase-outs of pain medications. By presenting such data and setting the light on some problems with the OxyContin® discontinuation experience from a patient's perspective, taking appropriate measures to avoid similar problems and ensure smoother transition in future discontinuations of other painkillers is likely to be achievable. Better understanding is expected to provide safeguards against making the same errors and causing the same negative outcome.

That patients learned about the discontinuation from resources other than their healthcare providers was surprising and raised a concern about patient-physician communication effectiveness and exchange of information. Nonetheless, other factors such as patients being

between visits and media channels announcing the change before doctors could inform patients about it contributed to this misfortune. Even though all family doctors perceived that they had achieved a successful switch to an alternate medication for the great majority of their patients, this was not reflected in the shared experiences of a number of their patients whose pain control was negatively impacted by the switch. Two possible reasons for this contradiction could be the patients' lack of sufficient communication of their pain relief status to their physicians or potential physician recall bias given the time factor and small number of switch incidents. The first presented an interesting notion as it was contradictory to quantitative data obtained from patients' interviews, which demonstrated that the majority of patients (92.3%) indicated the ease of asking questions to their medical staff, hence reflecting unlikely barriers in communication.

In addition, a communication gap between patients' pharmacists and physicians was also identified through the details shared about perceived extent of integrating medical care. This was consistent with findings from a recent provincial survey exploring pharmacists' perceptions and experiences regarding opioid dispensing in Ontario (Kahan et al., 2011c). Forty three percent of pharmacists reported the difficulty of directly reaching physicians by telephone, and 28% indicated that physicians did not return their calls in a prompt manner (Kahan et al., 2011c).

Another frequent complaint was the lack of involvement in the decision-making process following discontinuation experienced by patients. Some were neutral to this situation, while others appeared upset about it inducing pro-active information-seeking behaviors. A review of the published surveys investigating patients' preferences for partnering with their physicians in decision-making about their treatments found that it is common for some patients to prefer participating in developing medical plans for their illnesses and for others to adopt a passive attitude towards it (Benbassat et al., 1998). Deber and colleagues (1996) demonstrated that

patients desire participation in the decision-making process but prefer passing on responsibility of problem solving to physicians (Deber et al., 1996). Physicians who involve their patients in the treatment decision-making process tend to have more satisfied patients than physicians who are more authoritarian (Anderson and Zimmerman, 1993). These findings support the protests of patients regarding the importance of being more informed and involved in decision-making.

Also, some patients in the current study perceived the information provided about discontinuation as being insufficient and it was often noted that physicians did not meet their patients' expectations in terms of informational needs on many occasions. Patients' desire to obtain as much information as possible is reported to be under-estimated by clinicians (Ong et al., 1995). Ong and colleagues identified the two main reasons behind patients' information-seeking and information-giving behaviors as "the need to know and understand" and "the need to feel known and understood" (Ong et al., 1995). In the present study findings, those two notions were apparent in patients' search for information whether from clinicians or other sources and their willingness to openly communicate concerns and perceptions to physicians.

One common perception that was conveyed by some patients was feeling unheard and having to struggle to deliver a particular concern as a result. This was reflected in some patients' experiences with ineffective alternative medications following discontinuation despite trying to verbally communicate such concerns. This is a huge concern and might be indicative of shortcomings in patient-oriented individualized care within current practices. In reviewing the significance of carefully listening to patients and attending to their needs in medical behavioral research and how that approach can influence their perceived quality of care, well-documented incongruities appeared between clinicians' orientation towards illness and patients' personal experiences of illness (Frantsve and Kerns, 2007;Stillman et al., 1977;Zola, 1973). Historical

evidence demonstrates that a patient-centered approach helps to optimize the services offered to patients (Robinson et al., 2008;Smyth, 1962;Wanzer et al., 2004).

Platt and colleagues (2001) stressed the importance of language used by physicians in communicating to patients to demonstrate that their opinions are valued (Platt FW et al., 2001), encouraging more effective patient-physician relationships – a concept that is highly applicable and necessary in the field of pain management. Attentiveness to patients' "clues" (also known as active listening), and not just verbally expressed matters, was also encouraged by researchers to further emphasize the important role entailed in listening to both voiced and non-voiced patient information (Lang et al., 2000). For example, White and colleagues (1994) found that, at the end of 21% of interviews, "Oh, by the way…" statements gave rise to new patient concerns (White et al., 1994). Neighbour (1987) introduced the concept of "the inner consultation" and suggested that physicians pay attention to information-rich moments identified through several spoken or unspoken "cues" such as long pauses, avoiding sensitive issues, increasing energy level of speech or even physical gestures like bodily stillness or changes in gaze (Neighbour, 1987).

Some patients identified a lack of pharmacist intervention through the discontinuation process and in general medical care that was rather disturbing. Only a few patients sought or obtained help from their pharmacists. This appeared to be due to their uncertainty in gaining additional benefit from pharmacy services or their better relationships with their physicians. Findings from a recent survey administered to pharmacists in Ontario demonstrated a minimal role played by pharmacists in the care of chronic pain patients (Kahan et al., 2011c). An exploration of the perceptions of community-dwelling older patients of their relationship with their primary healthcare providers are consistent with this theme (Keshishian et al., 2008). Older patients in the study perceived a better quality of relationship with their physicians than with

their pharmacists (Keshishian et al., 2008). Furthermore, unlike the evidence associated with patient-physician relationships, the absence of proof that the quality of patient-pharmacist relationship predicts medication-related knowledge, medication-related outcome expectations, and self-efficacy for medication management indicated that pharmacists are not optimally meeting patients' medical needs and are expected to fulfill their true potential through adopting a patient-centered approach (Keshishian et al., 2008). This would also help compensate for physician and/or specialist care inaccessibility issues, encountered by some patients in this study, by enhancing the role of pharmacists as primary care givers within the pain community.

5.5 Comfort levels of administering or prescribing OxyContin®

In the current study, specialists appeared to be at a remarkably higher comfort level when prescribing opioids as compared to GPs. Most family doctors preferred to rely on medications other than opioids for pain management in their practices. Social constraints on these practitioners, including being subject to scrutiny due to the abuse problem linked to opioid use, are among potential reasons for reluctance to prescribe such medications. This raised a concern of compromising patient pain relief and quality of life, especially with under-treatment of pain due to under-utilization of opioid medications for chronic non-cancer pain as previously reported in Canadian studies (Moulin et al., 2002).

The perceptions conveyed by participants are echoed in multiple studies (Scanlon MN and Chugh U, 2004;Victor et al., 2009). A study conducted to explore attitudes of family doctors towards the use of opioids in chronic nonmalignant pain in Calgary demonstrated a need for GPs to increase their comfort levels toward opioids, thought to be low due to the lack of sufficient physician education on appropriately handling opioids (Scanlon MN and Chugh U, 2004). Similarly, Victor and colleagues (2009) reported findings indicative of higher comfort levels of

prescribing emergency room formulations of opioids in specialists as compared to GPs. The likelihood of specialists to prescribe ER formulations was shown to be 50% higher than that of GPs (Victor et al., 2009). Benett & Carr (2002) also recognized "opiophobia" as a barrier to effective opioid analgesia (Bennett and Carr, 2002).

Positioning GPs at a lower comfort level for opioids was done by patients in the present study, indicating that feelings of discomfort were transferred from physicians to their patients. This might be problematic for some patients who have been administering the medication for extended durations as it could leave a patient feeling medically insecure, skeptical of their doctors' capability in optimizing care, or even ashamed of taking the medication (as was noted with some participants).

The low comfort level associated with OxyContin® was not just captured in physicians' reluctance to prescribe it, but was also apprehended in some patients' unwillingness to administer it. Current findings illustrated a theme among patients indicative of patient concerns about long-term therapy with OxyContin® and the physical dependence that accompanies its use. A study conducted to measure the correlation between patients' attitudes toward opioids and barriers they likely pose to treatment identified fear of addiction, tolerance, and adverse events from medication as the major concerns about using opioids (Ward et al., 1993). This finding explains some patients' lower comfort level towards administering OxyContin®.

Opiophobia might present a serious obstacle to the ability to optimize pain management within our community, and the presence of adequate opioid use guidelines to aid physicians through safe and effective prescribing has been repeatedly emphasized in the current pool of literature. Moreover, by sufficiently grasping and following those regulations, physicians are expected to waive any concerns causing anxiety for patients hence increasing patients' comfort

levels with administering opioids and enhancing their overall experience. Wachter (2007) supports this notion and provides several opioid-specific recommendations to address opiophobia in current practice (Wachter, 2007).

5.6 Need for optimizing current patient care

The majority of patients in the present study felt that they deserved to receive better healthcare services to optimize their pain management. All physicians felt that they should be able to optimize their services and achieve better care to patients, not only referring to themselves as physicians but also involving members of the whole healthcare infrastructure within their vision. This revealed general consensus on the need for optimizing current pain management practices and overall patient care.

Various approaches to diminish the risk of abuse were proposed by patients who were disadvantaged by and opposed discontinuing OxyContin®. They claimed the possibility of tackling the abuse problem without having to compromise pain management by decreasing effective options available to patients. Such claims of providing effective pain management while reducing risk of diversion were documented by researchers in several studies that investigated the margin between pain and drug abuse (Passik and Kirsh, 2008; Webster & Fine, 2010). Suggestions included monitoring opioid prescribing and use, individualizing pain management practices and limiting opioid prescriptions to chronic pain sufferers and not for managing acute pain. These suggestions are supported by numerous studies and commentaries that also provided evidence that detection and control of opioid misuse can be achieved in primary care by following such recommendations (Kahan et al., 2011a;Kahan et al., 2011b;Passik, 2009;Sehgal et al., 2012;Volkow and McLellan, 2011).

The notion of existent flaws within current practices of pain management was alluded to by most physicians. The main challenge seemed to be in finding a balance between effectively managing opioid abuse and maintaining optimum pain control for chronic pain sufferers. Thus, maximizing the benefits of effective and safe medications like OxyContin® while minimizing the huge diversion risk that accompanies its use, was a difficult equation that did not seem achievable within the current medical practice, according to physicians. Most physicians therefore contributed to the theme of 'Need for optimizing patient care' by making some suggestions to better regulate opioid use to avoid diversion.

Among the strategies proposed was developing a national database to enable monitoring the use of opioids, developing pain contracts, and performing urine screening for illicit drug use on a random basis. Kahan and colleagues (2011) also recognized a provincial prescription database among the most helpful approaches for improving opioid dispensing (Kahan et al., 2011c). Prescription drug monitoring programs are believed to reduce opioid abuse while fostering appropriate analgesia to patients (Gugelmann and Perrone, 2011). Manchikanti and colleagues (2006) conducted a prospective, consecutive study and found that the risk of abuse was significantly reduced by combining compliance monitoring and random urine drug testing (Manchikanti et al., 2006). A recent review reported the practicality of urine drug testing in practice and identified it as a "vital first step" towards containing abuse risk for optimizing pain treatment with prescription opioids (Christo et al., 2011). Another study conducted by Gourlay and colleagues (2005) described a ten-step "universal precautions" approach for assessing and managing the chronic pain patient that recognized treatment agreement and urine drug testing as essential steps (Gourlay et al., 2005). Furthermore, Saira (2010) emphasized the importance of coordinating medical services by adopting an integrated healthcare team approach in managing

opioid dependence (Jan, 2010). This notion was not as clear in the current study, yet there were several physician interviews in which this concept was subtly implied.

It was strongly established that the current national and international guidelines for opioid use are adequate for ensuring appropriate and responsible prescribing of narcotics. Recently, new Canadian guidelines for opioid use in chronic non-cancer pain were published, with the aim of guiding physicians through prescribing and monitoring long-term use of opioids in the most safe and effective manner possible (Furlan et al., 2010). Kahan and colleagues (2011) published two parallel summaries of the Canadian guidelines for opioid use targeted at family physicians to provide them with a practical outline for opioid prescribing for general and special populations (Kahan et al., 2011a;Kahan et al., 2011b). A range of other guidelines for opioid use geared toward helping physicians and other healthcare providers to guarantee optimum pain control with available opioids (Chou et al., 2009;Jovey et al., 2003;Manchikanti et al., 2006). Physicians in the current study did not indicate a need for enforcing more recommendations for opioid use, which seems logical given the numerous resources available. However, they highlighted the non-compliance of many prescribers with guidelines, as well as insufficient education and training of professionals as problem areas that need urgent attention. Such perceptions were consistent with findings from a survey which demonstrated that clinicians have inadequate understanding of the regulations and policies that govern prescribing and use of opioid analgesics (Gilson et al., 2007). Consistently, Victor and colleagues (2009) obtained and analysed data from a national database in the U.S.A., and hypothesized that the availability of pain-treatment guidelines and education alone might not suffice in influencing pain management practices (Victor et al., 2009). Hence, it is apparent that professionals believe that there is still room for optimizing patient care

despite ample guidelines, and call for further research assessing the benefits and pitfalls of current practices.

In the present study, while specialists confirmed the capability of family doctors to prescribe medications like OxyContin® despite their belief that GPs lack sufficient training and education to handle opioids with the same comfort level as pain specialists, some patients expressed their uncertainty of GPs' proficiency in managing such medications. Patients backed up their assumptions by making claims that GPs that overprescribed OxyContin® and made it available to unsuitable individuals, were the primary contributors to the high rates of abuse. Indeed, based on data from the 2006 National Survey of Drug Use and Health, Denisco and colleagues (2008) found that the majority of prescription opioid abuse appears to be associated with the increased environmental availability of opioids rather than illicit use of directly prescribed medications (Denisco et al., 2008). This means that higher abuse risk is imposed through sharing medications with family and friends, which further characterizes the need for stricter opioid monitoring techniques such as pill counts and those strategies proposed by patients and physicians.

Darer and colleagues (2004) surveyed a sample of physicians from different levels of the healthcare hierarchy (including nonsurgical specialists and family doctors) about their perceptions of the adequacy of chronic illness care training in ten competencies (Darer et al., 2004). Four of the ten competencies; chronic pain, patient education, coordination of services and interdisciplinary teamwork were of particular importance to the present study. Alarmingly, most physicians reported less than adequate chronic disease training in all ten competencies (Darer et al., 2004). This was consistent with the specialists' views on the insufficiency of training and education received by healthcare providers (especially GPs) in this study, which

they referred to in justification of some patients' negative experiences with the discontinuation of OxyContin®. Furthermore, the authors denoted the growing need for revising curricula in medical schools to prepare physicians for treating the increasing masses with chronic illnesses – a notion that was referred to by one specialist in the current study. Other studies also recommended more physician education on matters like deciding on patients' need for referrals to pain specialists and/or other appropriate resources (Jan, 2010). In 2009, a panel of pain specialists identified the need for user-friendly education tools that familiarize physicians with several pain-related topics to be developed and made available (Varrassi et al., 2010).

Pharmacists' comments in the Ontario survey conducted by Kahan and colleagues (2011) made recommendations that align with the need for providing more training to opioid prescribing physicians (Kahan et al., 2011c). Similar to results from the current study, the theme of inadequate guidance and monitoring of physicians' prescribing was derived from pharmacists' experiences in practice, and raised concerns about prescribing higher than needed doses, prescribing to wrong candidates, and readily making early refills (Kahan et al., 2011c).

The discussed shortcomings in the current pain management practices should be prioritized as major barriers to optimum patient care which could amplify an already huge problem within our community. It is therefore essential for professionals from all levels of the hierarchy to co-operate with health officials in addressing the identified flaws and in employing some of the strategies proposed through this study, most of which are well-documented recommendations in current pain literature.

5.7 Study strengths, limitations and future directions

Current study findings significantly contribute to the existing body of knowledge in pain research and serve in filling a gap that has not been addressed earlier. This study focused on

individual lived-experiences of patients and their physicians related to the discontinuation of OxyContin®, a painkiller that was shown to be safe and effective for use in moderate to severe chronic pain. Participants provided novel information about the perceived impact of discontinuation on pain control, which allowed for better understanding of experience details including efficacy of alternative medications. Through sharing their experiences, participants also identified numerous flaws within the discontinuation process, thus calling for optimizing the currently employed pain management practices. The current research study provides baseline information on the effect of chronic medication discontinuances on patients and healthcare professionals in the pain community, by delivering rich in-depth descriptions of patients' and physicians' experiences.

Inclusion of a diverse sample of patients and physicians represents one of the main strengths of the current study. Exploring experiences of physicians' at different clinical levels of hierarchy (i.e. GPs and pain specialists) as well as retrieving information from a group of chronic pain patients residing in rural and urban communities across the province presented a highly heterogeneous sample with respect to characteristics. This allowed for diverse perspectives on the process and outcomes to be captured, which is always warranted in pain research due to the subjectivity of the topic so that a wide range of opinions is sought. Also, obtaining perceptions from both a patient angle and a physician angle illuminated certain points of agreement and controversy about the topic. This gave rise to additional venues for exploring discontinuation experiences from both standpoints and for considering the flaws and strategies proposed by both groups, and perhaps even for validating them in future research.

Another point of strength lies in that the patients' themselves were reflecting on their experiences and findings were directly derived from the clustering themes that emerge. Patient

feedback on the discontinuation was surprisingly the only one lacking among the other expressed opinions of professionals, health officials and politicians. This adds value and credibility to the study findings on the identified perceptions, especially for those ones that overlap with physicians' insights as well.

Although this study has contributed useful information to research by providing detailed descriptions of patient and physician discontinuation experiences, there are several limitations to the study. Firstly, a small sample of community-dwelling adults provided the findings which might therefore not be generalizable to other population groups like older or younger individuals suffering from chronic pain and patients in long-term care facilities. For example, older adults were under-represented in the current study and therefore findings might not necessarily apply to this critical age group, thus presenting a limitation of the study. However, this might justify a need for future research on those areas in which stratifying larger samples and following a subgroup analysis approach to investigate applicability of current study findings on a broader scope could produce interesting discoveries. For example, future research could aim to discover differences and/or similarities in perceptions of patients from urban and rural communities as well as differences in perceived impact of discontinuation and consequent quality of care among patients from general primary care as compared to patients from specialty practice. Future studies should also sample patients from different Canadian provinces, particularly those where OxyContin® was not delisted, to allow for comparing differences and/or similarities between the perceived impact according to patients and healthcare providers. Such comparisons could be made by administering a questionnaire to large samples based on frequent themes that emerged from this study.

Secondly, a potential sampling bias could have occurred from the patient recruitment techniques utilized in this study. This is because patients who directly responded to the posters or were referred through physicians could have been those with strong opinions (positive or negative) about the subject being investigated. Perceptions obtained in this case might not necessarily be indicative of the general population of chronic pain patients. As a result, future directions for other studies include recruiting and randomizing large samples to collect prospective quantitative and qualitative data since looking at the progressive change of patients' perceptions could build up on the foundational information provided by the current study.

Thirdly, this study relied on patients' and physicians' personal recall of their experiences with the discontinuation which occurred over a year ago. Thus, findings are subject to potential recall biases among participants. Also, most patients tend to place maximum focus on the negative happenings in their experiences. Further reporting bias could occur as a result.

Finally, due to time and resource limitations, pharmacists' perceptions were not included in the current study which provides more opportunities for future directions targeted towards investigating pharmacists' opinions. Obtaining input from not only patients, but all the involved parties, about all aspects of pain management would firstly benefit patients themselves and then the whole healthcare infrastructure by implementing future approaches recommended for optimizing pain management.

5.8 Conclusion

The current research study was primarily geared to exploring the perceptions of chronic pain patients on the impact of the discontinuance of OxyContin® on their pain control, thus tackling and filling a gap in research where further investigation was warranted due to the absence of reported findings about Canadian patients' experiences. Evidence obtained from the

body of literature about the discontinuation of OxyContin® was very minimal, which meant that the current study was not guided by solid findings from a similar experience. Therefore, this study has delivered preliminary and novel data by providing thorough descriptions of patients' and physicians' discontinuation experiences. Several aspects that automatically come into play when seeking opinions on pain control, therapeutic effectiveness, and overall medical care were explored among the details covered in this study. As a result, numerous inadequacies within the process acting as barriers to optimum care were identified by patients and physicians, which gave rise to prominent themes representing a need for optimizing current pain management practices. Several strategies were proposed by participants that could be employed in future discontinuations of chronic medications in order to enhance medical outcomes by avoiding the shortcomings encountered with the discontinuation of OxyContin®. This inquiry yielded comprehensive data that is very personal and individualized about each participant's experience that is imperative to attain full understanding of the first discontinuation and reformulation (into a tamper-resistant form) of an opioid indicated for chronic pain in Canada.

References

Afilalo,M, M S Etropolski, B Kuperwasser, K Kelly, A Okamoto, H Van, I, A Steup, B Lange, C Rauschkolb, J Haeussler, 2010, Efficacy and safety of Tapentadol extended release compared with oxycodone controlled release for the management of moderate to severe chronic pain related to osteoarthritis of the knee: a randomized, double-blind, placebo- and active-controlled phase III study: Clin Drug Investig., v. 30, p. 489-505.

Agency for Health Care Policy and Research, 1992, Acute pain management: Operative or medical procedures and trauma, Acute Pain Management Guideline Panel.Clinical practice: Rockville MD USA, Department of Health and Human Services.

AGS Panel on Persistent Pain in Older Persons, 2002, The management of persistent pain in older persons: J Am Geriatr Soc, v. 50, p. S205.

American Geriatrics Society, 1998, The management of chronic pain in older persons. AGS Panel on Chronic Pain in Older Persons.: Geriatrics, v. 53 Suppl 3, p. S8-24.

American Pain Society Subcommittee on Quality Assurance Standards, 1990, Standards for monitoring quality of analgesic treatment of acute pain and cancer pain.: Oncol Nurs Forum, v. 17, p. 952-954.

Anderson,LA, M A Zimmerman, 1993, Patient and physician perceptions of their relationship and patient satisfaction: a study of chronic disease management: Patient.Educ.Couns., v. 20, p. 27-36.

Andrade,DC, J W V Faria, P Caramelli, L Alvarenga, R Galhardoni, S R D Siqueira, L T Yeng, M J Teixeira, 2011, The assessment and management of pain in the demented and non-demented elderly patient: Arq Neuro-Psiquiatr, v. 69, p. 387-394.

Argoff,CE, S P Stanos, M S Wieman, 2013, Validity testing of patient objections to acceptance of tamper-resistant opioid formulations: J Pain Res, v. 6, p. 367-373.

Artuso A, 2012, OxyContin to be harder to get in Ontario: Available at: http://cnews.canoe.ca/CNEWS/Politics/2012/02/17/19395201.html..

Benbassat,J, D Pilpel, M Tidhar, 1998, Patients' preferences for participation in clinical decision making: a review of published surveys: Behav.Med, v. 24, p. 81-88.

Bennett,DS, D B Carr, 2002, Opiophobia as a barrier to the treatment of pain: J Pain Palliat.Care Pharmacother, v. 16, p. 105-109.

Blyth,FM, L M March, A J Brnabic, L R Jorm, M Williamson, M J Cousins, 2001, Chronic pain in Australia: a prevalence study: Pain, v. 89, p. 127-134.

Boulanger,A, A J Clark, P Squire, E Cui, G L Horbay, 2007, Chronic pain in Canada: have we improved our management of chronic noncancer pain?: Pain Res Manag., v. 12, p. 39-47.

Bruckenthal,P, 2008, Assessment of pain in the elderly adult: Clin Geriatr Med, v. 24, p. 213-2vi.

Burton,AK, G Waddell, K M Tillotson, N Summerton, 1999, Information and advice to patients with back pain can have a positive effect. A randomized controlled trial of a novel educational booklet in primary care: Spine (Phila Pa 1976.), v. 24, p. 2484-2491.

Busby,C, W B P Robson, 2013, Managing Healthcare for an Aging Population: Does the Demographic Glacier Portend a Fiscal Ice-Age in Ontario?: CD Howe Institute E-brief, v. 148.

Canadian Agency for Drugs and Technologies in Health, 2011, The Use of OxyContin and OxyNeo in Adults: A Review of the Evidence on Safety: Available at: http://www.cadth.ca/media/pdf/htis/sept-2011/RC0301_OxyNEO_final.pdf.

Canadian Center on Substance Abuse, 2011, OxyContin FACTSHEET: Available at: http://www.ccsa.ca/Eng/Pages/default.aspx.

Cassidy,TA, P DasMahapatra, R A Black, M S Wieman, S F Butler, 2014, Changes in prevalence of prescription opioid abuse after introduction of an abuse-deterrent opioid formulation: Pain Med, v. 15, p. 440-451.

CBC News, 2012, Time Bomb: Available at: http://www.cbc.ca/fifth/2011-2012/timebomb/.

Charmaz,K. Constructing grounded theory: A practical guide through qualitative research. 2006. London: Sage.

Chau,DL, V Walker, L Pai, L M Cho, 2008, Opiates and elderly: use and side effects: Clin Interv.Aging, v. 3, p. 273-278.

Chou,R, G J Fanciullo, P G Fine, J A Adler, J C Ballantyne, P Davies, M I Donovan, D A Fishbain, K M Foley, J Fudin, A M Gilson, A Kelter, A Mauskop, P G O'Connor, S D Passik, G W Pasternak, R K Portenoy, B A Rich, R G Roberts, K H Todd, C Miaskowski, 2009, Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain: J Pain, v. 10, p. 113-130.

Christo,PJ, L Manchikanti, X Ruan, M Bottros, H Hansen, D R Solanki, A E Jordan, J Colson, 2011, Urine drug testing in chronic pain: Pain Physician, v. 14, p. 123-143.

Cicero,TJ, M S Ellis, H L Surratt, 2012, Effect of abuse-deterrent formulation of OxyContin: N Engl J Med, v. 367, p. 187-189.

Cicero,TJ, J A Inciardi, A Munoz, 2005, Trends in abuse of Oxycontin and other opioid analgesics in the United States: 2002-2004: J Pain, v. 6, p. 662-672.

Clark VLP, Creswell JW, Green DO, Shope RJ, 2008, Mixing quantitative and qualitative approaches : An introduction to emergent mixed methods research, Handbook of emergent methods: Newark, Guilford Press.

Cleeland,CS, K M Ryan, 1994, Pain assessment: global use of the Brief Pain Inventory: Annals of the Academy of Medicine, Singapore, v. 23, p. 129-138.

Code,B, J Bonica. Epidemiology of pain. 2001. Philadelphia, PA, Lippincott, Williams & Wilkins.

Costantini,M, P Viterbori, G Flego, 2002, Prevalence of pain in Italian hospitals: results of a regional cross-sectional survey: J Pain Symptom Manage, v. 23, p. 221-230.

Cresswell,JW, 2002, Mixed methods procedures, Research design.In: Qualitative, quantitative and mixed method: p. 208-227.

Creswell,JW, 2013, Research design: Qualitative, quantitative, and mixed methods approaches, Sage.

Crook,J, E Rideout, G Browne, 1984, The prevalence of pain complaints in a general population: Pain, v. 18, p. 299-314.

Cupp M, 2012, New Oxycodone Formulation: OxyNeo: PL Detail-Document #280121.

Daly,KJ, 2007, Qualitative methods for family studies and human development, Sage Publications.

Darer,JD, W Hwang, H H Pham, E B Bass, G Anderson, 2004, More training needed in chronic care: a survey of US physicians: Acad Med, v. 79, p. 541-548.

Daut,RL, C S Cleeland, R C Flanery, 1983, Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases: Pain, v. 17, p. 197-210.

Deber,RB, N Kraetschmer, J Irvine, 1996, What role do patients wish to play in treatment decision making?: Arch Intern Med, v. 156, p. 1414-1420.

Denisco,RA, R K Chandler, W M Compton, 2008, Addressing the intersecting problems of opioid misuse and chronic pain treatment: Exp Clin Psychopharmacol, v. 16, p. 417.

Denzin,NK, Y S Lincoln, 2011, Introduction: The Discipline and Practice of Qualitative Research, in NK Denzin and YS Lincoln (eds), The SAGE handbook of qualitative research: Thousand Oaks, Sage.

Dhalla,IA, M M Mamdani, M L Sivilotti, A Kopp, O Qureshi, D N Juurlink, 2009, Prescribing of opioid analgesics and related mortality before and after the introduction of long-acting oxycodone: CMAJ, v. 181, p. 891-896.

Elliott,AM, B H Smith, K I Penny, W C Smith, W A Chambers, 1999, The epidemiology of chronic pain in the community: Lancet, v. 354, p. 1248-1252.

Evans,CJ, E Trudeau, P Mertzanis, P Marquis, B M Peña, J Wong, T Mayne, 2004, Development and validation of the Pain Treatment Satisfaction Scale (PTSS): a patient satisfaction questionnaire for use in patients with chronic or acute pain: Pain, v. 112, p. 254-266.

Fejer,R, C Leboeuf-Yde, 2012, Does back and neck pain become more common as you get older? A systematic literature review: Chiropr Man Therap, v. 20, p. 1-6.

Ferrell,B, C E Argoff, J Epplin, P Fine, F M Gloth, K Herr, J D Katz, D R Mehr, C Reid, L Reisner, 2009, Pharmacological management of persistent pain in older persons: J Am Geriatr Soc, v. 57, p. 1331-1346.

Ferrell,BA, K R Josephson, A M Pollan, S Loy, B R Ferrell, 1997, A randomized trial of walking versus physical methods for chronic pain management: Aging Clin Exp Res, v. 9, p. 99-105.

Ferrell,BR, M Rhiner, B A Ferrell, 1993, Development and implementation of a pain education program: Cancer, v. 72, p. 3426-3432.

Frantsve,LM, R D Kerns, 2007, Patient-provider interactions in the management of chronic pain: current findings within the context of shared medical decision making: Pain Med, v. 8, p. 25-35.

Freedman,GM, 2002, Chronic pain. Clinical management of common causes of geriatric pain: Geriatrics, v. 57, p. 36-41.

Frost,H, S E Lamb, J A Klaber Moffett, J C T Fairbank, J S Moser, 1998, A fitness programme for patients with chronic low back pain: 2-year follow-up of a randomised controlled trial: Pain, v. 75, p. 273-279.

Fukshansky,M, M Are, A W Burton, 2005, The role of opioids in cancer pain management: Pain Pract, v. 5, p. 43-54.

Furlan,AD, R Reardon, C Weppler, 2010, Opioids for chronic noncancer pain: a new Canadian practice guideline: CMAJ, v. 182, p. 923-930.

Gilson,AM, M A Maurer, D E Joranson, 2007, State medical board membersGÇÖ beliefs about pain, addiction, and diversion and abuse: a changing regulatory environment: J Pain, v. 8, p. 682-691.

Glare,P, G Aggarwal, K Clark, 2004, Ongoing controversies in the pharmacological management of cancer pain: Intern Med J, v. 34, p. 45-49.

Gloth III,FM, 1996, Concerns with chronic analgesic therapy in elderly patients: Am J Med, v. 101, p. S19-S24.

Gourlay,DL, H A Heit, A Almahrezi, 2005, Universal precautions in pain medicine: a rational approach to the treatment of chronic pain: Pain Med, v. 6, p. 107-112.

Greene,JC, 2007, Mixed methods in social inquiry, John Wiley & Sons.

Greene,JC, V J Caracelli, 1997, Advances in mixed-method evaluation: The challenges and benefits of integrating diverse paradigms, Jossey-Bass Publishers.

Greene,JC, V J Caracelli, W F Graham, 1989, Toward a conceptual framework for mixed-method evaluation designs: Educ Eval Policy Anal, v. 11, p. 255-274.

Gugelmann,HM, J Perrone, 2011, Can prescription drug monitoring programs help limit opioid abuse?: JAMA, v. 306, p. 2258-2259.

Hartung,DM, L Middleton, D G Haxby, M Koder, K L Ketchum, R Chou, 2007, Rates of adverse events of long-acting opioids in a state Medicaid program: Ann Pharmacother, v. 41, p. 921-928.

Heidrich,DE, 2001, Controlled-release oxycodone hydrochloride (Oxycontin): Clin Nurse Spec, v. 15, p. 207-209.

Henschke,N, R W Ostelo, M W van Tulder, J W Vlaeyen, S Morley, W J Assendelft, C J Main, 2010, Behavioural treatment for chronic low-back pain: Cochrane Database Syst Rev, v. 7, p. CD002014. doi: 10.1002/14651858.CD002014.pub3.

Herr,KA, P R Mobily, F J Kohout, D Wagenaar, 1998, Evaluation of the Faces Pain Scale for use with the elderly: Clin J Pain, v. 14, p. 29-38.

Hilton,S, E Smith, 2010, Public views of the UK media and government reaction to the 2009 swine flu pandemic: BMC public health, v. 10, p. 697.

Hoffman,BM, R K Papas, D K Chatkoff, R D Kerns, 2007, Meta-analysis of psychological interventions for chronic low back pain: Health Psychol, v. 26, p. 1.

Inciardi,JA, J L Goode, 2003, OxyContin and prescription drug abuse: Consumers' Research, v. 86, p. 17-21.

International Association for the Study of Pain., 2012, IASP Taxonomy: Available at: http://www.iasp-pain.org/Content/NavigationMenu/GeneralResourceLinks/PainDefinitions/default.htm.

Jan, SA, 2010, Patient perspective, complexities, and challenges in managed care: Journal of managed care pharmacy: v. 16(1 Suppl B), p. 22-25.

Jayawant,SS, R Balkrishnan, 2005, The controversy surrounding OxyContin abuse: issues and solutions: Ther Clin Risk Manag, v. 1, p. 77.

Joranson,DE, K M Ryan, A M Gilson, J L Dahl, 2000, Trends in medical use and abuse of opioid analgesics: JAMA, v. 283, p. 1710-1714.

Jovey,RD, J Ennis, J Gardner-Nix, B Goldman, H Hays, M Lynch, D Moulin, 2003, Use of opioid analgesics for the treatment of chronic noncancer painGÇöa consensus statement and guidelines from the Canadian Pain Society, 2002: Pain Res Manag, v. 8, p. 3A-28A.

Kahan,M, A Mailis-Gagnon, L Wilson, A Srivastava, 2011a, Canadian guideline for safe and effective use of opioids for chronic noncancer pain Clinical summary for family physicians. Part 1: general population: Can Fam Phys, v. 57, p. 1257-1266.

Kahan,M, L Wilson, A Mailis-Gagnon, A Srivastava, 2011b, Canadian guideline for safe and effective use of opioids for chronic noncancer pain Clinical summary for family physicians. Part 2: special populations: Can Fam Phys, v. 57, p. 1269-1276.

Kahan,M, L Wilson, E F Wenghofer, A Srivastava, A Resnick, E Janecek, C Sheehan, 2011c, Pharmacists' experiences with dispensing opioids Provincial survey: Can Fam Phys, v. 57, p. e448-e454.

Keller,S, C M Bann, S L Dodd, J Schein, T R Mendoza, C S Cleeland, 2004, Validity of the brief pain inventory for use in documenting the outcomes of patients with noncancer pain: Clin J Pain, v. 20, p. 309-318.

Keshishian,F, N Colodny, R T Boone, 2008, Physician-patient and pharmacist-patient communication: Geriatrics' perceptions and opinions: Patient Educ Couns, v. 71, p. 265-284.

Kirkey S., 2012, OxyContin's removal could cause whole new set of problems: Available at: http://www.canada.com/health/OxyContin+removal+could+cause+whole+problems/6229543/story.html.

Kirkup K., 2012a, OxyContin removed from Canadian market: Available at: http://www.torontosun.com/2012/02/29/oxycontin-removed-from-canadian-market.

Kirkup K., 2012b, Six drug companies to produce generic OxyContin: Available at: http://www.torontosun.com/2012/11/26/6-drug-companies-to-produce-generic-oxycontin.

Koes,BW, L M Bouter, G J M G van der Heijden, 1995, Methodological Quality of Randomized Clinical Trials on Treatment Efficcact in Low Back Pain: Spine, v. 20, p. 228-235.

Lang,F, M R Floyd, K L Beine, 2000, Clues to patients' explanations and concerns about their illnesses: A call for active listening: Arch Fam Med, v. 9, p. 222.

LeFort,SM, K Gray-Donald, K M Rowat, M E Jeans, 1998, Randomized controlled trial of a community-based psychoeducation program for the self-management of chronic pain: Pain, v. 74, p. 297-306.

Levy,MH, 1996, Pharmacologic treatment of cancer pain: N Engl J Med, v. 335, p. 1124-1132.

Lexchin,J, J C Kohler, 2011, The danger of imperfect regulation: OxyContin use in the United States and Canada: Int J Risk Saf Med, v. 23, p. 233-240.

Lipman,AG, K C Jackson, 2000, Use of opioids in chronic noncancer pain: Purdue Pharma, Norwalk, p. 1-12.

Little,P, L Roberts, H Blowers, J Garwood, T Cantrell, J Langridge, J Chapman, 2001, Should we give detailed advice and information booklets to patients with back pain?: a randomized controlled factorial trial of a self-management booklet and doctor advice to take exercise for back pain: Spine, v. 26, p. 2065-2072.

MacLure,M, 2003, Discourse in educational and social research, Open University Press.

Manchikanti,L, R Manchukonda, V Pampati, K S Damron, D E Brandon, K A Cash, C D McManus, 2006, Does random urine drug testing reduce illicit drug use in chronic pain patients receiving opioids?: Pain Physician, v. 9, p. 123.

Mandema,JW, R F Kaiko, B E N J OSHLACK, R F Reder, D R Stanski, 1996, Characterization and validation of a pharmacokinetic model for controlled-release oxycodone: Br J Clin Pharmacol, v. 42, p. 747-756.

Mars,SG, P Bourgois, G Karandinos, F Montero, D Ciccarone, 2014, "Every 'Never' I Ever Said Came True": Transitions from opioid pills to heroin injecting: Int J Drug Policy, v. 25, p. 257-266.

McCaffery M., 1968, Nursing practice theories related to cognition, bodily pain, and man-environment interactions, Los Angeles CA.

McCaffery M., Pasero C., 1999, Pain Clinical Manual. Theoretical Nursing Development & Progress , p. 29-49.

McCarberg,BH, R L Barkin, 2001, Long-acting opioids for chronic pain: pharmacotherapeutic opportunities to enhance compliance, quality of life, and analgesia: Am J Therapeutics, v. 8, p. 181-186.

McCracken,LM, 1998, Learning to live with the pain: acceptance of pain predicts adjustment in persons with chronic pain: Pain, v. 74, p. 21-27.

McCracken,LM, C Eccleston, 2005, A prospective study of acceptance of pain and patient functioning with chronic pain: Pain, v. 118, p. 164-169.

McGrath,PA, 1994, Psychological aspects of pain perception: Arch Oral Biol, v. 39, p. S55-S62.

McMillan J.H., Schumacher S., 2001, Research in Education: A Conceptual Introduction, New York NY.

Melzack,R, 1987, The short-form McGill pain questionnaire: Pain, v. 30, p. 191-197.

Mercadante,S, 1999, Opioid rotation for cancer pain: Cancer, v. 86, p. 1856-1866.

Miles,MB, A Huberman, 1994, Qualitative data analysis: An expanded sourcebook. Sage.

Moffett,JK, D Torgerson, S Bell-Syer, D Jackson, H Llewlyn-Phillips, A Farrin, J Barber, 1999, Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences: Bmj, v. 319, p. 279-283.

Morley,S, C Eccleston, A Williams, 1999, Systematic review and meta-analysis of randomized controlled trials of cognitive behaviour therapy and behaviour therapy for chronic pain in adults, excluding headache: Pain, v. 80, p. 1-13.

Moulin,DE, A J Clark, M Speechley, P K Morley-Forster, 2002, Chronic pain in Canada--prevalence, treatment, impact and the role of opioid analgesia: Pain Res Manag.

National Centers for Health Statistics, 2006, Chartbook on Trends in the Health of Americans, Special Feature: Pain, Available at: http://www.cdc.gov/nchs/data/hus/hus06.pdf.

National Institute on Drug Abuse, 2011, Research Report Series, Prescription drug abuse, Available at: http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids.

National Survey on Drug Use and Health, 2004, Abuse of OxyContin: Available at: https://nsduhweb.rti.org/respweb/homepage.cfm.

Neergaard,MA, F Olesen, R S Andersen, J Sondergaard, 2009, Qualitative description-the poor cousin of health research?: BMC Med Res Methodol, v. 9, p. 52.

Neighbour, R, 2005, The inner consultation: how to develop an effective and intuitive consulting style. Radcliffe Publishing.

Nickel,R, H H Raspe, 2001, [Chronic pain: epidemiology and health care utilization]: Der Nervenarzt, v. 72, p. 897-906.

Novak,S, W C Nemeth, K A Lawson, 2004, Trends in Medical Use and Abuse of SustainedGÇÉRelease Opioid Analgesics: A Revisit: Pain Medicine, v. 5, p. 59-65.

O'Cathain,A, E Murphy, J Nicholl, 2007, Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study: BMC Health Serv Res, v. 7, p. 85.

Ofman,JJ, C H MacLean, W L Straus, S C Morton, M L Berger, E A Roth, P Shekelle, 2002, A metaanalysis of severe upper gastrointestinal complications of nonsteroidal antiinflammatory drugs: J Rheumatol, v. 29, p. 804-812.

Ogbru O., 2014a, Acetaminophen, Tylenol and others, Available at: http://www.medicinenet.com/acetaminophen/article.htm.

Ogbru O., 2014b, Nonsteroidal Anti-inflammatory Drugs (NSAIDs), Available at: http://www.medicinenet.com/nonsteroidal_antiinflammatory_drugs/article.htm.

Ogilvie M., 2012, OxyContin will soon be pulled from Canadian pharmacies, Available at: http://www.ohsutp.ca/index.php/news/oxycontin-will-soon-be-pulled-from-canadian-pharmacies/.

Ong,EC, 2008, Controlled-release oxycodone in the treatment of neuropathic pain of nonmalignant and malignant causes: Oncology, v. 74, p. 72-75.

Ong,LML, J C J M De Haes, A M Hoos, F B Lammes, 1995, Doctor-patient communication: a review of the literature: Soc Sci Med, v. 40, p. 903-918.

Ontario Ministry of Health and Long Term Care, 2012, Ontario's Narcotics Strategy: Change in Funding Status of Oxycodone Controlled Release Tablet - (Discontinuation of Oxycontin and introduction of OxyNeo), Available at: http://www.health.gov.on.ca/en/public/programs/drugs/ons/oxy_faq.aspx, 2012..

Pan,H, Z Zhang, Y Zhang, N Xu, L Lu, C Dou, Y Guo, S Wu, J Yue, D Wu, 2007, Efficacy and tolerability of oxycodone hydrochloride controlled-release tablets in moderate to severe cancer pain: Clin Drug Investig, v. 27, p. 259-267.

Passik,SD. Issues in long-term opioid therapy: unmet needs, risks, and solutions. In: Mayo Clinic Proceedings. 84[7], 593-601. 2009. Elsevier.

Passik,SD, K L Kirsh, 2008, The interface between pain and drug abuse and the evolution of strategies to optimize pain management while minimizing drug abuse: Exp Clin Psychopharmacol, v. 16, p. 400.

Patton M.Q., 2002, Qualitative research & evaluation methods, Thousand Oaks CA.

Pinn,J, 2001, Crises of representation, Butterworth-Heinemann Medical, p. 185-198.

Pitkala,KH, T E Strandberg, R S Tilvis, 2002, Management of Nonmalignant Pain in HomeGÇÉDwelling Older People: A PopulationGÇÉBased Survey: J Am Geriatr Soc, v. 50, p. 1861-1865.

Platt FW, Gaspar DL, Coulehan JL, Fox L, Adler AJ, Weston WW, Smith RC, Stewart M, 2001, "Tell me about yourself": The patient-centered interview.: Ann Intern Med, v. 134, p. 1079-1085.

Portenoy,RK, K M Foley, 1986, Chronic use of opioid analgesics in non-malignant pain: report of 38 cases: Pain, v. 25, p. 171-186.

Potter, J, M Wetherell, 1987, Discourse and social psychology: Beyond attitudes and behaviour. Sage.

Potter,J, M Wetherell, 2004, Discourse analysis: Handbook of data analysis, p. 607-624.

Public Health Agency of Canada, 2012, Canadian Sexual Health Indicators Survey—Pilot Test And Validation Phase:Final Technical Report, Available at:

http://www.creces.uqam.ca/Page/Document/Sexual_Health_Indicators_Survey_EN_Web.pdf..

Purdue Pharma, 2009, OxyContin Product Monograph: Available at: http://www.purdue.ca/files/2011-11-08_OxyContin_148343_ENG%20Final_Mkt%20Sizes.pdf.

Registered Nurses' Association of Ontario, 2007, Assessment and Management of Pain in the Elderly: Self-directed learning package for nurses in long-term care.

Reitsma,M, J E Tranmer, D M Buchanan, E G Vandenkerkhof, 2012, The epidemiology of chronic pain in Canadian men and women between 1994 and 2007: longitudinal results of the National Population Health Survey: Pain Res Manag, v. 17, p. 166-172.

Reitsma,ML, J E Tranmer, D M Buchanan, E G Vandenkerkhof, 2011, The prevalence of chronic pain and pain-related interference in the Canadian population from 1994 to 2008: Chronic Dis Inj Can, v. 31, p. 157-164.

Robinson,JH, L C Callister, J A Berry, K A Dearing, 2008, Patient-centered care and adherence: Definitions and applications to improve outcomes: J Am Acad Nurse Pract, v. 20, p. 600-607.

Rustoen,T, A K Wahl, B R Hanestad, A Lerdal, S Paul, C Miaskowski, 2005, Age and the experience of chronic pain: differences in health and quality of life among younger, middle-aged, and older adults: Clin J Pain, v. 21, p. 513-523.

Salzman,RT, M S Roberts, J Wild, C Fabian, R F Reder, P D Goldenheim, 1999, Can a controlled-release oral dose form of oxycodone be used as readily as an immediate-release form for the purpose of titrating to stable pain control?: J Pain Symptom Manage, v. 18, p. 271-279.

Sandelowski,M, 2000, Focus on research methods-whatever happened to qualitative description?: Res Nurs Health, v. 23, p. 334-340.

Scanlon MN, Chugh U, 2004, Exploring physicians' comfort level with opioids for chronic noncancer pain: Pain Res Manag, v. 9, p. 195-201.

Scharff,L, D C Turk, 1998, Chronic pain and depression in the elderly: Clin Geriatr, v. 6, p. 30.

Schneider,JP, 2005, Chronic pain management in older adults: with coxibs under fire, what now?: Geriatrics, v. 60, p. 26-28.

Schopflocher,D, P Taenzer, R Jovey, 2011, The prevalence of chronic pain in Canada: Pain Res Manag, v. 16, p. 445.

Sehgal,N, L Manchikanti, H S Smith, 2012, Prescription opioid abuse in chronic pain: a review of opioid abuse predictors and strategies to curb opioid abuse: Pain Physician, v. 15, p. ES67-ES92.

Skinner BJ, 2012, Net societal economic impact in Canada from withholding regulatory approval for generic OxyContin, Available at: http://www.canadianhealthpolicy.com/downloads/research-pdfs/skinner-september-2012-oxyneo-study-final.pdf.

Sloan,P, N Babul, 2006, Extended-release opioids for the management of chronic non-malignant pain: Expert Opin Drug Deliv, v. 3, p. 489-497.

Smith,BH, A M Elliott, W A Chambers, W C Smith, P C Hannaford, K Penny, 2001, The impact of chronic pain in the community: Fam Pract, v. 18, p. 292-299.

Smyth,FS, 1962, The place of the humanities and social sciences in the education of physicians: Acad Med, v. 37, p. 495-499.

Stambaugh,JE, R F Reder, M D Stambaugh, H Stambaugh, M Davis, 2001, Double-Blind, Randomized Comparison of the Analgesic and Pharmacokinetic Profiles of Controlled- and Immediate-Release Oral Oxycodone in Cancer Pain Patients: J Clin Pharmacol, v. 41, p. 500-506.

Starks,H, S B Trinidad, 2007, Choose your method: A comparison of phenomenology, discourse analysis, and grounded theory: Qual Health Res, v. 17, p. 1372-1380.

Statistics Canada, 2014, Statisitcs Canada Population Projections: http://www5.statcan.gc.ca/subject-sujet/subtheme-soustheme.action?pid=3867&id=3433&lang=eng&more=0.

Stillman,PL, D R Brown, D L Redfield, D L Sabers, 1977, Construct validation of the Arizona clinical interview rating scale: Educ Psychol Meas, v. 37, p. 1031-1038.

Strachan Y., 2012, Forced OxyContin removal in Canada makes mass crisis imminent, Available at: http://digitaljournal.com/article/319825.

Sullivan-Bolyai,S, C Bova, D Harper, 2005, Developing and refining interventions in persons with health disparities: The use of qualitative description: Nurs Outlook, v. 53, p. 127-133.

Tan,G, M P Jensen, J I Thornby, B F Shanti, 2004, Validation of the Brief Pain Inventory for chronic nonmalignant pain: J Pain, v. 5, p. 133-137.

Tariq S., Woodman J, 2013, Using mixed methods in health research: JRSM short reports, v. 4, p. 2042533313479197.

Tashakkori,A, C Teddlie, 2010, Sage handbook of mixed methods in social & behavioral research, Sage.

Tripp,DA, E G Vandenkerkhof, M McAlister, 2006, Prevalence and determinants of pain and pain-related disability in urban and rural settings in southeastern Ontario: Pain Res Manag, v. 11, p. 225.

Turk,DC, R Melzack, 2011, Handbook of pain assessment, Guilford Press.

Turk,DC, H D Wilson, A Cahana, 2011, Treatment of chronic non-cancer pain: Lancet, v. 377, p. 2226-2235.

U.S.Food and Drug Administration, 2009, What are generic drugs?: Available at, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm..

Van Zee,A, 2009, The promotion and marketing of oxycontin: commercial triumph, public health tragedy: Am J Pub Health, v. 99, p. 221.

Varrassi,G, G Müller-Schwefe, J Pergolizzi, A Oronska, B Morlion, P Mavrocordatos, C Margarit, C Mangas, W Jaksch, F J P M Huygen, 2010, Pharmacological treatment of chronic pain-the need for CHANGE: Curr Med Res Opin, v. 26, p. 1231-1245.

Victor,TW, N A Alvarez, E Gould, 2009, Opioid prescribing practices in chronic pain management: guidelines do not sufficiently influence clinical practice: J Pain, v. 10, p. 1051-1057.

Volkow,ND, T A McLellan, 2011, Curtailing diversion and abuse of opioid analgesics without jeopardizing pain treatment: JAMA, v. 305, p. 1346-1347.

Von Korff,M, S F Dworkin, L Le Resche, A Kruger, 1988, An epidemiologic comparison of pain complaints: Pain, v. 32, p. 173-183.

Wachter,K, 2007, Don't Let Fear of Opioid Abuse Inhibit Therapies: Pain Med.

Wanzer,MB, M Booth-Butterfield, K Gruber, 2004, Perceptions of health care providers' communication: relationships between patient-centered communication and satisfaction: Health Comm, v. 16, p. 363-384.

Ward,SE, N Goldberg, V Miller-McCauley, C Mueller, A Nolan, D Pawlik-Plank, A Robbins, D Stormoen, D E Weissman, 1993, Patient-related barriers to management of cancer pain: Pain, v. 52, p. 319-324.

Webster, LR, P Fine, 2010, Approaches to improve pain relief while minimizing opioid abuse liability: The Journal of Pain, v. 11, p. 602-611.

Weeks C., 2012, OxyContin delisting not the answer to opioid addiction, experts say: Available at: http://www.theglobeandmail.com/life/health-and-fitness/health/conditions/oxycontin-delisting-not-the-answer-to-opioid-addiction-experts-say/article548948/.

Weiner,DK, E Ernst, 2004, Complementary and alternative approaches to the treatment of persistent musculoskeletal pain: Clin J Pain, v. 20, p. 244-255.

White,J, W Levinson, D Roter, 1994, Oh, by the wayGÇª: J Gen Intern Med, v. 9, p. 24-28.

Wienecke,T, P C Gotzsche, 2004, Paracetamol versus nonsteroidal anti-inflammatory drugs for rheumatoid arthritis: Cochrane Database Syst Rev, v. 1.

Williamson,A, B Hoggart, 2005, Pain: a review of three commonly used pain rating scales: J Clin Nurs, v. 14, p. 798-804.

World Health Organization, 2012, Good health adds life to years: Global brief for World Health Day 2012.

World Health Organization, 2013, WHO's pain ladder. 2012: World Health Organization website: http://www.who.int/cancer/palliative/painladder/en/Last accessed, v. 30.

Zerzan,JT, N E Morden, S Soumerai, D Ross-Degnan, E Roughead, F Zhang, L Simoni-Wastila, S D Sullivan, 2006, Trends and geographic variation of opiate medication use in state Medicaid fee-for-service programs, 1996 to 2002: Medical care, v. 44, p. 1005-1010.

Zola,IK, 1973, Pathways to the doctorGÇöfrom person to patient: Soc Sci Med (1967), v. 7, p. 677-689.

Appendices

Appendix A: Recruitment Poster/Flyer

School of Pharmacy University of Waterloo
PARTICIPANTS NEEDED FOR RESEARCH IN CHRONIC PAIN MANAGEMENT

We are looking for volunteers to take part in a study of the perceptions of chronic pain patients about their pain management following the discontinuation of OxyContin®.
As a participant in this study, you would be asked to complete an interview with a researcher and two questionnaires.
Your participation would involve one session, which is approximately 90 minutes.
In appreciation for your time, you will receive a $10 gift card at the end of the session.

You are eligible if you are:
- A chronic pain patient
- 45+ years
- Able to speak and write in English
- With no history of cognitive impairment
- A previous OxyContin® user for a minimum of six months until February 2012.

For more information about this study, or to volunteer for this study, please contact: Sara Ibrahim, M.Sc. Candidate School of Pharmacy at 519-888-4567 Ext. 21390 or Email: s9ibrahi@uwaterloo.ca
This study has been reviewed by, and received ethics clearance through, the Office of Research Ethics, University of Waterloo.

Appendix B: Screening checklist

Inclusion Criteria	**YES**	**NO**
Chronic pain patient		
Age: 45+		
Able to speak in English i.e. No language Barrier		
Administered OxyContin for at least six months until Feb 2012		
If YES to all, is patient willing to do Mini-Cog?		

Appendix C: Physician Focus Group Guide

1. What were your personal perceptions about the discontinuation of OxyContin®?

- Notice period before discontinuation
- Extent of knowledge about discontinuation process
- Extent of knowledge about the medication replacing it (OxyNeo®)
- Personal opinions about the discontinuation, primary thoughts, immediate reactions
- Specific concerns about impact on pain control
- Comments about the transition phase for patients

2. What was the information you provided to your patients about the discontinuation?

3. What were the other options you discussed with them? What were the final therapeutic decisions usually based upon?

4. What were your patients' perceptions about the discontinuation of OxyContin®?

- Personal opinions about the discontinuation , immediate reactions, patients' experiences
- Frequent questions that were asked by your patients
- Frequent feedback from patients about alternative medications
- General concerns, withdrawal symptoms

5. What are your insights about the overall impact of OxyContin's discontinuation on pain management?

- Efficacy of alternative pain medications
- Current situation of pain control as compared to prior to OxyContin's discontinuation

6. What are your opinions about the Exceptional Access Program?

- Experiences with it, applications for certain patients
- Ease/difficulty of procedure

7. What are your thoughts about the generics that were introduced following discontinuation regarding different aspects including efficacy, cost or prescribing them to your patients?

8. What are your future visions for pain management in Canada with regard to:

(i) Discontinuations of chronic medications like OxyContin®?

(ii) Balancing benefit of OxyContin® or other opioids versus their abuse potential?

Appendix D: Patient Interview Guide

The guideline is divided into three broad categories of topics for discussion:

I. Discontinuation Process

A. OxyContin® discontinuation

- Timing of discontinuation

- Dosage at discontinuation

- For how long has patient administered OxyContin® before discontinuation?

- When and how did patients learn about discontinuation?

- What was patients' immediate reaction after learning about discontinuation?

- What were patients' concerns after learning about discontinuation?

B. Knowledge dissemination

- What information did patients receive from pharmacists?

- What information did patients receive from physicians?

- How useful did patients find the provided information?

- Who did patients contact when they had questions and why?

- What questions did patients ask their healthcare providers?

C. Withdrawal Symptoms

- What, if any, were the withdrawal symptoms experienced by patients?

- How did patients react when they started experiencing them?

- For how long did those symptoms persist?

- What was done to deal with those symptoms? Immediate-release meds?

- Were they warned about those symptoms? By whom?

II. Pain Relief

- What do patients currently think of their pain relief?

- What is their pain intensity? Location? Frequency?

- How does pain affect their activities of daily living?

- How do patients find their pain relief as compared to before discontinuation?

III. Current Pain Medication

- What is the current pain medication?

- What is the daily dose?

- When was the patient started on it?

- Is it the first medication they switched to after stopping OxyContin®?

- What information did they get from their physicians/pharmacists?

- What are the side effects if any? How often are they experienced?

- Are they satisfied with their current medication? Why?

- Are they willing to continue administering it?

Appendix E: Patient Information-Consent Letter

DEPARTMENT LETTERHEAD
University of Waterloo
Date

Dear ***(participant's name):***

This letter is an invitation to consider participating in a study I am conducting as part of my Master's degree in the School of Pharmacy at the University of Waterloo under the supervision of Professor Feng Chang. I would like to provide you with more information about this project and what your involvement would entail if you decide to take part.

Chronic pain is a major health problem and research has been increasingly contributing to this issue over the past decade. OxyContin® was one of the most commonly used medications for treating pain, but was recently discontinued and delisted from the Ontario Drug Formulary. Consequently, the unknown impact of this discontinuation on chronic pain patients is the driving force for this study. The purpose of this study, therefore, is to obtain patients' perceptions about their discontinuation process and their pain management following the discontinuation of OxyContin®.

This study will focus on patient experiences and perspectives on how their pain control has been after discontinuing OxyContin®. When faced with a trigger event such as the discontinuation of their pain medication, it is important to understand the kind of impact this provincial action had on them. Therefore, I would like to invite you to participate in my study. I believe that because you were directly affected by the discontinuation of OxyContin®, you are best suited to speak to the various experience issues, such as discontinuation process, medical care, pain control, alternative pain medication and other matters of importance.

Participation in this study is voluntary. It will involve completion of two questionnaires as well as an interview of approximately 60 minutes in length to take place in a mutually agreed upon location. You may decline to answer any of the interview questions if you so wish. Further, you may decide to withdraw from this study at any time without any negative consequences by advising the researcher. With your permission, the interview will be audio recorded to facilitate collection of information, and later transcribed for analysis. Shortly after the interview has been completed, I will send you a copy of the transcript to give you an opportunity to confirm the accuracy of our conversation and to add or clarify any points that you wish. All information you provide is considered completely confidential. Your name will not appear in any thesis or report resulting from this study, however, with your permission anonymous quotations may be used. Data collected during this study will be retained for 12 months in a locker in my supervisor's office. Only researchers associated with this project will have access. There are no known or anticipated risks to you as a participant in this study.

If you have any questions regarding this study, or would like additional information to assist you in reaching a decision about participation, please contact me at 519-888-4567 ext. 21390 or by email at s9ibrahi@uwaterloo.ca. You can also contact my supervisor, Dr. Feng Chang at 519-888-4567 ext. 21321 or email feng.chang@uwaterloo.ca. 41

I would like to assure you that this study has been reviewed and received ethics clearance through the Office of Research Ethics at the University of Waterloo. However, the final decision about participation is yours. If you have any comments or concerns resulting from your participation in this study, please contact Dr. Maureen Nummelin in the Office of Research Ethics at 1-519-888-4567, Ext. 36005 or maureen.nummelin@uwaterloo.ca.

I hope that the results of my study will be of benefit to those patients directly involved in the study, other patients not directly involved in the study, healthcare clinicians, as well as to the broader research community.

I very much look forward to speaking with you and thank you in advance for your assistance in this project.

Yours Sincerely,

Sara
Student Investigator

CONSENT FORM

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

_____

I have read the information presented in the information letter about a study being conducted by Sara Ibrahim of the School of Pharmacy at the University of Waterloo. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I wanted.

I am aware that I have the option of allowing my interview to be audio recorded to ensure an accurate recording of my responses.

I am also aware that excerpts from the interview may be included in the thesis and/or publications to come from this research, with the understanding that the quotations will be anonymous.

I was informed that I may withdraw my consent at any time without penalty by advising the Researcher.

This project has been reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact the Director, Office of Research Ethics at 519-888-4567 ext. 36005.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.
YES NO

I agree to have my interview audio recorded.
YES NO

I agree to the use of anonymous quotations in any thesis or publication that comes of this research.
YES NO

Participant Name: _____ (Please print)

Participant Signature: _____

Witness Name: _____ (Please print)

Witness Signature: _____

Date: _____

Appendix G: Pain Treatment Satisfaction Scale

General

1. In general do you feel that your health is: *(check one)*

☐1	☐2	☐3	☐4	☐5
Excellent	Very Good	Good	Fair	Poor

The following statements ask you about the level of pain that you suffer from. On a scale from 0 to 10, with 0 representing "no pain" and 10 representing the "worst pain possible," please circle the number that represents:

2.	How much pain you had in the **last week.**										
	0	1	2	3	4	5	6	7	8	9	10
	No pain										Worst pain possible
3.	How much pain you had in the **last 24 hours.**										
	0	1	2	3	4	5	6	7	8	9	10
	No pain										Worst pain possible
4.	How much pain you have **right now.**										
	0	1	2	3	4	5	6	7	8	9	10
	No pain										Worst pain possible
5.	The level of pain you reach before **asking** your doctor for medication.										
	0	1	2	3	4	5	6	7	8	9	10
	No pain										Worst pain possible
6.	The level of pain you reach before **taking** your medication.										
	0	1	2	3	4	5	6	7	8	9	10
	No pain										Worst pain possible

Reference: Evans CJ, Trudeau E, Mertzanis P, Marquis P, Peña BM, Wong J, et al. Development and validation of the pain treatment satisfaction scale (PTSS): A patient satisfaction questionnaire for use in patients with chronic or acute pain. Pain 2004; 112(3):254-266.

Information About Pain and Its Treatment

The following questions ask about your **pain and its treatment**. Please answer each question below by *checking the box* that best represents your opinion (check only one box per question).

How much **information** would you have liked to have received about each of the following:		I would have liked much more information	I would have liked a little more information	The amount of information was right for me	I would have liked less information	I would have liked no information
7.	My illness or injury	☐1	☐2	☐3	☐4	☐5
8.	The cause(s) of my pain	☐1	☐2	☐3	☐4	☐5
9.	Treatment options for my pain	☐1	☐2	☐3	☐4	☐5
10.	Pain medication, in general	☐1	☐2	☐3	☐4	☐5
11.	Possible side effects of pain medication	☐1	☐2	☐3	☐4	☐5

Medical Care

The following statements ask about your **medical care**. Please answer each question below by *checking* the box that best represents your opinion (check only one box per question).

How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
12.	It is easy to ask the medical staff questions.	☐1	☐2	☐3	☐4	☐5
13.	The medical staff always do their best to keep me from worrying.	☐1	☐2	☐3	☐4	☐5
14.	The medical staff is willing to provide me with the pain medication that I feel I need.	☐1	☐2	☐3	☐4	☐5
15.	The medical staff provide adequate follow-up care.	☐1	☐2	☐3	☐4	☐5
16.	The medical staff does not ask me about the pain I experience.	☐1	☐2	☐3	☐4	☐5

Current Pain Medication

The following statements are about your **current pain medication**. Please answer each question below by *checking the box* that best represents your opinion (check only one box per question).

How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
17.	My pain medication has a positive effect on my **physical health**.	☐1	☐2	☐3	☐4	☐5
18.	My pain medication helps me have a better **outlook on life**.	☐1	☐2	☐3	☐4	☐5
19.	My pain medication allows me to perform my **daily activities** more easily.	☐1	☐2	☐3	☐4	☐5
20.	My pain medication allows me to participate in my **leisure activities** more often.	☐1	☐2	☐3	☐4	☐5
21.	My pain medication helps me do things **independently**.	☐1	☐2	☐3	☐4	☐5
22.	My pain medication allows me to have better **relationships with others**.	☐1	☐2	☐3	☐4	☐5
23.	My pain medication improves my **mood**.	☐1	☐2	☐3	☐4	☐5
24.	My pain medication allows me to **concentrate** better.	☐1	☐2	☐3	☐4	☐5

Pain Medication Route of Administration

How is your current pain medication administered? Please check all that apply and complete those sections.

☐ Orally (pills, capsules, liquid, etc.) → GO TO SECTION A

☐ By intravenous injections → GO TO SECTION B

☐ By patches → GO TO SECTION C

SECTION A

TO BE ANSWERED BY PATIENTS TAKING **ORAL** PAIN MEDICATION

How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
25.	My oral pain medication is easy to swallow.	☐$_1$	☐$_2$	☐$_3$	☐$_4$	☐$_5$
26.	My oral pain medication leaves an after-taste.	☐$_1$	☐$_2$	☐$_3$	☐$_4$	☐$_5$

SECTION B

TO BE ANSWERED BY PATIENTS TAKING **INTRAVENOUS (IV)** PAIN MEDICATION

How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
27.	My IV pain medication works quickly.	☐1	☐2	☐3	☐4	☐5
28.	My IV pain medication hurts when it is injected.	☐1	☐2	☐3	☐4	☐5
How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
29.	My IV injections leave too many bruises.	☐1	☐2	☐3	☐4	☐5

SECTION C

TO BE ANSWERED BY PATIENTS TAKING **PATCH** PAIN MEDICATION

How much you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
30.	My patch pain medication irritates my skin.	☐1	☐2	☐3	☐4	☐5
31.	My patch pain medication is easy to apply to my skin.	☐1	☐2	☐3	☐4	☐5
32.	My patch pain medication is easy to take off.	☐1	☐2	☐3	☐4	☐5
33.	My patch pain medication falls off easily.	☐1	☐2	☐3	☐4	☐5

Side Effects of Medication

The following statements ask about **side effects** of your current pain medication. Please answer each question below by *checking the box* that best represents your opinion (check only one box per question).

Because of your pain medication, how much were you **bothered** by the following:		Did not experience	Not bothered at all	A Little bothered	Moderately bothered	Quite bothered	Extremely bothered
34.	Unintentional weight gain	☐0	☐1	☐2	☐3	☐4	☐5
35.	Excessive fatigue	☐0	☐1	☐2	☐3	☐4	☐5
36.	Drowsiness	☐0	☐1	☐2	☐3	☐4	☐5
37.	Inability to concentrate	☐0	☐1	☐2	☐3	☐4	☐5
38.	Nausea	☐0	☐1	☐2	☐3	☐4	☐5
39.	Diarrhea	☐0	☐1	☐2	☐3	☐4	☐5
40.	Dizziness	☐0	☐1	☐2	☐3	☐4	☐5
41.	Constipation	☐0	☐1	☐2	☐3	☐4	☐5
42.	Skin rashes	☐0	☐1	☐2	☐3	☐4	☐5
43.	Stomach aches	☐0	☐1	☐2	☐3	☐4	☐5
44.	Heartburn	☐0	☐1	☐2	☐3	☐4	☐5
45.	Vomiting	☐0	☐1	☐2	☐3	☐4	☐5

Satisfaction with Current Pain Medication and Care

The following statements are about your satisfaction with your **current pain medication and the care you receive**. Please answer each question below by *checking the box* that best describes your level of satisfaction (check only one box per question).

How satisfied are you with each of the following:		Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
46.	The **information** that you received about your pain and its treatment	☐1	☐2	☐3	☐4	☐5
47.	The **amount of time** that doctors devoted to you during their visits/consultations	☐1	☐2	☐3	☐4	☐5
48.	The **care** provided by the nurses for your pain and its treatment	☐1	☐2	☐3	☐4	☐5
49.	The **form** of your medication (for example, pill, capsule, patch or injection)	☐1	☐2	☐3	☐4	☐5
50.	How **often** you take your medication	☐1	☐2	☐3	☐4	☐5
51.	The **amount of pain medication** you take	☐1	☐2	☐3	☐4	☐5

How satisfied are you with each of the following:		Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
52.	The **time** that it takes your pain medication to work	☐1	☐2	☐3	☐4	☐5
53.	The **level or amount** of **pain relief** provided by your pain medication	☐1	☐2	☐3	☐4	☐5
54.	The **duration** of pain relief provided by your pain medication	☐1	☐2	☐3	☐4	☐5

55. **Overall**, how satisfied are you with your current pain medication?

☐1	☐2	☐3	☐4	☐5
Very Satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied

56. **Overall**, how does your **level of pain relief** meet your expectations of pain relief?

☐1	☐2	☐3	☐4	☐5
Greatly exceeds my expectations	Somewhat exceeds my expectations	Meets my expectations	Does not quite meet my expectations	Does not meet my expectations at all

57. Do you think that your current pain medication **could be** more effective in relieving your pain?

☐1	☐2	☐3	☐4	☐5
Yes, definitely	Probably yes	I don't know	Probably not	Definitely not

58. Would you like to **continue** taking your current pain medication?

☐1	☐2	☐3	☐4	☐5
Yes, definitely	Probably yes	I don't know	Probably not	Definitely not

59. Some people say that they get nervous at the thought of taking a pain medication for a **short time period**. Please check the closest description of how nervous you feel about taking your current pain medication for a short time period.

☐1	☐2	☐3	☐4	☐5
Not at all nervous	A little nervous	Moderately nervous	Very nervous	Extremely nervous

60. Some people say that they get nervous at the thought of taking a pain medication for a **long time period**. Please check the closest description of how nervous you feel about taking your current pain medication for a long time period.

☐1	☐2	☐3	☐4	☐5
Not at all nervous	A little nervous	Moderately nervous	Very nervous	Extremely nervous

61. Have you ever **used** another pain medication?

☐	☐
Yes	No

If Yes, overall, how would you compare your current pain medication with the other one?

☐1 This medication is much better than my other one
☐2 This medication is somewhat better than my other one
☐3 This medication is about the same as my other one
☐4 This medication is somewhat worse than my other one
☐5 This medication is much worse than my other one

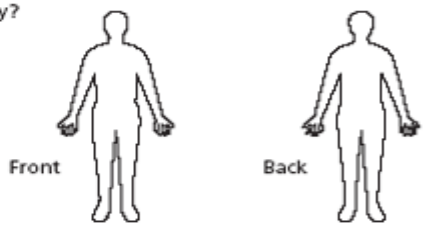
Thank you for your help.

Appendix H: Brief Pain Inventory

Brief Pain Inventory

Name Date Time

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, toothaches). Have you had pain other than these everyday types of pain today?
   1. Yes 2. No
2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the past 24 hours.

   0 1 2 3 4 5 6 7 8 9 10
   No pain *Pain as bad as you can imagine*

4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

   0 1 2 3 4 5 6 7 8 9 10
   No pain *Pain as bad as you can imagine*

5. Please rate your pain by circling the one number that best describes your pain on average.

   0 1 2 3 4 5 6 7 8 9 10
   No pain *Pain as bad as you can imagine*

6. Please rate your pain by circling the one number that tells how much pain you have right now.

   0 1 2 3 4 5 6 7 8 9 10
   No pain *Pain as bad as you can imagine*

7. What treatment or medication are you receiving for the pain?

   _____
   _____
   _____
   _____
   _____

8. In the past 24 hours, how much relief have pain treatments or medication provided? Please circle the one percentage that most shows how much relief you have received.

   0% 10 20 30 40 50 60 70 80 90 100%
   No relief *Complete relief*

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

   A. General activity

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

   B. Mood

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

   C. Walking ability

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

   D. Normal work (includes both work outside the home and housework)

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

   E. Relations with other people

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

   F. Sleep

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

   G. Enjoyment of life

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

   H. Ability to concentrate

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

   I. Appetite

   0 1 2 3 4 5 6 7 8 9 10
   Does not interfere *Completely Interferes*

Reference: Brief Pain Inventory. Charles Cleeland, PhD. Pain Research Group. Copyright 1991.

Available for public use.