A PILOT STUDY USING A CASE STUDY APPROACH OF THE EFFECTIVENESS AND MANAGEABILITY OF CONTINUOUS SUBCUTANEOUS INFUSION DRUG ADMINISTRATION FOR PATIENTS WITH CHRONIC MALIGNANT PAIN

by

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We accept this thesis as conforming to the required standard

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Abstract

The prevalence and complexity of unrelieved pain remains high among cancer patients, posing a challenge for health care providers to provide effective pain management. This becomes particularly challenging when the patient can no longer tolerate oral medications. Although continuous subcutaneous infusion (CSCI) via a low-technology syringe driver is commonly used as an alternative modality to oral administration in other countries, it has not been used much in Canada. The aim of this pilot study was to assess the feasibility of using a case study approach to gain insight into the decision to initiate CSCI via syringe driver and to test the effectiveness of CSCI related to pain and pain-related symptoms, and its comfort and manageability for use by patients who cannot tolerate oral medications and are experiencing severe or unstable pain. Both quantitative and qualitative approaches were used to gather information from the patient, family/caregiver, physician and community health care nurse. Data pertaining to levels of pain and pain-related symptoms were collected daily for two weeks and at a follow up point two weeks later using the Brief Pain Inventory and the Edmonton Symptom Assessment Scale plus questions related to frequency of breakthrough doses given and medication dosage. Questions were also asked about comfort and manageability in using CSCI via syringe driver.

Although the plan was to include four case studies, only one case was included because of difficulty with recruitment of people who met the study criteria. In the case examined, CSCI via syringe driver was initiated after other modalities (transdermal fentanyl patch and intermittent subcutaneous injections) were found to be ineffective or labour intensive. Syringe drivers were accessible in the community where the study was conducted and health care providers were competent in their use. The patient's wife was willing and
able to manage the modality and to assess her husband’s pain accurately, provide bolus doses appropriately and report difficulties in administration of CSCI or in management of her husband’s pain. In terms of effectiveness in managing pain, the administration of continuous and bolus doses of hydromorphone in increasing amounts was able to maintain the patient’s average daily pain levels between 1 and 3.5 (on a numeric scale of 0-10). When pain levels reached a 4, the patient’s wife administered a bolus dose. Least pain levels ranged from 0 and 0.5 daily, during the first two weeks. Two weeks following the main study period, the pain had increased considerably with average daily pain rated as 4 and worst pain rated as 9. Total hydromorphone administered increased from 114 mg to 204 mg during the first two weeks to a total of 378 mg per day (180 mg as continuous dose plus 11 breakthrough doses each of 18 mg) in the follow-up period. At that point, although better pain control would likely have been achieved by switching to methadone, switching would require patient hospitalization for medication adjustment. Neither the patient nor family wanted the patient to be hospitalized so the patient continued on CSCI at home until his death shortly after. In terms of pain-related symptoms, the main symptoms experienced related to elevated anxiety and tiredness. In terms of manageability, the patient’s wife managed CSCI via syringe driver and the administration of bolus doses with relative ease and reported changes in her husband’s condition when necessary.

Although limitations pertain to the small sample and the use of proxy pain assessments by the wife, the findings suggest that CSCI via syringe driver is generally effective in administering an opioid that could be quickly titrated to meet the individual needs of the patient and easily managed in the home. A case study approach is appropriate and feasible. Implications for theory, practice, education and research are suggested.
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CHAPTER ONE
INTRODUCTION

In this thesis, a pilot study that takes a case study approach to explore the effectiveness and manageability of continuous subcutaneous infusion drug administration via a syringe driver for patients with chronic malignant pain who are unable to tolerate oral opioids is described. The approaches used are consistent with the Multidimensional Model of Pain (Ahles, Blanchard & Ruckdeschel, 1983) that was the theoretical model that guided this study. The background to the pilot study is described in this chapter.

Background

One of the main symptoms that terminally ill patients seek to control is chronic malignant pain and its management continues to pose a challenge for health care providers (D'Olimpio, 2001; Heller, 2000; Stjernsward, 1997). Unrelieved chronic malignant pain remains a concern to both cancer patients and health care providers. Over 60% of cancer patients experience chronic malignant pain (Ahles, Blanchard & Ruckdeschel, 1983; Twycross, 1995) and of those, 65% to 80% continue to experience unrelieved pain (D'Olimpio, 2001; Fink & Gates, 2001; Heller, 2000; Stjernsward, 1997).

Pharmacological interventions, based on the severity of pain, provide the basis for the management of chronic malignant pain (Fallon & O’Neill, 2000). The use of oral opioid analgesic, primarily morphine, is the preferred pharmacological intervention (Deachman & Howell, 2001; Fallon & O’Neill, 2000), however, many patients with chronic malignant pain are unable to tolerate oral analgesics due to poor oral intake or poor gut absorption especially as their disease progresses. In these situations, alternative drug administrative modalities are used to increase medication absorption such as transdermal fentanyl patches, rectal...
suppositories, intermittent subcutaneous injections (ISCI), continuous subcutaneous infusions (CSCI) and intravenous infusions (IV) (Fallon & O'Neill, 2000).

Of the alternatives available, continuous subcutaneous infusion (CSCI) is an effective mode of medication administration in the management of chronic malignant pain when the oral route is no longer tolerated (Capes, Martin & Underwood, 1997; Dickman, Littlewood & Varga, 2002; Lynch, Butler, Huerta, Tsals, Davidson & Hamm 2000). When using CSCI, opioids remain in the system longer than either intravenous infusions (IV) or oral administration (Campbell, Mason & Weiler, 1983; Dawson, Brockbank, Carr & Barrett, 1999; Herndon & Fike, 2001; Lynch et al., 2000). Because of this, CSCI is able to maintain a steady plasma drug concentration, avoiding peaks and troughs that require breakthrough analgesic (Gomez, 2000). Preventing breakthrough pain is a major goal in the management of chronic malignant pain (McCaffery & Pasero, 1999). In addition to pain control, CSCI has the capability of providing continuous symptom control for nausea and vomiting (Arnold; 1994; Bruera, 1990; Pasero, 2002) and agitation (Kennedy, Lockhart-Wood & Fielding, 1999) because of its capability to administer multiple drugs simultaneously at one site (Dickman et al., 2002).

CSCI is delivered by a portable pump such as a syringe driver or a computer administrative device (CAD pump). In choosing an ideal portable device to accommodate different situations, the complexity of the device, the functional capability, the ease of management, the overall cost of the device and the medication preparation should be considered (Bruera, 1990). The syringe driver is a low technology, light-weight device that is easy to use, accommodates single or multi medication delivery, is less expensive than other delivery devices and does not require a special environment for medication preparation.
(Bruera, 1990; Kennedy et al., 1999). The syringe driver has been widely used in the United Kingdom, Ireland, Australia and New Zealand since the 1970’s as the route of choice for patients no longer able to tolerate oral analgesics (Herndon & Fike, 2001; O’Doherty, Hall, Schofield & Zeppetella, 2001).

Surveys in the United States reveal that approximately 75% of hospices in the United States use CSCI for administration of analgesics delivered by either the syringe driver or the CAD pump (Pasero, 2002). To date, no surveys have been conducted in Canada on how often CSCI is used, what delivery devices are used or how this modality is perceived in practice by patients, families and/or caregivers.

Problem Statement

A challenge for health care professionals is choosing the best treatment modality when the patient is unable to tolerate the oral route. The treatment needs to control chronic malignant pain, provide comfort and be easy to use. Guidelines are described in the literature that facilitate health care providers in choosing the correct medication or combination of medications for optimal pain management, but there are no established guidelines for the choice of an alternative modality when the oral route is not an option. In British Columbia, the transdermal fentanyl patch and intermittent subcutaneous injections are the delivery methods most commonly used when the oral route is not tolerated, although CSCI via syringe driver is being used in a few communities (R. Monrufet and C. Robinson, personal communication, October, 2002). A review of the literature did not identify the criteria used by health care providers in British Columbia to choose an alternative modality to the oral route.

Research conducted at the Edmonton General Hospital, Edmonton, Alberta (Bruera,
1990) suggests that CSCI has advantages over other alternative treatment modalities to the oral route by its ability to provide continuous pain relief and, if required, multi-symptom control. There is no information in the literature that has examined how CSCI via syringe driver affects the ease of use or comfort level of patients and their families/caregivers in managing chronic malignant pain.

Purpose

The purpose of this research is fourfold. Firstly, the factors considered by health care providers when making a decision to put a patient on CSCI via a syringe driver will be described. Secondly the level of pain control achieved when using CSCI in the management of chronic malignant pain and related symptoms will be described for a small group of cancer patients. Thirdly, the patients’, families’ and/or caregivers’ perception of ease and comfort with using CSCI via syringe driver will be described. Finally, this is a pilot study and as such the focus will be on determining the feasibility of carrying out such a study.

Research Questions

Review of the literature and clinical observations lead to the following research questions regarding patients coping with chronic malignant pain who are unable to tolerate oral medications and who are receiving pain relief through CSCI via the syringe driver. They are:

1. What factors do health care providers consider when making a decision to initiate the use of CSCI via a syringe driver for a patient experiencing chronic malignant pain?

2. How does the level of self-reported chronic malignant pain change for patients receiving analgesics via CSCI using a syringe driver from before they begin using it to two weeks later?
3. What is the frequency and severity of self-reported breakthrough pain in 24 hour periods with patients receiving analgesics via CSCI using a syringe driver?

4. What is the severity of self-reported symptoms (tiredness, nausea, depression, drowsiness, appetite, shortness of breath and constipation) and how does severity change for patients receiving analgesics and perhaps other medications via CSCI using a syringe driver?

5. What are the perceived benefits and/or difficulties related to pain and symptom management, ease of use and comfort level for patients and families/caregivers when medications are administered via CSCI using a syringe driver?

Significance of the Pilot Study

The significance of this pilot study is to provide insight into the effectiveness of CSCI via syringe driver with a small group of cancer patients. The patterns and frequencies of characteristics noted could be useful in providing an understanding or explanation of the characteristics surrounding the initiation of CSCI via syringe driver and its effectiveness in managing chronic malignant pain and related symptoms. Furthermore this pilot study is helpful in determining the feasibility of carrying out such a study and useful in providing guidelines from which future research may draw.

Overview of Thesis

This thesis consists of six chapters. In Chapter One, an introduction to the thesis is described consisting of the background information, the problem and purpose, the research questions and the significance of the study. In Chapter Two the literature review is presented. Definitions and two theories on pain, an overview of treatment modalities, both non-pharmacological and pharmacological, pain related symptoms and the decision making
process are described. In Chapter Three, the methods used in the pilot study are described. The case study approach is described as well as the sampling procedures, data collection procedures, instrumentation, data analysis procedures and the ethical considerations. In Chapter Four, the findings related to Mr. A are presented. In Chapter Five the findings are discussed in light of the literature and the experience in using the method as well as a discussion on the feasibility of the research. The thesis is completed in Chapter Six, with the summary, conclusions and implications for theory, practice, education and research.
CHAPTER TWO
LITERATURE REVIEW

In the review of the literature, the accepted definitions of pain and pain mechanisms will be examined followed by a discussion of theories on pain. Emphasis will be put on the Multidimensional Model of Pain presented by Ahles, Blanchard and Ruckdeschel (1983) as that model acknowledges the complexities of malignant pain in particular. Management strategies, primarily pharmacological, based on the accepted definitions, mechanisms of action and theories will then be described. This will be followed by a discussion of the decision making process utilized by health care providers to choose the optimal pain management strategy that includes not only the pharmacological agent(s) but also the modality of medication administration.

Definitions of Pain

The International Association for the Study of Pain, (IASP), (1979), defines pain as “a sensory or emotional experience associated with tissue damage” (Fink & Gates, 2001, p. 53). McCaffery, a nurse, recognized the individual nature of pain and further defined it as being “whatever the experiencing person says it is, existing whenever the experiencing person says it does” (McCaffery, 1980, p. 26). However, in some cases, a patient is unable to communicate verbally, but is still experiencing pain. In acknowledgement of this omission the IASP Council (2001) included in part of the IASP formal definition of pain that “the inability to communicate in no way negates the possibility that an individual is experiencing pain and is in need of appropriate pain relieving treatment” (IASP, retrieved August 15, 2002). Taken together, the revised ISAP definition of pain and the contribution made by McCaffery (1980) emphasize the personal and multidimensional nature of an individual’s
pain experience while recognizing that a multitude of factors impact on the psychosocial and physical state of the individual—especially if the pain is chronic (McCaffery & Pasero, 1999).

**Chronic Malignant Pain**

Chronic pain is defined as long-term pain persisting for several months (Caraceni & Weinstein, 2001; Wujcik & Utley, 1997). Chronic pain is associated with changes in lifestyle, personality, functional abilities, plus signs and symptoms of depression (Wujcik & Utley, 1997). Malignant pain is defined as pain resulting from neoplastic processes caused by either the tumor and/or tumor invasion into surrounding tissue or by cancer therapy (McCaffery & Pasero, 1999; Parris, 1997). Recent reports and surveys found malignant pain to be a direct result of the tumor in 70% to 80% of cancer patients and from the cancer treatments in 20% of patients (Caraceni & Weinstein, 2001; Twycross, 1995; Wujcik & Utley, 1997). It is important to note that individuals who have long term chronic pain can experience episodes of acute or short term pain. The acute episode is often caused by a complication in the disease process and can result in hospitalization of the patient and a change in pain management strategies.

**Classification of Cancer Pain**

Many researchers have studied the complex phenomenology of cancer pain, initially pioneered by Foley and Twycross in the 1970’s. A classification of cancer pain syndromes evolved from the research that identified the three most prevalent syndromes as somatic, visceral and neuropathic (Caraceni & Weinstein, 2001; Twycross, 1995). It is important to differentiate between the three syndromes as each responds differently to therapeutic treatments (Fallon & O’Neill, 2000; McGuire & Sheilder, 1997; Wujcik & Utley, 1997). The location, intensity and quality of the pain sensation, as described by the patients themselves,
provide the added tool to accurately classify the pain syndrome. Somatic and visceral pain are classified as nociceptive pain that is usually responsive to non-opioids and/or opioids, while neuropathic pain classified as non-nociceptive requires additional medications or adjuvant medications to opioids (McCaffery & Pasero, 1999).

Somatic pain stems from the bone, joint, muscle, skin or connective tissue (McCaffery & Pasero, 1999). It is generally well localized, made worse on movement (Librach & Squires, 1997) and is described as aching or throbbing (McCaffery & Pasero, 1997). Visceral pain is due to a visceral lesion described as aching, dull, and cramping (Caraceni & Weinstein, 2001). It is often associated with bloating (Fallon & O’Neill, 2000), that may or may not be attributed to tumor involvement (McCaffery & Pasero, 1999). It is often poorly localized and constant (Librach & Squires, 1997; Wujcik & Utley, 1997).

Neuropathic pain is the abnormal processing of sensory input caused by a primary lesion or dysfunction in the central or peripheral nervous system (IASP, 2002; McCaffery & Pasero, 1999). Neuropathic pain has been described as lancinating, burning, stabbing, stinging or aching (Fallon & O’Neill, 2000; Wujcik & Utley, 1997).

Other terminology relevant to the management of chronic malignant pain includes the following terms:

- **Pain-threshold** refers to the “least experience of pain that a subject can recognize” or “the level at which 50% of stimuli are recognized as painful” (IASP, retrieved August 15, 2002).

- **Pain-tolerance level** a subjective experience that refers to duration or intensity of pain that the patient is willing to tolerate (IASP, retrieved August 15, 2002; McCaffrey, 1980).
Breakthrough pain  "pain that increases above the pain addressed by the ongoing analgesics" (McCaffery & Pasero, 1999, p. 162).

Breakthrough dose  analgesic dose provided when the pain breaks through the patient’s pain tolerance level (Librach & Squires, 1991).

Long-acting  analgesics that provide a sustained release of opioid, reaching a peak absorption and remaining effective for a longer period of time (Librach & Squires, 1991).

Short-acting  analgesics that provide an immediate release of opioid (Librach & Squires, 1991).

Bioavailability  refers to the quantity of drug that is absorbed from the site of administration and distributed via the systemic circulation to the tissues of the body (Johnson, Hannah & Rankin Zerr, 1992).

Half-life  the time it takes for the body tissues or organs to metabolize half the amount of an administered medication (Johnson et al., 1992).

Theory of Pain

Pain theories have evolved that parallel our understanding of human anatomy, physiology and behaviour (Neilson, 2001). Chronic malignant pain is a complex pain phenomenon, influenced by a myriad of factors. The physical pain the patient experiences is only one dimension of the suffering the patient endures (Saunders, 2000). Pain affects many dimensions of a patient’s life, including how they perceive themselves and interact with significant others. Formulations that conceptualize pain as a multidimensional experience, such as the Gate Control Theory and the Multidimensional Model of Pain, provide the most comprehensive approach to optimal management of chronic malignant pain.
The Gate Control Theory

In the Gate Control Theory proposed by Melzack and Wall (1965), pain is described as a multidimensional rather than a unidimensional phenomenon. The theory evolved from Descartes' specificity theory that explains only the sensory dimension of pain (Ahles et al., 1983; Melzack & Wall, 1965; Nilson, 2001). The premise of the Gate Control Theory is that peripheral nerve fibers carrying the sensation of pain to the spinal cord can have their input modified at the spinal cord level thereby interrupting transmission of pain to the brain (Melzack & Wall, 1965). According to the Gate Control Theory psychological (cognitive and affective) factors as well as physiological (sensory) factors are recognized as influencing pain by acting on the gate control system to moderate or reduce the sensory perception of pain experienced by the individual (Melzack, 1991, 1993; Melzack & Wall, 1965). Ahles et al. (1983) built on the Gate Control Theory to develop a Multidimensional Model of Pain that further explores the complexity of the pain as experienced by the cancer pain populations with additional emphasis on the behavioural and sociocultural dimensions.

The Multidimensional Model of Pain

Examining how individual patients interpret symptoms associated with their pain experience furthers understanding of the complexity of cancer-related pain. Ahles et al. (1983) studied the impact of various dimensions of pain as it related to the individual with cancer. Five dimensions of cancer-related pain (physiological, sensory, affective, cognitive and behavioural) were observed within cancer patients who had similar diagnoses. The cancer patients were divided into two groups, one group for cancer patients experiencing pain and the second group for cancer patients not experiencing pain. The two groups were observed for their level of disturbance within the five dimensions (physiological, sensory,
affective, cognitive and behavioural) and compared. The findings supported the multidimensional conceptualization of cancer-related pain in that patients reporting pain also reported disturbances or changes within the five dimensions, whereas patients reporting no pain did not (Ahles et al., 1983). A brief description of each dimension within the multidimensional model proposed by Ahles et al. (1983) will follow.

The physiological dimension, relates to the organic etiology or type of pain and addresses three cancer-related pain syndromes: somatic, visceral and neuropathic that are either tumor-related or treatment-related (McGuire & Sheidler, 1997). The sensory dimension considers the location, intensity and quality of the pain unique to each individual (Ahles et al., 1983; McGuire & Sheidler, 1997).

Patients, not only experience pain location, duration and severity, but also experience an emotional reaction that is addressed in the affective, cognitive and behavioural dimensions. For this reason, pain management strategies may use a combination of pharmacological and non-pharmacological approaches to provide optimal pain management (Kwekkeboom, 1999). The affective dimension consists of psychological factors and/or personality traits associated with the pain experience (Ahles et al., 1983; McGuire & Sheidler, 1997). Constant pain or an increase in pain is often associated with disease progression and may instill anxiety, fear, depression, irritability or hostility (Ahles, et al., 1983; Kwekkeboom, 1999; McGuire & Sheidler, 1997; Pargeon & Hailey, 1999). Relief from chronic malignant pain can have a direct positive effect on emotional well-being while unrelieved pain demoralizes and disturbs interpersonal relationships, leading to anxiety, loneliness, depression and fear, isolating patients from family and friends and often instilling feelings of helplessness (Miettinen, Tilvis, Karppi & Arve, 1998).
The cognitive dimension encompasses how a patient perceives himself/herself, how the pain affects their thought processes and their comprehension of the pain experience and its management strategies (Ahles et al., 1983; McGuire & Sheidler, 1997).

The behavioural dimension includes observable behaviours related to pain such as; activity levels, analgesic intake, and how patients manifest or report pain to family members and caregivers (Ahles et al., 1983; McGuire & Sheidler, 1997).

McGuire (1987) (cited in McGuire & Sheidler, 1997) expanded the Multidimensional Model of Pain by adding a sixth component identified as the sociocultural dimension. The sociocultural dimension encompasses many factors impacting a patient’s life that include demographics, ethnicity, culture, spiritual or religious affiliations and familial support (McGuire & Sheidler, 1997). Figure 1 illustrates the relationship of the pain experience radiating out to influence the six dimensions and each dimension radiating in to influence the pain experience.

*Figure 1.* Schematic diagram of the Multidimensional Model of Pain.

Adapted from Ahles et al. (1983)
Ahles et al.'s (1983) original work thus stresses the interrelated nature of the dimensions studied and their impact on the patient’s perception of cancer-related pain. For optimal management of cancer-related pain, a complete and accurate assessment of the patient’s individual experience of pain is needed. A multidimensional approach explores the physiological and sensory dimensions and also the affective, cognitive, behavioural and sociocultural dimensions impacting the patient’s self-report of the pain experience.

Overview of Treatment Modalities

As part of a thorough assessment of the patient’s pain experience, the choice of an individualized treatment plan should be addressed. Interventions are pharmacological and/or non-pharmacological in nature.

*Non-Pharmacological Strategies*

Non-pharmacological approaches to pain control that are directed to the sensory and behavioural dimensions of pain include palliative radiation, surgery, acupuncture, biofeedback, nerve blocks and skin stimulation (Fallon & O’Neill, 2000; Health Canada, 1997; Jones & Pegis, 2001). Application of heat or cold, massage, exercise, repositioning, transcutaneous electrical nerve stimulation, therapeutic touch, reiki, and reflexology in conjunction with other interventions have also been found effective in relieving pain (Deachman & Howell, 2001). Psychological approaches that are directed to the affective and cognitive dimensions include support groups, psychotherapy, religious counseling, hypnosis, distraction, relaxation and imagery techniques, art, music and aromatherapy (Deachman & Howell, 2001; Health Canada, 1997; Jones & Pegis, 2001). These approaches are often used in conjunction with pharmacological interventions in both curative and palliative situations.
Pharmacological Strategies

Pharmacological strategies not only affect the physiological and sensory dimensions. They also impact on the affective, cognitive, behavioural and sociocultural dimensions of an individual’s pain experience. Analgesics, primarily opioids, form the basis of cancer pain management based on the severity of the pain (Fallon & O’Neill, 2000). Opioids reduce pain by stimulating opioid receptors in the central nervous system that inhibit the release of pain impulses (Johnson et al., 1992; Melzack & Wall, 1983). Some opioid receptors located in the brain stem, limbic system and hypothalamus, however, have an adverse effect when stimulated effecting respiration, vomiting, mood, behaviour and endocrine changes (Johnson et al., 1992; Librach & Squires, 1997). The ability to maintain a steady plasma concentration of opioid while minimizing opioid induced side effects will thus need to be considered when choosing the medication and mode of delivery most suitable for the patient (Mitten, 2001).

Long acting or slow release analgesics work most effectively when a steady plasma concentration is achieved (see Figure 2). Breakthrough analgesic, usually a quick-acting opioid, is given when the pain peaks above the pain-threshold or is not being controlled by the long acting opioid (McCaffery & Pasero, 1999) either due to a drop in the plasma concentration of the opioid or an increase in the severity of the pain that could be due to increased mobility or disease progression.

The use of adjuvant medications, where the primary indication is not pain management, also have an analgesic effect primarily with neuropathic pain (Fallon & O’Neill, 2000). They include anticonvulsants for pain relief caused by nerve damage, antidepressants for chronic pain, steroids to relieve pressure caused by swelling, and muscle relaxants (Cameron-Muir, Krammer, Cameron & von Gunten, 1999; Deachman & Howell,
The World Health Organization (WHO) established a three-step analgesic ladder (see Appendix A) to aid in the selection of the right medication for mild, moderate or severe pain. Each step recommends the use of a non-opioid and/or opioid and the choice of an adjuvant based on the severity of the pain and not the stage of the disease (Fallon & O’Neill, 2000). Unfortunately the three-step ladder does not provide guidance for the mode of medication administration and it has been known to encourage many practitioners to start low on the ladder resulting in chronic or sustained under-treated pain (D’Olimpio, 2001; Hagen, 2001).

Choice of route for opioid administration includes oral, rectal suppositories, transdermal fentanyl patches, intermittent subcutaneous injections, continuous subcutaneous infusions, intravenous infusions and epidermal infusions (see Appendix B for analgesic routes). The oral route is the first route of choice because it is easy to administer and is cost effective. An appropriate selection of medication(s), dosage, and route flows from an accurate assessment of the pathophysiology of the cancer and intensity, character and

Figure 2. Steady plasma concentration of analgesic.
location of the pain reported by the patient.

**Oral Analgesics**

Approximately 80-90% of pain due to cancer can be relieved with oral analgesics and adjuvant medication in accordance with the WHO guidelines (D’Olimpio, 2001; Fallon & O’Neill, 2000) (see Appendix B). Morphine, a purified derivative of opium, is considered the “gold standard” of opioid therapies and is the most common opioid analgesic as it is widely tolerated and relatively inexpensive (Deachman & Howell, 2001; Fallon & O’Neill, 2000; Lynch et al., 2000; Mercadante et al., 2001; Neighbors, Bell, Wilson & Dodd, 2001). It is absorbed in the upper bowel and metabolized in the liver (Stuart-Harris, Joel, McDonald, Currow & Slevin, 1999). Some cancer pain responds only to extremely high doses of opioids, such as morphine, resulting in increased toxicities and adverse effects that include drowsiness, nausea, vomiting, constipation, dry mouth and muscle cramps (Deachman & Howell, 2002; Fallon & O’Neill, 2000). Opioid alternatives to morphine, used when a patient is unable to tolerate morphine due to an allergic reaction or increased side effects, include hydromorphone, fentanyl, diamorphine and methadone (Fallon & O’Neill, 2000; Mercadante et al., 2001).

**Alternative Methods of Administering Opioids**

Alternatives to the oral route are used when there is poor oral intake, poor gut absorption or lack of compliance. These include the use of rectal suppositories, transdermal fentanyl patches, intermittent subcutaneous injections (ISCI) and continuous subcutaneous infusions (CSCI) (D’Olimpio, 2001). Characteristics of the oral, transdermal fentanyl patch, ISCI, CSCI and IV routes of administration are outlined in Appendix B. The intravenous infusion route is used for acute episodes, such as treatment-induced mucositis pain and not
for ongoing chronic palliative pain, although studies that compare the efficacy of opioids administered via CSCI and ISCI with IV administration will be discussed in this paper.

**Rectal Suppositories**

Rectal suppositories are a low cost alternative to taking medications by mouth. Their bioavailability is equal to that of the oral route (D'Olimpio, 2001; Fallon & O’Neill, 2000). Many patients prefer alternative routes to the rectal route for convenience and comfort (Fallon & O’Neill, 2000). This route is also contraindicated in patients who are neutropenic or thrombocytopenic as it could put them at risk for infection or bleeding.

**Transdermal Fentanyl Patch**

A safe effective alternative to oral opioids is the use of the transdermal fentanyl system that has been on the market since 1989 (D’Olimpio, 2001). The fentanyl patch is a self-adhesive patch that provides a transcutaneous delivery of a strong opioid (Fallon & O’Neill, 2000). The fentanyl patch is considered step three on the WHO analgesic step ladder, although it is not discussed in the WHO guidelines, probably because it was new on the market at the time the guidelines were written (Neighbors et al., 2001). Studies have shown that the transdermal fentanyl patch can be an effective modality for controlling chronic malignant pain in AIDS patients (Newshan & Lefkowitz, 2001). Due to its distinct chemical structure, fentanyl is an acceptable alternative for patients allergic to morphine (Neighbors et al., 2001). It is however, contra-indicated in patients requiring rapid titration of their medication for severe uncontrolled or unstable pain because a steady plasma concentration of the opioid is not achieved for 12 to 24 hours after application of the patch (Librach & Squires, 1997; Neighbors et al., 2001). The recommended ceiling dose of 300 micrograms makes it unsuitable for severe pain (Librach & Squires, 1997). Other
considerations are the resulting skin deposit of medication after removal of the patch that may prolong adverse effects experienced by the patient (Librach & Squires, 1997). The fentanyl patch must be applied to hairless, clean, dry skin that could pose a problem for patients with gross edema, skin rashes, night sweats or other major problems of adhesion (Librach & Squires, 1997).

Intermittent Subcutaneous Injections

Intermittent subcutaneous injections (ISCI) are administered to patients who require a few regular injections over a 24-hour period. A small-gauge butterfly needle is inserted subcutaneously to provide comfort against repeated injections (Librach & Squires, 1997). Although the technique is less expensive and less complex than continuous subcutaneous infusions, it is not appropriate for large doses and may cause increased side effects of nausea and vomiting related to the peak effects of the bolus dosing (Librach & Squires, 1997).

Continuous Subcutaneous Infusions

Continuous subcutaneous infusion (CSCI) has been found to be effective for cancer pain management (Lynch, et al., 2000). CSCI can be administered either by a portable syringe driver or a computerized administration device (CAD pump). The infusion device can be individualized to provide multisymptom management with three to four medications combined (antiemetics, anticonvulsants or antidepressants) or strictly for pain management with the provision of self-administered breakthrough boluses (Dickman et al., 2002; O'Doherty et al., 2001; Perdue, 2004). Studies have examined the efficacy of opioids administered via CSCI, the safety and continuity of administration, and the effectiveness of CSCI as a modality for chronic malignant pain management (Dawson et al., 1999; Deachman & Howell, 2002; Herndon & Fike, 2001; McCormick, Cooper, Sutherland & Stewart, 2001;
Moulin, Kreeft, Murray-Parsons & Bourquillon, 1991; O’Doherty et al., 2001; Nelson, Glare, Walsh & Groh, 1997; Stuart-Harris et al., 2000). A common message of these studies is that the CSCI, independent of the delivery device, is the most effective mode of delivering a sustained level of opioid concentration, thereby minimizing the frequency of breakthrough analgesic and optimizing pain relief. The findings of these studies will now be described.

Studies in support of CSCI. A randomized trial of 81 patients undergoing gynecological surgery found that patients receiving CSCI-administered diamorphine required less breakthrough analgesic over 48 hours than those receiving it intermittently by IV administration (Dawson et al., 1999). The larger bolus delivered by CSCI absorbed more slowly and sustained a peak plasma concentration over a longer time period, therefore limiting the peaks and troughs that were evident with the intermittent IV infusion (Dawson et al., 1999).

Three studies used a within-patient-crossover design, where the same subject experienced different modalities of medication administration, to compare the bioavailability and pharmokinetics of the medication between the different modalities. Two studies compared morphine given via IV infusion to CSCI (Nelson et al., 1997; Stuart-Harris et al., 2000) and a third study compared hydromorphone via IV infusion to CSCI (Moulin et al., 1991). The three within-patient-crossover studies found no difference in the plasma concentration of the morphine or hydromorphone between the two routes. Stuart-Harris et al. (2000) reported that the bioavailability of morphine was less with CSCI than IV administration, but did not deem the finding to be clinically significant. The bioavailability, or amount of drug available systemically after administration of oral morphine was 25%.
This is considerably less than the finding of 70% bioavailability when morphine was administered by CSCI and 75% via the IV route (Stuart-Harris et al., 2000).

In terms of analgesic efficacy, Moulin et al. (1991) and Nelson et al. (1997) found that pain control and side-effect profiles were quite similar and acceptable between CSCI and IV infusions of opioids. Moulin et al. (1991) measured pain intensity, pain relief, general mood and sedation over 48 hours on 15 cancer patients using visual analogue scales, 0 to 10 centimeters in length, and found no statistically significant difference in analgesic efficacy or side effects between intravenous and subcutaneous infusions of hydromorphone. Nelson et al. (1997) measured pain intensity on 40 cancer patients twice daily for 48 hours on a visual analogue scale, where 0 = no pain and 100 = worst pain possible, and on a categorical pain questionnaire (0 = none, 1 = mild, 2 = moderate and 3 = severe). Side effects were measured on the categorical questionnaire only. Nelson et al. (1997) concluded that the 40 patients who completed the study had adequate pain control and no dose limiting toxicity with both subcutaneous and intravenous infusions. The study by Stuart-Harris et al. (2000) investigated the pharmokinetics of morphine given by subcutaneous injection, CSCI and IV on 6 healthy individuals and therefore did not measure the efficacy of the analgesic.

All three studies indicated CSCI to be a cost effective alternative for parenteral administration for both morphine and hydromorphone that can be managed effectively within hospital and community settings by health care professionals or family members. CSCI has easy site access with a lower incidence of infection since it is less invasive than the IV route (Herndon & Fike, 2001). Another advantage of CSCI over IV administration is that the problem of administering excess fluid to a palliative patient is avoided since CSCI allows for
the infusion of small amounts of concentrated medication into the subcutaneous compartment (Herndon & Fike, 2001).

**CSCI delivery via syringe driver versus CAD pump.** CSCI can be delivered by a portable pump such as the low-tech syringe driver or by a more complicated computer administrative device (CAD pump). In choosing an ideal portable device to accommodate different situations the complexity of the device, the functional capability, the ease of management, the overall cost of the device and the medication preparation should be considered (Bruera, 1990).

The syringe driver is easy to use with only three controls: start button and two dials for rate settings with an automatic turn-off when the syringe is empty (MarCal, 2003) while the CAD pump is more complex with a 24-key numeric keypad and built-in 400 event memory (Abbott, 2002). Both the syringe driver and the CAD pump provide symptom control while allowing for independence and freedom of movement for the patient. However, the syringe driver, widely used in parts of the world, is relatively inexpensive, and easy to use compared to the CAD pump, which is also relatively complicated to use (Lynch et al., 2000). The syringe driver is light-weight, weighing approximately 6 ounces in a shoulder or belt holster (MarCal, 2003) compared to the CAD pump that weighs approximately 17 ounces (Abbott, 2002). Ease of use affects the comfort level of the patient, family and caregiver and should be considered when choosing the appropriate pump for the administration of CSCI.

In 1978, the International Conference on Primary Health Care recommended the “development, adaptation, and application of appropriate health technology that the people can use and afford” (WHO, 1978, p. 19). The cost of a syringe driver is half that of the CAD
pump. The syringe driver costs approximately $1300 to $1500 (US) plus batteries (Capes et al, 1997) while the CAD costs between $3000 and $5000 depending on the available functions (Abbot, 2002). Medications for the CAD pump are prepared by pharmacists in a special area using a laminar flow hood (L. John, personal communication, October, 2002) while the medications for the syringe driver can be prepared by the community pharmacist or by a registered nurse, limiting cost and increasing accessibility (Kennedy et al., 1999).

The use of CSCI via syringe driver. The use of CSCI via syringe driver varies among countries. In Ireland and the United Kingdom, a survey of 208 palliative care in-patient units, resulting in a 79% response rate, was conducted to examine the use of syringe drivers as a mode of drug delivery for CSCI on the units (O’Doherty et al., 2001). The survey revealed that there was a consistency in use of syringe drivers and medication combinations combining analgesics with antiemetics, anticonvulsants or antidepressants for effective symptom control (Dickman et al., 2002; O’Doherty et al., 2001). In the United States, a similar survey was conducted among hospices (Herndon & Fike, 2001). Although the response rate was only 24%, CSCI was being used effectively in those facilities, but the CAD pump was used more than the syringe driver (Deachman & Howell, 2002). A literature search did not find a similar survey in Canada. However, two communities in British Columbia, central Vancouver Island (R. Monrufet, personal communication, September 26, 2002) and the Southern Central Interior (V. Gibault, personal communication, September 18, 2002) use the syringe driver for pain and/or symptom management in both hospital and community settings. CAD pumps are used in Vancouver and the lower mainland for CSCI administration in community settings only (J. Aleksich, personal communication, July 28, 2002). The WHO (1978) recommends that “technological equipment be appropriate for
community and all supportive levels especially those closest to the community such as health centres or district hospitals” (WHO, 1978, p. 61).

*Barriers to syringe driver use.* A lack of familiarity with the use of syringe drivers among physicians and nurses has resulted in the underutilization of CSCI in Canada and the United States (D'Olimpio, 2001) while it has been widely used in the United Kingdom, Australia and New Zealand since the 1970's (Herndon & Fike, 2001; O'Doherty et al., 2001).

The concern of safe administration of medications may hinder the decision to initiate CSCI via syringe driver. An investigation in an unexpected home death in Quebec, Canada, as a result of an increased dose of hydromorphone and midazalam mistakenly administered via syringe driver (C. Oliver, personal correspondence, August 8, 2003) and a research study conducted on the safe use of the syringe driver in Scotland (McCormick et al., 2001) reported similar recommendations for safe use. The recommendations included increased education in safe handling of the syringe driver for health care providers, patients and families/caregivers, increased familiarity for health care providers, the introduction of ongoing audit of drug prescribing and syringe driver use and that a safety lock feature be provided by the manufacturer (C. Oliver, personal correspondence, August 8, 2003; McCormick et al., 2001).

Palliative care facilities that use the CSCI approach for pain management advocate that CSCI be the preferred strategy for patients with chronic malignant pain (Herndon & Fike, 2001; Perdue, 2004). The ability to meet individual patient needs, to deliver multiple medications for multi-symptom control or to provide opioid delivery with provision of breakthrough boluses for pain relief can optimize the quality of life for patients, families and their caregivers. A treatment modality that is compact and easy to use, such as the syringe driver, enhances mobility for the patient and decreases anxiety for all concerned, however
lack of knowledge and familiarity with the use of the syringe driver present barriers to its safe use.

**Pain-Related Symptoms or Problems**

Pain-related symptoms or problems compromise the patient's quality of life and affect their ability to cope with activities of daily living. Opioid-induced toxicities include constipation, nausea and vomiting, drowsiness, confusion, hallucinatory effects, respiratory depression, myoclonus or muscle spasms, urinary retention and dry mouth (Librach & Squires, 1997). Incidents have occurred where patients find coping with the side effects from opioids unacceptable, causing them to lower their opioid dose at the risk of experiencing uncontrolled pain (Neighbors et al., 2001). Appropriate interventions can prevent or minimize opioid-induced side effects. The main side effects, their etiology and effective interventions are described in Table 1 (Librach & Squires, 1997; Wujcik & Utley, 1997).

**Table 1**

*Intervention for opioid-induced side effects*

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Etiology</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>Opioids bind to receptors in smooth muscle.</td>
<td>Stool softener with stimulant. Goal is bowel motility every 2-3 days; increase fluids to 2 litres; institute foods and fluids that support regular elimination.</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>Stimulation of chemoreceptor trigger zone; inhibition of gastrointestinal motility; stimulation of vestibular nerve.</td>
<td>Add Antiemetics. Switch opioid or try a different route of administration.</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>CNS depression.</td>
<td>Stepwise reduction of dose or stimulant. Assess sedation versus exhaustion; assess other etiology for sensation.</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Opioids bind to receptors in CNS.</td>
<td>Physical stimulation. Administer diluted naloxone if respirations less then 8 breaths per minute and unable to arouse.</td>
</tr>
</tbody>
</table>

(adapted from Librach & Squires, 1997; Wujcik & Utley, 1997)
Other problems associated with chronic malignant pain include anger, anxiety, depression and uncertainty that can shape the perception of pain (Cameron-Muir et al., 1999; Twycross, 1995). The patient’s perception of pain is influenced by the affective, cognitive, behavioural and sociocultural dimensions of their pain experience and can influence self-reporting of the pain phenomenon.

Utilization of the Multidimensional Model of Pain

The Multidimensional Model of Pain can assist the health care provider in addressing the various dimensions of the total pain experience, thereby guiding an accurate assessment of the patient’s pain. The physiological and sensory dimensions acknowledge an accurate description of the pain syndrome that is used to determine the optimal pharmacological approach to pain management. The physiological dimension describes the duration, pattern and organic etiology of the pain that directs the choice of pharmacological intervention. Somatic and visceral pain respond to opioids, whereas neuropathic pain requires an additional adjuvant to maximize pain control. The sensory dimension describes the severity of the pain experience that corresponds with the patient’s pain-threshold guiding health care providers to determine the most appropriate medication dose for optimal comfort and relief from pain.

The affective, cognitive, behavioural and sociocultural dimensions reflect the patient’s emotional response to pain. They provide insight into the patient’s ability to cope with and communicate their pain experience. The affective dimension impacts the patient’s self-report of pain when the experience includes emotions of anxiety, depression and fear. Level of cognition can also influence the patient’s ability to effectively communicate their experience of pain experience. Within the cognitive dimension, expectations, formed from
past experiences, may increase a patient’s anticipatory fear of pain, which in turn may influence their willingness to try various treatment options, or to fairly evaluate their effectiveness (Kwekkeboom, 1999; McCaffrey, 1980; Riddell & Fitch, 1997). Cognitive deficits have been known to occur during the initiation and titration of an opioid but subside once opioid levels stabilize (McGuire & Sheidler, 1997). Understanding how the affective and cognitive dimensions affect the patient’s perception of pain and their ability to effectively communicate their pain experience should be a consideration when selecting the most appropriate medication, dose and mode of delivery for optimal pain management.

Behavioural indicators of pain within the behavioural dimension include grimacing, guarded movements, decreased mobility and decreased daily activities (McGuire & Sheidler, 1997; Miettinen et al., 1998). The behavioural dimension can guide the use of non-pharmacological therapeutic interventions, such as distraction, to provide comfort and also influence the pharmacological treatment modality to enhance freedom of movement and independence while decreasing reliance on caregivers.

The sociocultural dimension describes the impact on the social and moral support available to the patient in coping with their emotional and behavioural responses to pain. It also affects the patient’s dependence on health care providers and could influence the choice of treatment modality to promote independence.

The dimensions require consideration independently and collectively to assist in choosing the most appropriate treatment option to achieve optimal management of chronic malignant pain that improves the patient’s adjustment to the illness, increases daily function and decreases dependence on others for pain relief. Pharmacological strategies appeal mainly to the physiological and sensory dimensions of the pain experience, but the mode of
administration can have a profound effect on the affective, cognitive, behavioural and sociocultural dimensions of the patient’s well-being. Pain experts widely acknowledge, that if the patient’s pain and pain-related side effects are managed effectively the well-being of the patient is also enhanced (Ferrell, Wisdom, Wenzl & Brown, 1989; Saunders, 2000).

The utility of the Multidimensional Model of Pain is useful to the decision making process as it provides guidance for an individualized approach that addresses all aspects of the pain experience from which the treatment decision flows. It is also valuable in the ongoing evaluation of the effectiveness of the treatment strategy with continual observation of the interactions between dimensions.

Decision Making

To strengthen the decision making process for optimal pain management it is necessary for the health care provider to recognize pain as a multidimensional experience where the patient is the authority on the pain phenomenon (McCaffrey, 1980). Successful pain management can increase a patient’s function, alertness, and independence and improve their adjustment to their illness (Rowbotham, 1995; Saunders, 1986). Pain management fails when pain persists unchanged, while treatment plans are adhered to, or when pain improves but the residual pain remains disabling (Rowbotham, 1995).

Two predominant theoretical approaches to clinical decision-making are described in the literature as a systematic-positivist approach and an intuitive-humanist approach (Thompson, 1999). A systematic-positivist approach is based on four stages that include gathering clinical data, initiating hypotheses, interpreting interventions and finally evaluating the advantages and disadvantages of the decision (Thompson, 1999). An intuitive-humanist approach is based on intuition and professional knowledge that is more subjective in nature.
and is not defined by stages or steps (Thompson, 1999).

Obtaining an accurate assessment of an individual’s pain experience follows a systematic-positivist approach in the gathering of clinical data. Decision-making guidelines, algorithms and measurement tools provide the framework to guide health care providers in effective pain assessment (DuPen & DuPen, 2000; Hagen, 2001). The WHO and the Agency for Health Care Policy and Research (AHCPR) both published guidelines promoting interdisciplinary and multidimensional approaches to a comprehensive assessment of chronic malignant pain. The guidelines include the taking of a detailed history (see Table 2 for assessment), a thorough physical examination, a psychological assessment, diagnostic evaluation and psychosocial assessment (Pargeon & Hailey, 1999; Wujcik & Utley, 1997).

The fact that the patient remains the best source of information for the decision making process in choosing the optimal treatment option (Pargeon & Hailey, 1999) reflects the importance of considering the affective, cognitive, behavioural and sociocultural dimensions of the patient’s pain experience as they have a profound effect on the patient’s perceptions and self-reports of pain. The nurse acts as a facilitator by providing education and guidance that dispel myths and break down barriers while promoting skills in defining pain, describing intensity, location and sensation to attain an accurate report from the patient (Foster & Corless, 1999; McCaffey & Pasero, 1997). Frequent assessment and evaluation of the patient’s comfort level is a key factor to successful management (Hagen, 2001) because advancing disease causing increased pain may require continual adjustment of the individualized treatment plan (Fallon & O’Neill, 2000).

Choosing the optimal pharmacological agent that follows from the clinical assessment of the individual’s pain experience also follows a systematic-positivist approach to decision-
making. The WHO three-step analgesic ladder provides a guide in choosing the right medication(s) or combination for optimal pain management. However, choosing the administration modality when the oral route is not tolerated does not follow established guidelines. The decision-making process, at this point, becomes more subjective in nature, following an intuitive-humanist approach, as there are no clear guidelines or steps to follow when choosing between the alternative modalities of medication administration. The decision to choose the most appropriate mode of delivery relies on the knowledge and experience of the health care providers and the available resources.

Table 2

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Where is the pain?</td>
</tr>
<tr>
<td></td>
<td>Can you point to the location of the pain?</td>
</tr>
<tr>
<td></td>
<td>Does the pain move or remain in one place?</td>
</tr>
<tr>
<td>Onset</td>
<td>When did the pain begin?</td>
</tr>
<tr>
<td>Frequency</td>
<td>How often do you experience pain?</td>
</tr>
<tr>
<td>Duration</td>
<td>How long does the pain last?</td>
</tr>
<tr>
<td></td>
<td>Is the pain intermittent or constant?</td>
</tr>
<tr>
<td>Quality</td>
<td>Can you describe the pain?</td>
</tr>
<tr>
<td></td>
<td>Is it stabbing, burning, aching, throbbing, or piercing?</td>
</tr>
<tr>
<td>Precipitating factors</td>
<td>What starts the pain?</td>
</tr>
<tr>
<td></td>
<td>Is the pain affected by movement, position, or certain activities?</td>
</tr>
<tr>
<td>Alleviating factors</td>
<td>What relieves the pain?</td>
</tr>
<tr>
<td></td>
<td>Does medication, positioning, immobility, or massage relieve the level of pain?</td>
</tr>
<tr>
<td></td>
<td>How has the pain affected your ability to eat, sleep, or participate in activities?</td>
</tr>
</tbody>
</table>

From Wujcik and Utley (1997) p. 434
Decision making for optimal treatment options flows from the ongoing assessment of the patient's self-reported pain and related symptoms. When the patient reports a decrease in pain and side effects and an increase in level of comfort and satisfaction with the ease of a given treatment option, overall quality of life and well-being are enhanced.

Summary of the Literature Review

Chronic malignant pain is a complex pain experience, influenced by many factors that requires a comprehensive approach to optimal management. In this chapter, two pain theories were described; the Gate Control Theory (Melzack & Wall, 1965) and the Multidimensional Model of Pain that was developed specifically for cancer pain (Ahles et al., 1983). Six dimensions, identified in the Ahles et al. Model included the physiological, sensory, affective, cognitive, behavioural and the sociocultural dimensions (McGuire & Sheidler, 1997). An overview of treatment modalities was discussed with a focus on pharmacological strategies. Alternative modalities to the preferred oral route were then described with emphasis on CSCI via syringe driver that is widely and effectively used in other countries. The usefulness of the Multidimensional Model of Pain was then discussed, in relation to an accurate pain assessment that encompasses the many dimensions of cancer pain. Finally, two predominant approaches to clinical decision-making were identified as a systematic-positivist approach and an intuitive-humanist approach.
CHAPTER THREE

METHODS

In this Chapter, the research methods used in this pilot case study will be described including the case study approach, the procedures of sampling, data collection, instrumentation, data analysis and ethical considerations.

The purpose of this study was to explore whether using a syringe driver was an effective and easy to use modality for the management of chronic malignant pain in patients who could not tolerate oral analgesics. For this reason a case study approach was chosen to provide a microscopic view of a phenomenon within a context. The collection of both quantitative and qualitative data has the potential to lead to a clearer understanding and explanation of the research questions. A quantitative approach focused on specific concepts emphasizing the measurable attributes of the human experience, while a qualitative approach emphasized the holistic and individualized aspects of the human experience (Polit & Hungler, 1999).

This study was considered a pilot study and used as preliminary investigative research in assessing the study’s appropriateness, design, methodology, instrumentation and feasibility (Hinds & Gattuso, 1991). The findings of a pilot study provide guidelines that could alter the design, analysis or focus of future research studies (Hinds & Gattuso, 1991). This case study resembled a pilot study by testing the feasibility of conducting a larger study. It identified strengths and limitations with the design, methodology, inclusion/exclusion criteria for study participants, feasibility of recruiting a sample, time frame, usefulness and usability of instrumentation, clarity of instruction, appropriateness of the data collection method, adequacy of measures and data analysis that answered research questions related to the
study’s purpose and design (Allen & Copeland, 1998; Hinds & Gattuso, 1991; Perry, 2001).

Case Study Research

Case study research has been traditionally viewed as an intensive detailed investigation of the individual client (Bergen & While, 2000; Kazdin, 2003; Polit & Hungler, 1999). It addresses a distinct technical situation while focusing on an individual subject. It relies on information derived from multiple sources and it benefits from existing theory that guides the data collection and analysis (Bergen & While, 2000; Kazden, 2003). The case study is useful in linking clinical practice to research by increasing knowledge of treatment effects in a real life context (Bergen & While, 2000; Kazden, 2003). The individual case is referred to as the “unit of analysis” or the source of data collection and is clearly defined by the research questions (Bergen & While, 2000). For the purpose of this study, a case is defined as an individual who is experiencing chronic malignant pain where the decision to initiate CSCI using a syringe driver has been made by the health care providers.

In keeping with the case study approach, this pilot study drew on quantitative and qualitative data to gain a full picture of the case. The combination of the two approaches was expected to be useful in providing deeper insight, understanding and explanation of the characteristics surrounding the initiation of CSCI via a syringe driver, its effectiveness and perceived ease of use in managing chronic malignant pain. Data were collected from semi-structured interviews with the health care professional(s) involved in the decision to start the patient on CSCI, with the patient once the CSCI via syringe driver was initiated, with the patient’s family and with the primary nurse involved with the patient’s care. A brief review of the chart provided an overview of the disease and of the pain management strategies used immediately prior to the initiation of CSCI via syringe driver.
Quantitative data were collected using two accepted self-reporting numeric rating scales, the Brief Pain Inventory (BPI), the Edmonton Symptom Assessment Scale (ESAS) and two five-point scales that were developed for the study, specifically to document ease and comfort in using the CSCI. Responses on the BPI and ESAS were used to record the effectiveness of the CSCI via syringe driver in managing pain and related symptoms at fifteen data collection points. The ratings were collected daily for 2 weeks after initiation of CSCI via the syringe driver followed by a final data collection point on Day 28 in order to document daily changes and responses to the intervention over time. Responses to the numeric five-point rating scales on ease of use and level of comfort were collected at four data collection points, on Day 1, Day 7, Day 14 and Day 28 (i.e. O₁, O₇, O₁₄ and O₁₅). The patient and family were also asked to qualitatively describe their experience with using CSCI via syringe driver, including benefits, challenges and any concerns they had.

A symbolic representation of the design is provided (Figure 3) where O₁ to O₁₄ represent daily collection of data over a two-week period (for assessment of pain and symptom management) after CSCI has been initiated via the syringe driver. A final data collection point took place at O₁₅, which represents Day 28, two weeks after O₁₄ and four weeks after the initial interview following the initiation of CSCI (X).

**Figure 3:** Symbolic representation of data collection for a case

Subject: X O₁ O₂ O₃ O₄ O₅ O₆ O₇ O₈ O₉ O₁₀ O₁₁ O₁₂ O₁₃ O₁₄ O₁₅

X = Initiation of CSCI

O = Self-reported measurement points daily (O₁-O₁₄) and then 2 weeks later (O₁₅).

**Sample and Sampling Procedures**

Subjects experiencing chronic malignant pain were selected by way of purposive
sampling. It was my intent, as the researcher, to recruit four participants who met the inclusion criteria, on the advice of the health care professionals familiar with the individual cases. The patient could have been in Kelowna General Hospital, hospice or at home on the initiation of CSCI via syringe driver.

Inclusion criteria were restricted to cancer patients who were:

- experiencing chronic malignant pain that is either tumor-related or treatment-related
- expected to receive medications by CSCI via syringe driver for treatment of chronic malignant pain
- able to understand English
- oriented to time, person and place
- able to communicate their intentions (orally if the cancer is not effecting their speech or in other ways if it is)
- able to demonstrate the ability to complete the measurement tools
- at an adequate cognitive and functional ability as measured by the Palliative Performance Scale (PPS) of equal to or greater than 40% (Victoria Hospice Society, 1998) (see Appendix C and section on instrumentation).

Exclusion criteria included:

- patients with advanced cancer who are unable to concentrate for long periods of time

The Kelowna Palliative Care Team and the Pain and Symptom Management Team at the Cancer Agency for the Southern Interior (CSI), familiar with the proposed pilot study, identified potential subject (s) who met the inclusion criteria. The eligible participants, were then contacted by a health care professional, familiar with the case and appointed by the Kelowna Palliative Care Team or the Pain and Symptom Management Team at the CSI, to
obtain the patient’s permission for the researcher to approach him/her about participation in the pilot study. With the patient’s permission, the researcher met with him/her and their family member(s) to provide an explanation of the proposed pilot study and to outline the commitment required to participate. Recruitment, on consent of the patient, also included the family member(s) and health care providers directly involved with the patient’s care.

Data Collection Procedures

Once the patient and family member signed the informed consents (Appendix D), the researcher conducted an initial interview in the patient’s home to gain insight into the patient’s and family member’s perceptions and expectations of the initiation of CSCI via syringe driver (Appendix E). During that initial interview, demographic information was also obtained from the patient and family member(s) (Appendix F). Information related to the assessment of pain and symptom management was then collected using numeric rating scales. This took about 5-10 minutes. The same information that related to the assessment of pain and symptom management was collected each day for a two-week period.

Background information regarding the disease trajectory and details about recent pain management strategies were obtained from a brief overview of the patient’s health record. In addition, information about the patient’s diagnosis, the initial date of diagnosis, presenting characteristics prior to diagnosis, brief overview of the trajectory of the disease and treatments, the most recent PPS score, recent progress notes describing pain management strategies prior to the decision to initiate CSCI via syringe driver and the reason for hospital admission, if applicable, were gathered from the health record (Appendix G).

Health care professionals involved in the decision-making process and direct care of the patient were interviewed after letters of consent were signed (Appendix H). They were
asked to identify factors considered in initiating CSCI via syringe driver (Appendix I) and/or to comment on their perceptions of how the treatment modality worked and whether they had any concerns related to its use (Appendix J). The interviews were conducted within the first two weeks of data collection. The final interview and other data collection with the patient and family were conducted in person, one month after the initial interview.

**Instrumentation**

Both quantitative and qualitative approaches were chosen for the study to provide an in depth view of the use of CSCI via syringe driver in the management of chronic malignant pain. All instruments and approaches used are consistent with the Multidimensional Model of Pain (Ahles et al., 1983) in order to gain further insight into the total pain experience.

**Quantitative Measurement Tools**

The quantitative approach focused on the measurable attributes (Polit & Hungler, 1999). Measurement tools used included the Palliative Performance Scale (PPS), the Brief Pain Inventory (BPI) (Appendix K), the Edmonton Symptom Assessment Scale (ESAS) (Appendix L) and a five-point rating scale to assess perceived ease and comfort of both the patient and family in using CSCI via syringe driver (Appendixes M and N). In addition, a demographic information form, a chart review guide and a short answer questionnaire on the patient’s breakthrough pain experience were also used (Appendix O).

**Palliative Performance Scale.** The Palliative Performance Scale (PPS) (Appendix C) was introduced in 1996 and revised in 2001. It is a rating-scale that reflects the changing physical condition of terminally ill patients (Anderson, Downing, Hill, Casorso & Lerch, 1996; Victoria Hospice Society, 1998) and was used in this study to identify subjects who would not be physically or cognitively burdened by participating. A suitable PPS score for a
patient to participate in this study was 40% or greater. A score of 40% refers to a patient who is mainly in bed, but not bed ridden, requires assistance with self-care and is fully conscious.

The PPS is based on the Karnofsky Performance Scale (KPS) developed in 1948 that focuses on location of care (Anderson et al., 1996). However, the PPS focuses on the level of performance (Anderson et al., 1996; Victoria Hospice Society, 1998). The PPS guides assessment of functional performance by determining if the disease process has limited the patient’s ability to work, ambulate or care for himself/herself. If the patient’s condition is limiting activities of daily living, other factors are considered that include nutritional intake and level of consciousness (Anderson et al., 1996; Victoria Hospice Society, 1998).

The PPS has been found to be a useful, valid and reliable tool in grading a patient’s general condition from 0% (death) to 100% (normal) (Morita, Tsunoda, Inoue & Chihara, 1999; Virik & Glare, 2002). It has been highly correlated with the KPS (Spearman’s $p = 0.94$, $p<0.01$) (Morita et al., 1999). The PPS is a valid and reliable tool in predicting outcome and time to death/discharge that is dependent on the patient’s PPS score on admission to hospital (Virik & Glare, 2002). The PPS is also a useful tool for prognosis, research and program planning related to symptom control, drug costs, nursing, auxiliary requirements and respite care needs (Anderson et al., 1996).

**Brief Pain Inventory.** The Brief Pain Inventory (BPI) (Appendix K) was developed by Cleeland in 1982 specifically for patients with chronic pain and has been used worldwide to measure pain intensity and functional impact within a 24-hour period (Pain Research Group, 2003). In this study it was used to monitor the different levels of pain and the level of interference pain had on the patient’s activities of daily living over time. The BPI (Short Form) is a simple, easy to use self-reporting tool that takes approximately 5 minutes to
administer (Pain Research Group, 2003). Five 10-point rating scales address the level of pain a patient experiences. These scales are anchored by ‘0’ that represents “no pain” and ‘10’ as “pain as bad as you can imagine”. Seven 10-point rating scales address pain interference with general activity, mood, walking, working, relationships, sleep and enjoyment of life. These scales are anchored by ‘0’ that denotes “no interference” and ‘10’ as “completely interferes”. The BPI is a multidimensional measurement of cancer pain with questions designed to reflect pain relief, pain quality and the patient’s perception of pain (Cleeland, 1982).

Test-retest reliability of the pain rating items, identified as worst pain, average pain and least pain were completed on 22 patients in 7 days and reported correlations of $r=0.93$, 0.78 and 0.59. A second, larger sample of 56 patients was retested over time, with a mean of 91.5 days and reported correlations of $r=0.34$, 0.24 and 0.22 for the same items. (Cleeland, 1982). It was noted that an increase in pain intensity ratings corresponded to an increase in pain medications (Cleeland, 1982). Cronbach alpha reliability ranges from 0.77 to 0.91.

The BPI has been validated in twelve languages based on examination of the consistency of its two factors: severity of pain and impact of pain (Pain Research Group, 2003). The BPI short form is reliable and valid on assessing the pain intensity and functional impact, but does not include extensive information related to other symptoms such as nausea, appetite, fatigue and shortness of breath (Philip, Smith, Craft & Lickiss, 1998). It is, however, useful in the study of the epidemiology of cancer pain, routine clinical assessment of pain and the effectiveness of cancer pain treatments (Cleeland, 1982).

*Edmonton Symptom Assessment Scale.* The Edmonton Symptom Assessment Scale (ESAS) was used to measure pain and pain-related symptoms identified as tiredness, nausea, depression, anxiety, drowsiness, appetite, feeling of well being and shortness of breath on
corresponding numeric rating scales with ratings of 0 to 10 (Appendix L). The scales are anchored by words such as ‘not tired (0) – worst possible tiredness (10)’, ‘not nauseated (0) – worst possible nausea (10), no pain (0) – worst possible pain (10)’ (Bruera et al., 1991; Dudgeon, Harlos & Clinch, 1999).

The ESAS developed by Bruera (1991) and used since 1993, is a nine-item self-reporting instrument that is a valid and reliable tool for the assessment of physical and psychological symptoms in cancer patients (Bruera et al., 1991; Chang, Hwang & Feuerman, 2000; Dudgeon et al., 1999). Chang et al. (2000) demonstrated the ESAS to be a valid tool for use in symptom assessment of palliative patients by administering it concurrently with two other accepted instruments: the Memorial Symptom Assessment Scale (MSAS) and the Functional Assessment of Cancer Therapy (FACT) tool. The individual scores on the ESAS correlated with the corresponding measures on the MSAS and FACT in a prospective study of 240 cancer patients (Chang et al., 2000). Philip, Smith, Craft and Lickess (1998) compared the ESAS with the BPI and the Rotterdam Symptom Checklist (RSCL) for validation of the tool. It was found to be satisfactory for patients with incurable cancer in the components of face validity, construct validity and concurrent validity (Philip et al., 1998). The intent of the questions on the ESAS were easily recognized by both bed ridden and ambulatory patients. The responses that corresponded to the questions were acceptable to the palliative care practitioners involved in the study and were comparable with those on the BPI and RSCL (Philip et al., 1998). Philip et al. (1998) also reported the overall Cronbach alpha reliability for the ESAS to be 0.79. The ESAS is a reliable and valid tool that is easy to use, taking approximately 5 minutes to complete, limiting the burden placed on the patient (Chang et al., 2000).
It is recommended that the ESAS be completed on a weekly basis for patients in the community and on a daily basis for patients in a hospice or palliative care unit (Capital Health, 2001). For consistency, the ESAS was completed daily for two weeks regardless of the setting. Dudgeon et al. (1999) found that there was no significant difference between numeric scores measured in the morning with those measured in the evening on 147 participants. In view of this, it may not be detrimental to the results of this study if the measurements were not taken at the same time each day, although it was the intent of this researcher to do so.

Assessment of ease of use and comfort level using CSCI via syringe driver. In this study, two 5-point scales were used to measure the ease of use and the comfort level with the CSCI drug administrative modality (Appendixes M and N). The perception of the patient and their family on ease of use was measured on a scale with (1) being ‘somewhat difficult’ and (5) being ‘very easy to use’. The patient, family and/or caregiver’s perceived comfort level with the treatment modality was also measured on a 5-point scale where (1) is ‘not comfortable’ and (5) is ‘very comfortable’ (Newshan & Lefkowitz, 2001). The willingness of the patient and family and/or caregiver was also measured on a 5-point scale where (1) is ‘very unwilling to continue’ and (5) is ‘willing to continue’. Such 5-point scales are widely used in research to obtain reports from individuals on topics that are subjective in nature (Polit & Hungler, 1999).

The demographic information. The demographic form (Appendix F) was used to gather information from the patient on age, gender, dwelling and family support as well as illness-related information.

Questionnaire to assess breakthrough pain. The frequency or how often analgesic
for breakthrough pain was required over selected 24 hour periods was collected. Those reports were supplemented with the self-reported numerical ratings on the severity of pain, route and dose of medication administered (Appendix O). Constipation, an opioid related side effect, was also recorded as whether the patient had a bowel movement within a 24-hour period.

*Qualitative Interview Guides*

The qualitative approach emphasized the holistic and individualized aspects of the human experience through the process of semi-structured interviews (Polit & Hungler, 1999). Semi-structured interview guides were used with the patient, family member and health care providers to obtain information on decision making, effectiveness of pain management, perceived ease of use and level of comfort pertaining to the use of CSCI via syringe driver.

*Semi-structured interview with the patient.* The researcher conducted a semi-structured interview with the patient and/or family member (Appendix E) to gain insight into how the patient perceived the initiation of CSCI via syringe driver. The interview was audiotaped if the patient and/or family member were comfortable for the researcher to do so, otherwise the interviewer took field notes during the interview.

*Interview questions on the perceived ease of use and comfort level of CSCI via syringe driver.* In addition to a five-point scale, patients, families and/or caregivers were asked how they felt about the ease of use and their comfort level with CSCI via syringe driver as well as their perception of the changes it has made for them at four points in the study (Appendix M, Appendix N).

*Semi-structured interview for health care provider.* A semi-structured interview, guided by an interview guide, was conducted with the main health care provider (s) involved
in the decision making process to initiate the CSCI via syringe driver for the individual experiencing chronic malignant pain (Appendixes I and J). The health care providers were encouraged to talk freely about the factors considered prior to the initiation of CSCI via syringe driver. The interviews were conducted in an explorative fashion, whereby the main themes were identified and explored.

**Data Analysis Procedures**

Procedures were used to analyze both quantitative and qualitative data to provide insight into the perceived effectiveness and decision-making process with the use of CSCI via syringe driver.

*Quantitative data.*

Quantitative data collected from numeric rating scales consisting of the BPI, ESAS and five point scales were inputted into the computer program Statistical Package for Social Sciences (SPSS) for analysis. The data were subjected to descriptive analysis to obtain measures of central tendency and dispersion and presented in line or bar graphs and tables. Data collected from the BPI (Short Form) relating to interference with daily living (question 9 parts A to G) and level of pain were examined and presented in bar graphs representing the means of the seven questions on interference calculated for each day. The mean of the sum of the seven questions on interference (question 9 parts A to G) was used as the measure of impact of pain on daily living.

Data collected using the ESAS on the dependent variables identified as pain, tiredness, nausea, depression, anxiety, drowsiness, feeling of well-being, appetite and shortness of breath were depicted on graphs over time. The patterns of scores were described and any trends were also identified and described.
Data collected at four designated time intervals with the 5-point scales were described using descriptive analysis. The patterns of perceived ease of use and comfort were noted and described for the case. The frequency of breakthrough analgesic and the absence/presence of constipation were also noted and described over a time period of 2 weeks and on a 2-week follow-up.

Qualitative data.

All audiotaped recordings with health care professionals, patients and/or family members were transcribed verbatim. Content analysis was done to identify the developing themes within a case. The intent was to provide insight into the characteristics surrounding the use of CSCI via syringe driver in the given context of an individual experiencing chronic malignant pain who was unable to tolerate oral medication. A detailed description was provided by the health care professional(s), identifying the conditions and patient characteristics that contributed to the decision to initiate CSCI via syringe driver. Content analysis allows for meanings and insights to be elicited from the text in the development of emergent themes (Priest, Roberts & Woods, 2002). By reducing the qualitative data to core constructs one can identify key concepts or themes in the exploration of a particular situation. Key concepts were identified and then broken down into sub categories within the core theme. The themes and sub categories were presented and described to provide insight into the factors that contributed to the decision to initiate CSCI via syringe driver (Woods, Priest & Roberts, 2002). Semi-structured questions directed to the patient and the family/caregiver on perceived ease of use and comfort level were also categorized thematically and described.

Human Rights and Ethical Considerations

Permission to conduct this research was obtained from the University of British
Columbia's Behavioural Research Ethics Board. Permission to implement the study in Kelowna, British Columbia, was reviewed by the Palliative Care Program and ethically reviewed by both the community and Kelowna General Hospital. The Cancer Agency for the Central Interior (CSI) accepted the decision of UBC's Behavioural Research Ethics Board and did not require a separate application. Adjustments to the approach of the research were made in accordance to the ethics committee of Kelowna General Hospital and accepted by UBC's Behavioural Research Ethics Board.

Selected participants, who met the inclusion criteria were approached by a health care professional familiar with their individual case. On agreement, the researcher described the purpose and procedures of the study, outlined the required commitment and answered any questions concerning the process. The consent process also included asking the patient’s permission to access their health care records and approach family members and health care professionals involved in their care.

This pilot study, in no way put the patient at risk, as there was no manipulation of the independent variable, only observation of the phenomenon in context. Reassurance was given to the patient and their family that they were free not to participate and that withdrawal from the study at any time would not compromise the health care they received both in the hospital and in the community. The patient and the health care providers involved in the case were asked to sign a letter of informed consent (Appendices D and H) prior to participating. The researcher kept a copy and the subject kept the second copy. The signed letters of consent were kept in a locked filing cabinet at the British Columbia Cancer Agency (BCCA) in Vancouver.

To further protect the patient’s identity, personal information was minimized in the
case report. Subjects were ensured that all information provided for the study was kept confidential by using a code number for identification on all data collection forms. An opportunity for the patient to request a summary of the results of the pilot study, once completed, was also given.

Summary

A case study approach, using both quantitative and qualitative data, was chosen for this pilot study because it is useful in linking clinical practice to research by increasing knowledge of treatment effects, such as the use of CSCI via syringe driver in a real life context as with a patient experiencing chronic malignant pain. Inclusion criteria were restricted to cancer patients with a PPS of greater than or equal to 40%. A health care professional, other than the researcher, identified patients who met the inclusion criteria. Once consent was signed semi-structured interviews were conducted with the patient, family and health care professionals involved with the patient’s care. Data pertaining to levels of pain and pain related symptoms were collected daily for two weeks and at a follow up point two weeks later using the BPI, ESAS plus questions related to frequency of breakthrough doses given and medication dosage. Information pertaining to the manageability of the syringe driver was collected at four points during the course of the 28 day study. Quantitative data were then inputted into the computer for descriptive analysis using the Statistical Package for Social Sciences (SPSS) and presented in graphs and tables, while content analysis was done to identify developing themes from the qualitative data. The study was exploratory in nature resembling a pilot study that evaluates the appropriateness of the research method and provides guidelines for the design of subsequent research studies (Hinds & Gattuso, 1991).
CHAPTER FOUR
FINDINGS

The findings include a description of the data analysis collected through a case study approach exploring the decision making, effectiveness, ease and comfort level in the use of CSCI via syringe driver and an assessment of the appropriateness of the research design in keeping with the purpose of this pilot study. Because it was much more difficult to recruit subjects who met the sample criteria and even with an extended data collection period from six months to eight months, only one case was identified as meeting the criteria. The findings presented here will focus on Mr. A.

Mr. A

In presenting the data for Mr. A, the following information will be provided. An introduction to Mr. A will be given including his disease trajectory and the history of his pain and pain management strategies. The reasons why CSCI via syringe driver was initiated for him will be described from the patient and family’s point of view as well as that of the CHN and physician. Data related to the effectiveness of the pain and symptom management will be presented as it relates to changes over the 14 days and on the two-week follow up. Incorporated in this presentation will be information on the medications prescribed and their dosages in order to assist with observation of the effects of one on the other.

Demographic and Health-Related Information on Mr. A

Mr. A was a 59 year old male, diagnosed with squamous cell carcinoma of the left larynx in April, 2002. He lived with his wife, who acted as primary caregiver, in an urban single family dwelling in the Okanagan, where a room had been set up with a hospital bed and a dinner bell on a bedside table for use as a call bell. Mr. A had two grown children, both
of whom lived a fair distance from him but visited the home, when possible, to assist in his care and relieve their mother from her caregiving responsibilities. When the children were unable to assist in the care, Mrs. A called on a family friend who was a retired registered nurse to help as needed and to provide respite. At the time of data collection, the family had a large support group within the community. The CHN visited every second day and the physician made house calls as needed. Mr. A remained at home and his wife said she had the necessary support to manage his care comfortably at home.

For this study, Mr. and Mrs. A were initially approached by the CHN who asked them if they would be willing to participate. They agreed to meet with the researcher to discuss the commitment. I, as the principal researcher, met with them on February 21, 2004 in their home. When I met Mr. A, he was sitting in a high fowler's position in bed receiving oxygen via the tracheostomy tube. He had a syringe driver in his pajama pocket. I briefly explained that this study focused on the effectiveness, ease and comfort experienced in using a syringe driver. He indicated that he was willing to participate in the study with a nod and a smile. He then looked over the consent form and signed it in my presence.

Mr. A was alert and oriented to person, time and place with a PPS of 50% when the consent was signed. He was able to walk to the bathroom with assistance and tolerated sitting in a chair in the living room for up to two hours at a time. He communicated mainly by writing his thoughts or with hand signs. He could speak in a whisper if he removed the oxygen mask from over the tracheostomy tube but this took effort on his part. Mrs. A expressed concern that Mr. A would find it too tiring to interact with another person on a daily basis and anxiety provoking to answer a lot of questions. She requested that she relay the information on behalf of Mr. A to limit the burden on him. I asked Mr. A if it would be
acceptable to consult with Mrs. A on his daily condition. He nodded that it was. The daily information was collected over a period of two weeks by telephone after the initial visit. The one month follow up interview was conducted in person, again at the home, with both Mr. and Mrs. A for a short period of time and then continued in more depth with Mrs. A in a separate room at their request.

*Disease Trajectory of Mr. A*

Mr. A was diagnosed with squamous cell carcinoma of the left larynx in April 2002 after experiencing a partially paralyzed left vocal cord for three years. Three months prior to the diagnosis his voice became worse, he became short of breath on exertion and had difficulty swallowing. In April 2002 he had an emergency tracheostomy in Vancouver followed by five weeks of radiation to his neck from which he experienced skin irritation. He then had a left radical neck dissection in Vancouver, June 2003. This was followed by chemotherapy. Mr. A declined further chemotherapy or radiation due to the side effects that he endured which hindered his quality of life. He was registered on the Palliative Care Drug Benefits Program for British Columbia and had signed a Do Not Resuscitate form. With the support of the health care professionals, family and friends, Mr. A remained at home, as was his wish, until he died in the spring of 2004.

At the time of the study Mr. A had a tracheostomy tube that was inserted in April 2002, a jejunostomy tube (J tube) for medications and nutrition inserted in June 2003, a peripherally inserted central catheter (PICC) in his right arm for intravenous access since September 2003 and a CSCI via syringe driver initiated on February 2, 2004 for pain management. The community health care nurse had assessed his PPS at 50% when the CSCI via syringe driver was initiated. He ambulated to the bathroom with assistance and enjoyed
watching television in the living room. His hobbies included tying fly fish hooks and painting.

Pain Management Strategies Prior to Initiation of CSCI via Syringe Driver

Prior to the initiation of CSCI of dilaudid via syringe driver on February 2, 2004, a transdermal fentanyl patch, 250 micrograms (mcg) per hour with breakthrough liquid hydromorphone given through the J tube, were used to manage Mr. A’s pain. He was receiving up to eight breakthroughs of 16 to 20 milligrams (mg) of liquid hydromorphone via the J tube daily. Mrs. A was concerned that Mr. A was not receiving effective pain relief. In January, 2004, Mrs. A notified the family doctor that the fentanyl patch as a modality for pain management was ineffective saying, “I finally told the doctor... I don’t think it is working... he is getting no effect.” The family doctor then consulted the specialist with the Pain and Symptom Management Program at CSI and the decision was made to change the pain management strategy. The pain management strategy was changed from transdermal fentanyl patch to intermittent subcutaneous injections of hydromorphone. Hydromorphone was chosen instead of morphine because it is more soluble requiring a lower injection volume when high doses of subcutaneous injections are required (Librach, 1991).

Factors Influencing the Decision Making Process to Initiate CSCI via Syringe Driver

Mr. A was requiring frequent breakthrough doses using intermittent subcutaneous injections of hydromorphone that was very labour intensive for his wife and the community health nurses. It was decided that another alternative modality was necessary.

The physician stated that he was familiar with the effectiveness of CSCI via syringe driver from using it with other patients. He was also aware of how easy it was to use and that there was adequate support in the community as evidenced by his statement “The community
health nurses and hospital pharmacists who prepare the syringes are all familiar with its use and the patient’s wife was receptive to trying it.” It was then decided to administer a regular dose of hydromorphone by CSCI via syringe driver and to administer breakthrough bolus doses as needed also using the syringe driver. CSCI of hydromorphone via syringe driver was initiated on February 2, 2004 in the home.

Six factors were identified that influenced the decision to initiate CSCI via syringe driver. These were noted in the patient’s chart, confirmed by the patient’s physician, community health care nurse, patient and his wife. They included 1) lack of effective pain relief from the pain management strategy he was receiving, 2) the patient’s inability to tolerate oral medications, 3) ineffectiveness or 4) inconvenience of other alternative modalities, 5) familiarity in the use of the syringe driver by the health care providers and 6) the willingness of the patient and family to try it.

Effectiveness of CSCI in the Management of Pain

CSCI of hydromorphone 100 mg over 24 hours (hrs) via the syringe driver was initiated on February 2, 2004. According to information collected from Mrs. A and the CHN, Mr. A was immediately pain free, requiring no breakthrough analgesic. Mrs. A stated “I think it is great because right off the bat he was no longer in pain.” The CHN concurred with this observation by stating “It was amazing how quickly he got pain relief. He had a big smile on his face that he was pain free. He had been tolerating constant pain and constant pressure for so long.”

After one week Mrs. A expressed concern over the increased sedation Mr. A was experiencing and notified the CHN. The dose was reduced to 80 mg/24 hrs on February 9, 2004, but within 4 hours of the adjustment Mrs. A contacted the CHN again stating that the
dose was not adequate for pain management. The dose was then increased to 90 mg/24 hrs with good effect.

According to Mrs. A, Mr. A described the pain as a pressure with a feeling of tightness around the throat as if someone was choking him. He was unable to communicate verbally and therefore used hand gestures or wrote his thoughts. Mrs. A said that he would grab for his throat with both hands, then make a fist when he was in pain, but when his wife asked if he had pain he would shrug that he did not know. It was difficult to discern whether the sensation Mr. A experienced was pain or pressure.

This study commenced 19 days after the initiation of CSCI via syringe driver on February 21, 2004. Data were collected from Mrs. A, who acted as a spokesperson for Mr. A over two weeks and again two weeks later to gain further insight on whether or not CSCI of hydromorphone via syringe driver was adequately providing pain relief for Mr. A. The following is a description of the data collected on the effectiveness of pain management that included the reported level of pain using the BPI and ESAS measurement tools, description of analgesic and total daily dose including the number of breakthroughs given as described by Mrs. A and the CHN plus the perceived percentage of pain relief reported by Mrs. A on behalf of Mr. A.

Level of Pain

The levels of pain are presented as scores using the BPI and ESAS measurement tools in Figures 4 and 5 and reflect Mrs. A’s daily reports of Mr. A’s pain experience over 14 days and again on follow up, two weeks later. Data were collected usually around ten o’clock in the morning and each day’s report refers to the 24-hours prior to the telephone interview. Figure 4 shows four points on the graph for each observation day. Three of the points refer to
the last 24 hours of Mr. A’s pain experience that included the worst possible pain, the least amount of pain and the average pain, while the fourth point represents the ‘now’ or current pain that Mrs. A reported at the point of data collection. In Figure 5, one score is noted. Mrs. A was asked again to report the current level of pain that Mr. A was experiencing ‘now’ using the ESAS where 0 represented ‘no pain’ and ‘10’ the worst possible pain.

The BPI scores reported over the 14 day interval show a trend whereby the worst pain remained under 4.5 except for one day when it reached 5.5, the least pain ranged between 0 and 0.5 and the average pain stayed between 1.0 and 3.5. In terms of the worst pain the mean was 4.4 for the 14 day interval however, two weeks later on follow-up, Mrs. A reported the worst pain as 9.0 indicative of a ‘bad day’.

During both the first and second week, Mr. A’s least level of pain was between 0 and 0.5 with a mean of 0.25 over the two weeks thereby indicating he did have periods of no pain. On the two-week follow up the least pain score increased to 1.5.

In terms of average pain, in the first week Mr. A’s average pain ranged between 1.0 and 3.0 and then slightly increased during the second week between 1.0 and 3.5 with a mean of 2.0 over the two weeks. Two weeks later, Mr. A’s average pain was considerably higher and had increased to 4.0 despite increases in analgesic as described later.

In terms of current ‘now’ pain, Mrs. A reported that the ‘now’ pain ranged from 0 to 2.5 in the first week and from 0 to 1.5 in the second week, with a mean of 1.0 over the two weeks. The ‘now’ pain on the two week follow up was also 1.0. The decrease in the scores of the ‘now’ pain could be explained by the fact that Mrs. A reported that she had just given a breakthrough dose prior to my telephone call in the second week and also prior to the final interview that was conducted in their home.
**Figure 4.** Worst, least, average and now pain for Mr. A over 14 days and two weeks later for follow up using the BPI.

Possible scores = 0 to 10 where 0 is 'no pain' and 10 is 'pain as bad as you can imagine'.
Figure 5. Level of pain over 14 days and 2 weeks later for follow up using the ESAS.

Possible score 0 to 10 where 0 is 'no pain' and 10 is 'the worst possible pain'

Data on the level of pain were also collected using the ESAS (see Figure 5) after completion of the BPI. Mrs. A was directed to report the current level of pain that Mr. A was experiencing 'now'. During the two week interval the scores ranged from 0.5 and 2.5 with a mean of 1.0 reflecting similar scores noted on the BPI except for two days when the scores in Figure 5 did not coincide with the 'now' scores reported in Figure 4 using the BPI. On day 11 the BPI score for current or 'now' pain reported as 0 was lower then 0.5 reported on the ESAS. On day 14, however, the BPI score for current or 'now' pain at 1.5 was higher than
the 1.0 reported on the ESAS. The difference could be due to Mrs. A’s anxiety at the time of
the interview or the researcher’s lack of clarity in presenting the tool.

*Analgesics Ordered and Administered*

The medication doses ordered for both the regular dose and the breakthrough dose is
described in Table 3. The number of breakthrough doses administered on each day is
illustrated in Figure 6. During the course of this study, adjustments to the regular dose were
made based on Mr. A’s response to pain and the number of breakthrough doses administered
in a 24-hour period. The regular dose of hydromorphone was increased in stages from
90 mg/24 hrs to 120 mg/24 hrs and then to 180 mg/24 hrs. The breakthrough bolus doses
increased from 4 mg to 12 mg and then to 18 mg.

According to the initial interview with Mrs. A, a breakthrough bolus was given when
the worst pain score was equal to or greater than 4.0 to provide relief bringing the pain score
down to a 0 on many occasions. The breakthrough bolus doses of hydromorphone were given
by Mrs. A who was comfortable counting beeps on the syringe driver for the correct dose
following the instructions of the CHN.

The number of breakthrough doses given within a 24-hour period varied from 3 to 11
as illustrated in the bar graph in Figure 6 and presented in Table 3. During the first week 3 to
9 breakthrough doses were given per day, while in the second week 3 to 7 breakthrough
doses were given with a mean of 5 breakthrough doses daily for the two weeks. At the two-
week follow up interview Mrs. A reported giving 11 breakthrough doses when the worst pain
level was rated as 9.0 (see Figure 4).
Table 3

*Analgesic and dosage used with CSCI via syringe drive.*

<table>
<thead>
<tr>
<th>Observation Day</th>
<th>Regular dose of Hydromorphone over 24 hours</th>
<th>Breakthroughs dose of Hydromorphone given</th>
<th>Total daily dose Hydromorphone</th>
</tr>
</thead>
<tbody>
<tr>
<td>O₁ - O₂</td>
<td>90 mg</td>
<td>6 x 4 mg = 24 mg</td>
<td>114 mg</td>
</tr>
<tr>
<td>O₃</td>
<td>90 mg</td>
<td>4 x 4 mg = 16 mg</td>
<td>106 mg</td>
</tr>
<tr>
<td>O₄</td>
<td>90 mg</td>
<td>3 x 4 mg = 12 mg</td>
<td>102 mg</td>
</tr>
<tr>
<td>O₅</td>
<td>90 mg</td>
<td>4 x 4 mg = 16 mg</td>
<td>106 mg</td>
</tr>
<tr>
<td>O₆</td>
<td>90 mg</td>
<td>9 x 4 mg = 36 mg</td>
<td>126 mg</td>
</tr>
<tr>
<td>O₇</td>
<td>120 mg</td>
<td>2 x 4 mg = 8 mg 3 x 12 mg = 12 mg</td>
<td>164 mg</td>
</tr>
<tr>
<td>O₈ - O₉</td>
<td>120 mg</td>
<td>5 x 12 mg = 60 mg</td>
<td>180 mg</td>
</tr>
<tr>
<td>O₁₀</td>
<td>120 mg</td>
<td>7 x 12 mg = 84 mg</td>
<td>204 mg</td>
</tr>
<tr>
<td>O₁₁ - O₁₃</td>
<td>120 mg</td>
<td>6 x 12 mg = 72 mg</td>
<td>192 mg</td>
</tr>
<tr>
<td>O₁₄</td>
<td>120 mg</td>
<td>5 x 12 mg = 60 mg</td>
<td>180 mg</td>
</tr>
<tr>
<td>O₁₅</td>
<td>180 mg</td>
<td>11 x 18 mg = 198 mg</td>
<td>378 mg</td>
</tr>
</tbody>
</table>

Figure 6 indicates 2 days when the number of breakthrough doses were elevated: day 6 and at the two week follow up. On day 6, Mrs. A gave 9 breakthrough bolus doses each of 4 mgs. On that day, the CHN described the site as reddened, indicative of an infusion site problem. The site was changed on day 6 in the late morning. The report of increased breakthrough doses on day 6 reflected the previous 24 hours when analgesic absorption may have been a problem prior to the resiting of the syringe driver. On day 7, when 5
breakthrough bolus doses were given, the regular dose had been increased from 90 mg/24 hrs to 120 mg/24 hrs and the breakthrough bolus dose from 4 mg to 12 mg. At the two-week follow-up interview Mrs. A gave Mr. A, 11 breakthrough bolus doses that was indicative of a ‘bad day’. On that day, Mrs. A said “we have had a very bad day...I don’t think the medicine is working. We will probably have to change it.”

Figure 6. Number of breakthrough doses given.

The number of breakthrough doses given refers to a 24 hour period.
Figure 7 illustrates the total dose of hydromorphone that Mr. A received each day. It includes his regular daily dose and the total amount of breakthrough hydromorphone he received in a 24 hour period. Figure 7 shows a trend where the total dose of hydromorphone almost doubled from the first week to the second week and then again from the second week to the two week follow up.

Figure 7. Total dose in milligrams of hydromorphone given over 24 hours.

During the first five days, Mr. A had a daily dose of hydromorphone ranging from 102 mg to 114 mg. A slight increase to 126 mg for a daily dose of hydromorphone was noted on day 6 followed by a larger increase to 164 mg on day 7. The syringe driver had been resited on day 6 but there may have been a drop in plasma concentration of hydromorphone...
due to the problem with the site that could explain the need for an increase in hydromorphone on day 7. An increase in hydromorphone may have been needed to achieve an adequate plasma concentration to regain and maintain an adequate pain threshold level. During the second week the total daily dose of hydromorphone ranged from 164 mg to 204 mg after the increase in both the regular dose and the breakthrough dose had occurred on day 7. On the two week follow up there was another large increase in the total daily dose of hydromorphone from 180 mg on day 14 to 378 mg. Prior to the follow up interview the dose of hydromorphone had increased to 180 mg/24 hrs for the regular dose and 18 mg for the breakthrough dose.

*Perceived Pain Relief*

The frequency of breakthrough doses is likely to be a good indicator of how well the pain is being managed but it is also critical to gain insight into the patient's perception of pain relief. Figure 8 shows that Mr. A's overall pain relief during the first two weeks was 70% to 100% except on day 7 when it was reported that he was only receiving 10% pain relief (Figure 8). This corresponds to the problem with the analgesic absorption on day 6 that could have allowed the plasma concentration of hydromorphone to drop below the acceptable pain threshold allowing for the pain to breakthrough or peak more often corresponding to a decrease in pain relief.

The reported pain relief began to slowly improve after the repositioning of the syringe driver and the dose of hydromorphone was increased. On day 8 pain relief improved from 10% on day 7 to 45% and then on day 9 to 95%. During the remainder of the second week Mrs. A reported that Mr. A was getting 80% to 95% pain relief. That changed again on the two week follow up interview when breakthrough doses were increased to 11 and the pain
relief was reported to be only 25% indicating a possible problem with the pain management strategy. A problem could be caused by a change in the type of pain Mr. A was experiencing, a malfunction of the device, disease progression and/or opioid tolerance. An increased dose of opioid with minimal pain relief is indicative of opioid tolerance that will be discussed further in Chapter Five.

Figure 8. Perceived percentage of pain relief using the BPI.

![Graph showing perceived percentage of pain relief over time.]

Possible Scores = 0 to 100 where 0 is no pain relief and 100 is 100% pain relief

Pain-Related Symptoms

Pain-related symptoms or problems compromise the patient’s quality of life and affect their ability to cope with activities of daily living. Opioid-induced side effects can include symptoms such as tiredness, drowsiness, nausea, shortness of breath and
constipation. Pain-related problems may include anger, anxiety, depression, and uncertainty that can shape the patient’s perception of pain and interfere with their quality of life.

To further understand the total pain experience of Mr. A, data were collected on pain-related symptoms using the ESAS measurement tool and on the impact of pain interference with activities of daily living using the BPI. Throughout the course of the study Mr. A, through Mrs. A’s interpretation, consistently reported no depression using the ESAS, however there were reports of increased anxiety and pain interference with activities of daily living.

Level of Anxiety

Mr. A described his pain as a pressure or a feeling of choking. Dr. Fyles said “The sensation of choking can cause an increase in anxiety as one feels they are being suffocated. It can be very difficult to differentiate between pain and anxiety in this case” (personal communication, April 2, 2004).

Figure 9 illustrates Mrs. A’s report of Mr A’s level of anxiety using the ESAS. Mr. A’s reported level of anxiety ranged between 1.0 and 4.0 during the first week but remained elevated between 4.0 and 4.5 during the second week and on the two week follow up. It seemed that the experience with inadequate pain relief on and after day 6 increased Mr. A’s anxiety in the second week of the study. His reported anxiety remained elevated at 4.5 on the follow up, two weeks later, coinciding with Mrs. A’s report that they were having a ‘bad day’.

The fact that Mrs. A was the one who reported Mr. A’s level of anxiety could raise the question of whether the anxiety is indicative of the wife’s anxiety around his pain or his. As the researcher, I did observe an increase in agitation when I entered Mr. A’s room for the
final interview. From sitting calmly painting he began to move around in bed and his respirations quickened. When I assured him that I would be brief he settled. On questioning Mr. A, I validated his wife's interpretation of his pain level, his comfort with the use of the syringe driver and his consent for his wife to answer on his behalf. When I left the room I thanked Mr. A for his participation, he nodded, removed the oxygen mask from his tracheostomy and whispered 'thank you'. He then resumed his painting on a poster.

Figure 9. Level of anxiety using the ESAS.

Possible scores=0 to 10 where 0 is ‘not anxious’ and 10 is the ‘worst possible anxiety’. 
Figure 10 illustrates the levels of both pain and anxiety using the ESAS. A similar pattern between the level of pain and the level of anxiety is shown within the first week although the level of pain was a little lower than the level of anxiety. The level of pain ranged between 1.0 and 2.5 while the level of anxiety ranged between 1.0 and 4.0. During the second week, however, after the experience of inadequate pain control on and around day 7 as described above, the gap between the levels of pain and anxiety became greater.

*Figure 10. Levels of pain and anxiety using the ESAS.*

Possible scores = 0 to 10 where 0 is ‘no pain’ or ‘not anxious’ and 10 is ‘worst possible pain’ or ‘worst possible anxiety’.

Mr. A’s anxiety could be related to the episode when he required 9 breakthrough bolus doses to maintain an average pain rating of 2.0 on day 6. Unrelieved pain can lead to
anxiety and/or fear related to disease progression (Ahles et al., 1983; Pargeon & Hailey, 1999). The reported level of anxiety remained elevated in the second week ranging between 4.0 and 4.5 while the level of pain stabilized between 0.5 and 1.0 once the syringe driver was resited on day 6. The hydromorphone dose was increased from 90 mg/24 hrs to 120 mg/24 hrs for the regular dose and from 4 mg to 12 mg for the breakthrough bolus dose on day 7.

**Impact of Pain Interference on Activities of Daily Living**

Unrelieved pain impacts a person’s ability to have a sense of normalcy by interfering with general activity, mood, walking, ability to carry on with work or hobbies, relations with other people, sleep and enjoyment of life. The impact of pain interference on Mr. A’s activities of daily living based on Mrs. A’s reports is diagrammed in Figure 11.

Levels of impact or scores were reported over 14 days and on a two week follow up on seven components of activities of daily living that included general activity, mood, walking, normal work or hobbies, relations with other people, sleep and enjoyment of life using the BPI. Level of impact was reported on a 0 to 10 scale, where 0 is no pain interference on a specified activity of daily living and 10 is complete interference. The mean of the scores reported for the seven components was calculated for each day to indicate the overall impact of pain interference on the activities of daily living. Figure 11 shows the mean of the seven components for each observation day to illustrate the impact pain interference had on Mr. A’s activities of daily living.

Figure 11 indicates that pain interference was minimal during the first three days, as it was less than 2.0. The level of interference then increased considerably on day 4 to 6.0 but settled down again, not dropping below 3.5 for the remainder of the two weeks from day 5 to day 14. It did not increase on days 6 or 7 when the levels of pain and anxiety increased and
the percentage of perceived pain relief decreased to 10%. An explanation for this could be
due to unclear instructions from the researcher when administering the BPI or to the fact that
Mrs. A attributed Mr. A’s decline in activity to his disease process and increased weakness
rather than a direct result of pain interference. Two weeks later, the impact of pain
interference increased to 5.5 and was indicative of ‘a bad day’. On that day the pain relief
was low at 25% and the level of worst pain was elevated at 9.0.

Figure 11 illustrates that pain impacted Mr. A’s activities of daily living, however
according to Mrs. A, he was able to sit up, mobilize to the bathroom with a one-person assist
and enjoy working on his hobbies of painting and tying fish hooks.

Pain interference on general activity and walking ability are illustrated in Figure 12.
Mr. A’s level of pain interference with his walking ability ranged from 0.0 to 5.0 with a mean
of 3.3 and with his general level of activity from 0.0 to 4.5 with a mean of 3.0 during the two
week interval. There was a marked increase in pain interference with walking ability from
none to 3.0 and general activity from none to 4.0 on day 3 that then stabilized until day 14.
At the two week follow up, the impact of pain interference showed another marked increase
in general level of activity from 4.0 to 8.0 and a minor increase on walking ability from 3.5
to 4.0. Mrs. A attributed Mr. A’s difficulty with walking to increased weakness rather than
pain interference. He also found it more difficult to tolerate periods of sitting in a chair or
concentrate on his hobbies, although when I met with him for the final interview he was
painting.

The level of pain interference on walking ability and general activity correspond to
the pattern shown in Figure 11 on the impact of pain interference on activities of daily living
where an increase on day 4 and on the final interview day are also indicated.
Figure 11. Level of pain interference on activities of daily living using the BPI.

Possible scores 0 to 10 where 0 is no interference in activities of daily living and 10 is complete interference in activities of daily living. The impact is calculated for each observation day from the mean of scores on the seven components described as general activity, mood, walking, ability to carry on with hobbies, relations with other people, sleep and enjoyment of life.

The interference of pain on mood, enjoyment of life and relationships with other people are reflected in Figure 13. Pain interference on Mr. A’s mood in the first week increased from 0.0 to 5.0 on day 3 and then ranged between 2.5 and 5.0 for the remainder of the two weeks with a mean of 3.0. Pain interference on his enjoyment of life had a drop in the score on day 2 from 3.0 to 0.0 but then went up to 3.0 and stabilized for the remainder of the two weeks ranging between 3.0 and 4.5 with a mean of 3.6. Pain interfered with Mr. A’s
relationships with other people minimally, starting out as 0.0 at the beginning of the first week and slowly climbing to a 3.5 by day 4 and staying between 2.5 and 3.5 for remainder of the two weeks with a mean of 2.7.

Figure 12. Level of pain interference with general activity and walking ability using the BPI.

Possible Score = 0 to 10 where ‘0’ is ‘does not interfere’ and ‘10’ is ‘completely interferes’.

On the follow up interview there was a marked increase in pain interference noted on mood, enjoyment of life and relationships with other people that is illustrated in Figure 13. Pain interference on mood went up from 3.0 to 4.5, on enjoyment of life from 4.0 to 6.0 and on relationships with other people from 3.0 to 5.5. The levels of pain reported on the BPI and the ESAS were increased as were the levels of anxiety using the ESAS at the two week
follow up which could have impacted the increased level of pain interference reported on Mr. A’s mood, enjoyment of life and relationships with other people.

*Figure 13.* Level of pain interference with mood, enjoyment of life and relationships with other people using the BPI.

![Graph showing level of pain interference over time]

Possible Score = 0 to 10 where ‘0’ is ‘does not interfere’ and ‘10’ is ‘completely interferes’

The seventh component of the overall impact of pain interference on activities of daily living reported on the BPI is sleep. *Figure 14* shows an increase on the level of pain interference on Mr. A’s ability to sleep on day 5 when the interference increased from none to 4.5. The level of interference remained elevated ranging between 3.5 and 4.5 for the
remainder of the 14 days and also at the two-week follow up. The increase in the level of pain interference on sleep reported as 4.5 on day 4 corresponded to the increased level of pain interference with Mr. A’s ability to walk, his general activity and overall level of pain interference on activities of daily living. It did not, however, increase on the two week follow up interview but remained at 4.5 while the levels of pain interference increased on general activity to 8.0 and overall activities of daily living to 5.5.

Figure 14. Level of pain interference with sleep using the BPI.

Possible scores=0 to 10 where ‘0’ is ‘does not interfere’ and ‘10’ is ‘completely interferes’.
Opioid-Induced Side Effects

Data pertaining to symptoms such as tiredness, nausea, drowsiness, and shortness of breath that may result from opioid-induced toxicities were collected using the ESAS. Constipation, an opioid related side effect, was also monitored.

A consistent zero was reported on the ESAS relating to nausea, appetite and shortness of breath throughout the course of the study. Mr. A received nutritional intake through his J-tube four times per day and tolerated the feedings with no problems of nausea or appetite loss. The questionnaire relating to constipation revealed that Mr. A did not experience problems with constipation and had regular daily bowel movements.

Mrs. A reported that initially when the CSCI of hydromorphone was started on February 2, 2004, Mr. A experienced increased sedation. By February 21, 2004, 19 days later, Mr. A was still experiencing increased tiredness with scores of 6.0 and 6.5 and drowsiness of 4.0 as noted in Figure 15 on days 1 and 2. The scores of both drowsiness and tiredness dropped to 1.0 on day 5. Then Mr. A’s drowsiness stabilized after day 5 ranging between 0 to 1.0 on the ESAS with a mean of 0.9 until the two week follow up when it increased to 4.0 but Mr. A continued to experience intermittent tiredness throughout the course of the study as shown in Figure 15.

Mrs. A had explained that Mr. A was very tired when the CSCI of hydromorphone via syringe driver was first initiated at 100 mg/24 hrs and because of this she had requested that the dose be decreased. The dose was decreased to 80 mg/24 hrs but was not effective in providing pain relief for Mr. A and was readjusted to 90 mg/24 hrs where it was at the start of this study. During the first week of the study Mr. A’s tiredness was elevated on days 1 and 2 between 6.0 and 6.5 when he received a total daily dose of 106 to 114 mg of
hydromorphone. The dose remained constant and his tiredness decreased from 4.5 on day 3 to 1.0 on day 5. However, on day 6 and 7 an increase in breakthrough boluses were reported (see Figure 6) increasing a total daily dose of hydromorphone to 126 mg and 164 mg. On those occasions Mr. A's tiredness was again elevated and reported as 4.5 and 5.0. His level of tiredness then decreased ranging between 1.5 and 3.0 until days 11, 12 and 13 when Mr. A received a total daily dose of 192 mg of hydromorphone. On those days Mrs. A rated his level of tiredness between 4.5 and 5.5. On the two week follow up, Mr. A had received 11 boluses of hydromorphone plus his regular dose for a total daily dose of 378 mg and Mrs. A rated his level of tiredness as 4.0. On the days when tiredness was rated between 1.0 and 3.0 the number of breakthrough bolus doses were less, ranging between 3 and 5.

Figure 15. Level of drowsiness and tiredness using the ESAS.

Possible Scores = 0 to 10 where ‘0’ is no tiredness or drowsiness and ‘10’ is the worst tiredness or drowsiness.
Figure 16 illustrates a level of feeling of well-being or overall comfort level, both physical and otherwise that ranges between 4.5 and 5.0 in the first week and between 4.5 and 5.5 in the second week with a mean of 4.7 for the two week interval. The question of “How are you?” is reflected in the reported findings of well-being from data collected on the ESAS. Mrs. A was unable to rate Mr. A’s feeling of well-being on days 1 and 3 and therefore there are no scores recorded for those two days. On the two week follow up interview Mrs. A rated Mr. A’s feeling of well-being as becoming worse with a score of 6.5.

Figure 16. Feelings of well being using the ESAS.

Possible score 0 to 10 where ‘0’ is the best possible feeling of well-being and ‘10’ is the worst possible feeling of well-being.


Perceived Comfort and Ease of Use

Ratings of ease and comfort level with using CSCI via syringe driver were consistently rated as 5 on the five point scales from Day 1 to the follow up interview on day 28. These scores indicated that CSCI via syringe driver was considered ‘very easy’ to use; that both Mr. and Mrs. A were ‘very pleased’ with its use in administering medication; that they found it ‘very comfortable’ to use and that they were ‘willing to continue’ with its use.

The CHN said Mr. A was initially concerned with the change, but adapted quickly to using CSCI via syringe driver. His initial anxiety over the use of the syringe driver was rectified when he became familiar with the apparatus, choosing to keep it in the top pocket of his pajamas. When asked if he was comfortable using the syringe driver, he nodded and whispered “yes.” Mr. A continued using the syringe driver at home until he died in the spring, shortly after the completion of this study.

Mrs. A changed the syringes and administered the breakthrough doses as needed. The CHN said “it was very quick and easy to teach the management of the syringe driver to the wife.” When the dose was altered the CHN changed the syringe to the correct dose and reviewed the breakthrough procedure with Mrs. A. Mrs. A said she was very pleased with the syringe driver. She was comfortable changing the syringes and administering the breakthrough doses. She stated it was inconvenient to have to go to Kelowna General Hospital to pick up the weekly supply of preloaded syringes but that it was manageable. In the first two weeks of the study she had not changed the battery and hoped the CHN would do it for her but when asked at the two week follow up interview she stated she had changed the battery with no problem. Her main concern was to keep Mr. A comfortable and at home.

At the two week follow up interview Mrs. A expressed concern that Mr. A was not
receiving effective pain relief and said that the doctor had discussed the possibility of changing the opioid to methadone, but this would mean that Mr. A would have to be hospitalized until the dose was titrated for his individual needs. Mrs. A expressed her desire to keep Mr. A at home as per his wish and did not feel that methadone was an appropriate option for him. Mr. A remained at home with Mrs. A as his primary caregiver until he died in the spring of 2004. He continued to use the CSCI via syringe driver that was effective for pain relief, keeping him comfortable and at home (Dr. Fyles, personal communication, July 26, 2004).

Summary

Unfortunately, only one person was able to be recruited for this study who met the criteria, however findings for that person are helpful in informing us about the efficacy of CSCI and the feasibility of the research methods. CSCI via syringe driver was initiated for Mr. A for the following reasons: he was unable to swallow oral medications, other alternative modalities had been tried and found to be ineffective or labour intensive, the syringe driver was available, the physician and nurses were knowledgeable and competent with its use and the patient and family were willing to use it.

Mr. A’s pain was generally well controlled using the syringe driver for the continual subcutaneous infusion and intermittent breakthrough doses of hydromorphone. Although the amount of analgesic increased over a two-week period from a total of 114 mg to 204 mg per day, CSCI with breakthrough bolus doses maintained his average daily pain rating between 1.0 and 3.5 (on a scale of 0 – 10) during that period. Worst pain levels each day ranged from 4.0 to 4.5 other than for one day during the two weeks when it reached 5.5. Breakthrough doses were given when pain levels reached 4. Least pain ranged between 0 and 0.5 for the
two-week period. Two weeks following the main study period, his pain had increased considerably. Average pain was rated as 4 with worst pain being rated as a 9. During that period, his hydromorphone had been increased to 378 mg per day (180 mg as continuous dose plus 11 breakthrough doses each of 18 mg).

The main pain-related symptoms that Mr. A experienced over the two weeks were elevated levels of anxiety and tiredness. Initially, Mr. A’s anxiety levels showed a similar pattern to his pain levels, i.e. low ratings for the first six days, followed by a gradual increase until completion of the study. Elevated levels of tiredness coincided with increased doses of hydromorphone at various time points. Other than the anxiety and tiredness, Mr. A experienced minimal pain-related symptoms. Nausea, loss of appetite and depression were consistently rated as 0, as was shortness of breath except for one occasion at 2.5. Well-being however, was rated higher between 4.5 and 5.5, as was pain interference in activities of daily living that reached a 6.

In terms of comfort and ease of use, both Mr. and Mrs. A consistently rated a 5 (on a scale of 1 – 5) indicating that it was ‘very easy’, that they were ‘very pleased’, that they found it ‘very comfortable’ and that they were ‘willing to continue’ with its use. Mr. A continued to use CSCI via syringe driver for administration of hydromorphone at home until he died shortly after completion of this study.
CHAPTER FIVE
DISCUSSION

The following discussion attempts to comprehend the findings from the case study of Mr. A. The findings, for Mr. A, are discussed in relation to the literature and the research questions examining the effectiveness of CSCI via syringe driver for managing terminal cancer pain and related symptoms, gaining insight into the factors involved in making the decision to use CSCI, and assessing the feasibility of conducting such a study on a larger scale.

Effectiveness of CSCI in Pain and Symptom Management

This case study focused on Mr. A, a man diagnosed with squamous cell carcinoma of the left larynx, who was unable to swallow, who was experiencing unrelieved pain and who had a life expectancy of less than six months. His Palliative Performance Scale was 50% at the onset of the study, indicative of him having extensive disease, mainly sitting or lying, requiring considerable assistance with self-care and being fully conscious (Victoria Hospice Society, 1998). Four weeks later, his condition had deteriorated to where he was spending more time in bed and requiring more assistance with personal care. His state at that point was a PPS of 40% indicative of disease progression while being cognitively aware and capable of decision-making with or without possible periods of drowsiness and/or confusion.

During the course of his disease trajectory Mr. A had undergone numerous treatments and was at a point where the goal of his end of life care was to provide comfort preferably at home. Mrs. A acted as his primary caregiver. Her main concern was to provide Mr. A with comfort which included assessing his pain and responding to those assessments. The syringe driver, designed to administer a continuous infusion was available in the community where
Mr. A lived. He was started on CSCI via syringe driver 19 days prior to his involvement in this study.

**Management of Pain**

Mr. A’s average pain ranged between 1.0 and 3.5 over the first two weeks of the study. His worst pain levels ranged from 4.0 to 5.5 and his least daily pain ranged from 0 to 0.5 during that same period. His average pain increased generally from the first to the second week. At the two-week follow-up, his pain increased considerably with his worst pain rated as a 9, his average pain as a 4.0 and his least pain as a 1.5.

In order to maintain his pain levels at a reasonably steady state during the initial two weeks, the amount of opioid was increased substantially. Over the first two weeks, his dose of continuous hydromorphone increased from 90 mg/24 hrs to 120 mg/24 hrs and the breakthrough doses increased from 4 mg to 12 mg with the number of breakthrough doses ranging from 3 to 9. His total dose of hydromorphone, including the breakthrough doses, in a 24 hour period ranged from 102 mg to 204 mg during the initial two weeks and then increased to 378 mg during the two week follow-up period.

Generally within the first two weeks whenever Mr. A’s pain level was above 4.0 on a 0 to 10 scale, Mrs. A would administer a breakthrough bolus to lower his pain to average between 1.0 and 3.5 and on occasion to a 0. During this time a pain rating of less than 4.0 represented tolerable pain for Mr. A. Tolerable pain is a subjective experience defined as “the duration or intensity of pain that the patient is willing to tolerate” (IASP, retrieved August 15, 2002). Two weeks later on the follow-up interview Mrs. A was administering breakthrough doses to lower Mr. A’s pain below 9.0 to an average of 4.0 and on occasion to a 1.5. The pain ratings on follow up were considerably higher than previous ratings.
indicating either an increase in pain that could be due to disease progression, a decrease in Mr. A’s pain tolerance or a decrease in the effectiveness of the hydromorphone in controlling the pain. In general, he had reasonable pain control during the initial two weeks and it is likely due to the ability of CSCI to maintain steady plasma levels.

An underlying aim of providing continuous subcutaneous infusion of opioid medications is to attain and maintain a plasma concentration of analgesic in the blood stream in order to achieve sustained pain relief. The syringe driver is capable of delivering a continuous infusion of medication and has the capacity to give bolus doses as needed to reduce the impact of any breakthrough episodes of pain that may occur despite the continuous infusion. This device seemed to be effective for Mr. A. On the basis of study findings we can see that Mr. A required more than just the continuous infusion dose. Not only did he require an increase in the dose of continuous infusion, he also required more frequent administration of bolus doses to circumvent the impact of breakthrough pain that occurred more frequently as his disease progressed or as his pain tolerance decreased. Pain tolerance is individualized and refers to the intensity of pain that the patient is willing to tolerate (McCaffrey, 1980).

During the first two weeks, his worst pain ranged between 4.0 and 5.5. During this period, 3 to 7 breakthrough bolus doses were given to attain an average pain between 1.0 and 3.5, except for day 6 when 9 breakthrough bolus doses were required to attain an average pain rating of 2.0. The reason this occurred is in keeping with the literature. The most common reasons for ineffective pain relief from analgesic include the type of pain the patient is experiencing, a malfunction of the administrative modality, disease progression and/or opioid tolerance. For Mr. A, the disease was progressing and he was requiring more and
more hydromorphone. When inadequate pain control occurred on day 6, it was determined that although the medication was being administered, it was not being adequately absorbed because the insertion site was reddened, irritated and inflamed, indicating a problem (Kennedy et al., 1999). The inflamed insertion site may have caused a problem with the opioid absorption allowing the plasma concentration of hydromorphone to drop, lowering the pain threshold, letting the pain break through more frequently, peaking above Mr. A’s pain tolerance.

On the two-week follow-up, i.e. four weeks after starting the study, Mr. A’s pain was intense. According to Mrs. A, his pain had steadily been increasing during the fourth week to a point where his worst pain was 9.0, his average pain 4.0 and his least pain 1.5. Even with the increased dose of continuous hydromorphone and the increase in frequency of the breakthrough doses from 5 to 11, pain relief was not adequate. The physician attributed the lack of pain relief to be due to opioid tolerance caused from Mr. A’s long-term use of hydromorphone. Mr. A had been receiving liquid hydromorphone prior to the 6 weeks he had been using CSCI hydromorphone. He was continuing to require increased doses of hydromorphone to achieve the same level of pain control. The need for increased doses of the analgesic to achieve the same level of pain control is symptomatic of opioid tolerance (Victoria Hospice Society, 1998). During the first week of the study, Mr. A had been receiving 90 mg/24 hrs of hydromorphone and 4 mg breakthrough bolus doses for total daily doses that ranged from 102 mg to 126 mg. During the second week, the dose was increased to 120 mg/24 hrs of hydromorphone and 12 mg breakthrough bolus doses for total daily doses that ranged between 164 mg to 204 mg. Two weeks after that, Mr. A was receiving 180 mg/24 hrs of hydromorphone and 18 mg breakthrough bolus doses that did not maintain an
adequate pain threshold to provide adequate comfort. On the day of the follow-up interview, his worst pain was a 9 and his average pain was rated as 4.0, higher than his acceptable average pain levels ranging from 1.0 to 3.5.

There are various options to addressing the issue of opioid tolerance. The analgesic dose can be increased to provide pain relief, another route can be tried, another opioid can be considered or an adjuvant medication can be added (Victoria Hospice Society, 1998). In the case of Mr. A, the physician suggested two strategies that could alter the opioid tolerance: to switch the opioid from hydromorphone to methadone and to change the route from a continuous subcutaneous infusion to gut absorption using a J-tube. Methadone, administered through a J-tube, would require careful monitoring in a hospital setting until a suitable dose could be established. Mr. A was averse to being hospitalized and Mrs. A was supportive of him staying home. Respectful of Mr.’s and Mrs. A’s wishes, it was decided to remain with CSCI via syringe driver and to increase the dose of hydromorphone to attain adequate blood levels of analgesic to provide Mr. A comfort at home. Mr. A remained at home using CSCI hydromorphone via syringe driver until he died, shortly after completion of this study.

Pain-related Symptom Management

In terms of pain-related symptoms, Mr. A did not experience major side effects related to opioid induced toxicities. He had no problems with constipation and according to the ratings reported on the Edmonton Symptom Assessment Scale (ESAS) he had no problems with nausea, loss of appetite, shortness of breath or depression. However, increased tiredness was apparent each time the dose of hydromorphone was initially increased. Increased tiredness was manageable and did not warrant a change in medication. Tiredness is a common side effect experienced with the initiation or substantial dose increase of an opioid
Mr. A’s reported levels of anxiety were closely related to his levels of pain within the first week but remained elevated after an episode of unrelieved pain that occurred on and around the sixth day when the insertion site became reddened and pain relief was inadequate. Unrelieved pain is often associated with disease progression instilling feelings of anxiety, fear, depression, irritability or hostility that can impact the way a patient perceives pain (Ahles, et al., 1983; Kwikkeboom, 1999; McGuire & Sheidler, 1997; Pargeon & Hailey, 1999). Because Mrs. A rated the ESAS on behalf of Mr. A it was difficult to determine if the reported anxiety ratings reflected Mr. A’s pain-related anxiety or Mrs. A’s anxiety. The memory of the inadequate pain relief on day 6, as evidenced by the increased breakthrough bolus doses required, could account for Mr. A’s increased anxiety and fear resulting in less pain relief on day 7. Pain relief was rated as only 10% on day 7 but then improved to 45% on day 8 and 95% on day 9. Mr. A’s reported level of pain decreased on day 7 and stabilized but his anxiety remained elevated. Mr. and Mrs. A were both understandably anxious and concerned that the increased pain could be a sign of disease progression.

Pharmacological agents such as lorazepam and methotrimeprazine were offered and helped to provide some relief for Mr. A’s anxiety however, according to the physician, Mrs. A was reluctant to administer them. She did administer sub lingual lorazepam regularly at night. According to Mrs. A, the non-pharmacological strategy of distraction was found to be more effective in relieving Mr. A’s anxiety than the medication. It may be, however, that the bolus doses that Mr. A received to relieve his increasing occurrences of breakthrough pain also served to reduce associated anxiety. A bolus dose of an opioid such as hydromorphone can cause a momentary euphoric effect or ‘rush’ that can act as a relaxant as well as an
analgesic (Dr. Hawley, personal communication, June 29, 2004). The bolus doses were easy to administer using the syringe driver and gave immediate results except for the times mentioned above when the site required changing or the dose required adjustment.

Impact of Pain on Activities of Daily Living

Unrelieved pain impacts a person’s ability to have a sense of normalcy in their life by interfering with activities of daily living that include general activity, mood, walking, ability to carry on with work or hobbies, relations with other people, sleep and enjoyment in life. The impact of pain on Mr. A’s activities of daily living was minimal during the first three days of the study, remaining less than 2.0, increased substantially on day 4 to a 6.0 then stabilized to range between 3.5 and 5.5 but did not drop below 3.5. Mrs. A attributed Mr. A’s difficulty with walking and self care to increased weakness related to the disease progression rather than pain interference. He found it increasingly difficult throughout the study to sit in a chair, mobilize to the bathroom or concentrate on his hobbies of painting and tying fish hooks.

On the two week follow-up assessment, there was another marked increase on the impact of pain on activities of daily living to 5.5. At this point, increased levels of anxiety along with increased levels of pain could have contributed to the increased level of pain interference and Mr. A’s increased reliance on caregivers. Mrs. A continued to provide care and support to Mr. A at home until he died, still using CSCI of hydromorphone via syringe driver to manage his cancer pain experience with relative comfort.

Factors Considered in Making the Decision to Start CSCI with Hydromorphone

On the basis of data obtained from the interviews conducted with Mr. A’s primary physician, his nurses and Mrs. A, it is apparent that several factors were considered for
choosing and maintaining the use of the CSCI. It was also apparent that the overall pain management decision-making process was tailored to meet Mr. A’s individual and evolving pain care needs. As the physician spoke about the factors he considered in making the initial decision to use CSCI via syringe driver, it was evident that a fairly systematic process, rather than an intuitive process was used. The physician had systematically thought about what had been effective and what might work in the situation based on his own assessments and those reported by Mr. A, Mrs. A and the nurses. Figure 17 illustrates the decision making process that seemed to be followed by the physician to choose an appropriate modality for medication administration for Mr. A.

In terms of choice of analgesic, although the physician did not specify that he used the WHO analgesic step-ladder to guide the choice of the pharmacological agent, it seemed that he did follow a systematic approach to determine the most appropriate opioid. Mr. A described his pain as a ‘constant crushing pressure’ indicative of nociceptive pain. The literature describes two pain categories: nociceptive and non nociceptive or neuropathic pain. Neuropathic pain is described as lancinating, burning, stabbing, stinging or aching requiring additional or adjuvant medications to opioids to provide adequate relief (McCaffery & Pasero, 1999). Since Mr. A’s pain was classified as a nociceptive pain, the decision to administer an opioid without adjuvant medications was appropriate.

The physician’s choice of using fentanyl and then hydromorphone and then methadone also followed a logical and systematic process. Once Mr. A was no longer able to tolerate oral medication, a transdermal fentanyl patch was used. The fentanyl patch is considered to be step three on the WHO analgesic step-ladder (Neighbours et al., 2001). However, while using the transdermal fentanyl patch, Mr. A’s pain was reported as constant,
requiring up to eight breakthrough boluses of 16 to 20 mg liquid hydromorphone daily, given through a J-tube in addition to a 250 mcg/hr fentanyl patch. The literature recommends a ceiling dose of 300 mcg/hr for fentanyl and notes that the transdermal patch takes 12 to 24 hours to achieve a steady plasma concentration of fentanyl (Librach & Squires, 1997; Neighbors et al., 2001). The use of a transdermal fentanyl patch is not conducive in the situation of severe or unstable pain. For these reasons and based on the assessment of Mr. A’s pain, the physician decided to change from transdermal fentanyl patch to a continuous infusion of hydromorphone.

Hydromorphone, a semisynthetic derivative of morphine, was chosen because it is more soluble than the ‘gold standard’ morphine requiring a lesser injection volume for subcutaneous infusion (Dickman et al., 2002; Librach & Squires, 1997). The dose of hydromorphone was adjusted according to the number of breakthrough boluses given and the level of pain intensity reported by Mr. A, Mrs. A. and the CHNs.

When the dose of hydromorphone reached 180 mg/24 hours and required up to 11 breakthrough bolus doses of 18 mg over 24 hours with no adequate pain relief, based on the timely pain assessment feedback he received from Mrs. A and the nurse, the physician suggested changing hydromorphone to methadone given via the J-tube. This strategy was suggested to avoid opioid tolerance. This direction however was not pursued since Mr. A did not wish to be hospitalized to adjust the dose. Mr. A remained at home receiving a CSCI of hydromorphone via syringe driver.

The specific factors that went into the physician’s choice for selecting the CSCI via syringe driver were made on the basis of Mr. A’s unstable pain, inability to tolerate oral medications and his assessment of the responses of Mrs. A on pain control. Typically, the
oral route is the first route of choice because it is easy to administer and cost effective. Mr. A however, could not tolerate oral medication due to the location of his disease in his larynx and required an alternative modality. Alternative modalities to the oral route include rectal suppositories, gastrointestinal access via jejunostomy or gastrostomy tube, transdermal fentanyl patches, intermittent subcutaneous injections, CSCI and IV.

In the case of Mr. A the rectal route was not preferred, the transdermal fentanyl patch was ineffective for pain relief, bolus doses of hydromorphone given through the J tube and intermittent subcutaneous injections of hydromorphone proved labour intensive for Mrs. A and the CHN due to the number of doses required. The need for an alternative modality was required that took into consideration the unstable nature of Mr. A’s pain experience and his wish to receive care at home. CSCI via syringe driver allows for rapid adjustment in medication and can be managed in the home. From the interview with the physician it was clear that he had the knowledge and background to use CSCI via syringe driver. The syringe driver was the device used for CSCI in Kelowna, the nurses were competent with its use and the hospital pharmacy would provide the syringes.

In addition, Mr. A agreed to try it and Mrs. A was willing and able to monitor the care and give the required breakthrough boluses. It was important that Mrs. A had the ability and the willingness to do what was needed related to assessment and CSCI via syringe driver management. If she had not been, use of CSCI via syringe driver would not have been a possibility for Mr. A. Mrs. A was able and willing to report any changes in Mr. A’s status to the health care professionals.

Mrs. A was attentive in monitoring Mr. A’s condition. She was quick to respond to his behavioural signs of pain such as grabbing for his throat, making a fist, grimacing or
increased restlessness. Whenever Mrs. A perceived Mr. A’s pain level to be greater than a 4.0, she administered a breakthrough bolus dose of hydromorphone by counting 6 beeps on the syringe driver. If the breakthrough bolus dose did not provide the anticipated relief, Mrs. A contacted the physician promptly and the dose was adjusted based primarily on her assessments monitored by the CHN as noted on day 7 and at the beginning of the third week when the doses were increased. On day 6, the CHN acted on Mrs. A’s information and followed up with an assessment of the injection site to find there was a problem.

A pain rating of 4.0 on a 0 to 10 scale motivated Mrs. A to administer a breakthrough bolus dose of hydromorphone. This was in response to Mr. A’s desired pain control to sustain average pain levels between 1.0 and 3.5. It is difficult to determine, if the pain level rating of 4.0 represented Mr. A’s pain level or Mrs. A’s pain tolerance, but the fact remains that Mr. A remained relatively comfortable at home and a component of his pain relief was that Mrs. A was able to assess his pain on an ongoing basis and administer bolus doses for breakthrough pain.

Another factor that was relevant to the choice of CSCI via syringe driver for Mr. A was the fact that CSCI was being used in his community and the staff were knowledgeable and skilled with its use. At present only two communities in British Columbia have chosen to use CSCI via syringe driver. They are located in the southern central interior and central Vancouver Island. Local training is provided through community and hospital in services. Hospital pharmacists prepare syringes for use in the syringe driver under a laminar flow hood. Other communities in British Columbia use CSCI via the CAD pump. The CAD pump is more expensive and more complicated to use than the syringe driver (Lynch et al., 2000). Figure 17 illustrates the decision-making pathway to initiate CSCI via syringe driver.
Figure 17. Decision Making Tree illustrating choice for an appropriate route of medication administration for pain management.
**Comfort and Ease of Use of CSCI via Syringe Driver**

Mrs. A consistently rated a 5 on the five point scales related to comfort and ease of use, indicating that both she and Mr. A found the syringe driver ‘very easy’ to use, were ‘very pleased’ and ‘very comfortable’ with its use and were both ‘supportive to continue’ using it. The syringe driver is designed to enable patients to have more freedom to continue with normal activities unencumbered by large infusion devices (Mallet & Dougherty, 2004). Mr. A was comfortable using CSCI via syringe driver. It was light-weight, fitting into his pajama pocket and did not interfere with his tolerated activities of daily living.

Mrs. A was confident and comfortable in administering breakthrough bolus doses to Mr. A based on her assessments of his pain. She was quick to notify the health care providers if there was a change in the effectiveness of the modality whether related to a malfunction of the device or an increase in pain intensity experienced by Mr. A. Mrs. A was competent in changing the syringes that were provided by the hospital pharmacy and in changing the battery. Her willingness to participate in this study was based on her hope that the findings would help to benefit others in a similar situation. Her main concern was to provide Mr. A with comfort and using CSCI via syringe driver enabled her to do that at home. All those involved in Mr. A’s care concurred that the CSCI via syringe driver was a good choice for managing Mr. A’s pain at home.

**The Feasibility of Conducting the Research**

The overall purpose of this pilot study was, in addition to testing the efficacy of using CSCI via syringe driver for pain management in terminally ill cancer patients, to assess the feasibility and appropriateness of the research methods including the use of a case study approach. The methods and approaches used in this study are discussed related to its
challenges and limitations. The areas that will be discussed include: the feasibility and appropriateness of the case study approach, recruitment, the appropriateness and usefulness of the measurement methods and tools, and concerns related to intrusiveness, voluntary consent, using proxy assessments, vulnerability and intrusiveness.

**Feasibility and Appropriateness of a Case Study Approach**

The case study approach relies on information derived from multiple sources to gain a deeper understanding of the phenomenon in context linking clinical practice to research by increasing the knowledge of treatment effects in a real life context. It was highly relevant to this study as it facilitated a detailed investigation on the use of CSCI via syringe driver on an individual patient experiencing cancer pain in his home setting. In this study, information was obtained from the patient, the patient's wife, the general practitioner (GP), the specialist in Pain and Symptom Management Program at CSI and the community health nurse to explore the effectiveness of CSCI via syringe driver in managing pain and also the perceived ease and comfort of its use. With the use of both quantitative and qualitative techniques the research questions were explored in depth.

**Recruitment**

The main problem encountered in the study was being able to recruit sufficient participants. I was only able to recruit one patient into the study who met the inclusion criteria during an 8-month period. In this research study the inclusion criteria specified that the patient have a Palliative Performance Scale of equal to or greater than 40%, indicating that he/she was cognitively aware and capable of decision-making but may have periods of drowsiness and/or confusion. Specifying a PPS of greater than or equal to 40% in the inclusion criteria was in keeping with guidelines for palliative care research that indicate
potential participants should be formerly assessed to ensure that they are not cognitively impaired and unable to give informed consent. There is a concern that patient participation in palliative research could be a result of coercion or involuntary consent. For this reason it is recommended that the potential participants be screened for cognitive impairment (Bruera, 1994; Kristjanson et al., 1994).

The inclusion criteria were appropriate for the purpose of this study but problematic in identifying and locating study participants in and around Kelowna. In Kelowna, British Columbia, where this pilot study was conducted, 4 to 5 syringe drivers were in use within a given period, but the involved patients did not meet the inclusion criteria. Within the time frame of this study, the syringe driver was used primarily for pain management for palliative patients with a PPS of 20% to 30% and a life expectancy of a few weeks to a month. Towards the end of the 8-month time frame, the last patient in the community to use the syringe driver died within 6 days of its initiation (V. Gibault, personal correspondence, June 15, 2004).

Mr. A was an exceptional case in this community. He had a PPS of 50% at the onset of the study and a life expectancy of greater than 3 months. By the end of the study, Mr. A’s condition had deteriorated so that he was spending the majority of his time in bed and required assistance with all personal care and mobility indicative of a PPS of 40%.

In order to increase the number of cases for this particular study, the time frame would need to be lengthened further and/or more communities involved to widen the available pool of potential participants. To change the criteria and include patients with a PPS of less than 40% would shift the focus of the study to those who were actively in the
process of dying, rather than a focus on the effectiveness, ease and comfort of use that may enable patients to remain at home longer.

**Appropriateness and Usefulness of the Measurement Methods and Tools**

The measurement tools were chosen specifically to assess the research questions and to reflect a multidimensional approach to cancer pain described in the Multidimensional Model of Pain. Both quantitative and qualitative techniques were used. The use of the Brief Pain Inventory (BPI) and Edmonton Symptom Assessment Scale (ESAS) complemented each other in collecting data on the level of pain and related symptoms. The BPI provided a comprehensive assessment of the patient’s perceived pain by asking for the worst, least, average and ‘now’ pain within a 24 hour period while the ESAS focused on the current or ‘now’ pain. Although the ESAS question on ‘now’ pain was repetitive when using the BPI, it strengthened the findings on current or ‘now’ pain and provided an overview of the patient’s general condition. By using both the BPI and the ESAS, more information was gathered on pain related symptoms and the level of pain interference on activities of daily living. This provided a more comprehensive report on the patient’s total pain experience in keeping with the approach of the Multidimensional Model of Pain.

The frequency of the measurement was daily for two weeks and two weeks later for a follow up interview. The measurement tools were administered between 10:00 a.m. and 11:00 a.m. by telephone except during the initial and follow-up interviews that were conducted in person at the patient’s home between 3:00 and 4:00 p.m. The times were appropriate for two reasons. Firstly, they were Mrs. A’s preference and secondly, no significant difference between numeric scores measured in the morning with those measured in the evening has been found (Dudgeon et al., 1999).
In addition to the pain and symptom scales, the five point scales used to assess the ease of use and comfort level strengthened what was gleaned from the open-ended questions on the topic. These were administered four times throughout the study, at the onset, the end of the first and second weeks and at the follow up interview. The CSCI via syringe driver was perceived to be 'user friendly'.

Semi-structured interview guides were designed to illicit information on the contributing factors in the decision making process and on the perceived ease and comfort with the use of CSCI via the syringe driver. These trigger questions were useful in guiding the interview while allowing room for the discussion to evolve. Short answer questions were used to obtain information and keep a record on the number and dosage of analgesic breakthrough bolus doses given. This was useful to discern the effectiveness of the chosen analgesic and dose in providing pain relief.

Careful piloting of approaches to research are required to ensure that palliative care research does not place unnecessary risks on study participants and those close to them (Addington-Hall, 2002). The personal nature of questionnaires places an emotional burden on the patient and the family while the daily monitoring of symptom intensity takes time away from dealing with other personal matters. To minimize the risk of burden, questionnaires and measurement instruments should be kept simple and as few as possible (Dean & McClement, 2002).

Both the ESAS and the BPI, used in this study were appropriate. They are simple and easy to use taking approximately 5 minutes each to complete (Chang et al., 2000; Pain Research Group, 2003). However, some overlap in these questionnaires was noted that could be altered in future studies to limit the intrusion on the patient and family. Although, one
could argue that the overlap of questions was minimal and worked to strengthen the findings by addressing the same issue from different angles. I believe that changing the data collection points would be more effective in reducing intrusion. I would recommend for future studies that the monitoring of symptoms occur daily for 1 week, at the end of the second week on day 14 and a final two week follow up interview on day 28. This new time line would provide the data relevant to the research questions while respecting the patient’s and family’s valuable time.

The risk of burden was minimized in this case study by limiting personal contact with Mr. A and conducting daily monitoring by telephone involving Mrs. A as spokesperson. The design of the study was non-experimental and did not manipulate or change the treatment protocol in any way limiting any risk of harm to the patient. Given the patient’s poor prognosis it was not likely that he would benefit directly from the study results, however, he could profit from the knowledge that his study participation could benefit others in similar circumstances.

Voluntary Consent

Recruiting participants for this study required consideration regarding the willingness of the patient to give voluntary consent as well as his cognitive ability to do so. A concern is that because palliative patients often feel desperate and reliant on caregivers, they may feel obligated to participate in palliative care research for fear of not receiving the care they require. Three strategies recommended in the literature were used in this study in an attempt to prevent any elements of coercion or obligation. The strategies included using a third party to elicit recruitment, emphasis on voluntary consent and ensuring that care would not be jeopardized if, at any time, the patient withdrew from the study (Casarrett & Karlawish,
Mr. A was identified by the Palliative Care Team in Kelowna, B.C. and initially approached about participating in the study by the CHN. The CHN informed me at this time that Mrs. A was concerned about the number of questions Mr. A would be required to answer and requested to act as the spokesperson between Mr. A and myself for the majority of the daily questionnaires to limit the questions asked directly to Mr. A. The CHN was not involved in the study once she had obtained the recruitment of Mr. A.

On the initial visit, I, as the researcher, agreed to accept Mrs. A as a proxy for Mr. A and emphasized to Mr. A that participation was voluntary. Mr. A agreed to participate in the research with Mrs. A as proxy and signed the consent in my presence. Verbal and written comments ensured that in no way would Mr. A’s care be jeopardized by the study even if Mr. A withdrew. I, as the researcher was not involved in direct patient care thus avoiding the potential conflict between providing care and gathering data.

Using Proxy Assessments

Although patient ratings of symptoms are optimal there are situations, such as palliative care research, where proxy assessments may be necessary. A consensus of patient and proxy assessments would be ideal for conducting symptom assessments but again this is not always possible. In this study, data were collected by proxy assessments. I relied on Mrs. A for daily assessments of Mr. A’s pain and related symptoms to limit the intrusion on their time together and the burden of answering questions on Mr. A. However, the initial and the final interviews were conducted in person with both Mr. and Mrs. A for a short time and then in more depth with Mrs. A. As the researcher I was concerned about the credibility of the findings when the data were primarily collected using proxy assessments.
The reliability of using proxy assessments to assess the patient’s condition is controversial. Who the proxy is and what their relationship is with the patient, what measurement tools are used, the frequency of assessments and whether the assessment refers to the patient’s physical or psychological symptoms are all contributing factors to the reliability of the proxy assessment.

The use of proxies has been discussed at length in the literature related to the challenges and problems inherent in their use. Nekolaichuk, Bruera, Spachynski, MacEachern, Hanson and Maguire (1999a) conducted a study that compared patient with physician and nurse proxy assessments of symptoms in advanced cancer patients using the ESAS on three occasions. The three assessments were conducted one week apart. They concluded that nurse ratings more closely approximated patient ratings and recommended continuous integrated patient and proxy assessments. In another study, Nekolaichuk, Maguire, Suarez-Almazor, Rogers and Bruera (1999b) examined the reliability of patient, nurse and family/caregiver symptom assessments using the ESAS with 32 advanced cancer patients. They found that family members helped identify interventions for symptom relief throughout the illness trajectory and that the family member’s ratings could be used as an approximation of the patient’s experience. They also found that nurse’s and family caregivers’ proxy assessments were more reliable with physical symptoms than with psychological symptoms such as depression and anxiety when compared to the patient’s assessments.

Other studies question the reliability of proxy assessments, however these studies interviewed participants only once. Maguire, Walsh, Jeacock & Kingston (1999) conducted a study on 61 patients suffering from colo-rectal cancer using semi structured interviews to
identify physical complaints. The results were compared with the reports from caregivers and
general practitioners. The study concluded that caregivers were unreliable witnesses, stating
that patients often withheld the reality of their suffering to avoid burdening their loved ones
(Maguire et al., 1999). Duncan et al. (2002), in a study with stroke patients found the use of
proxy assessments appropriate but also reported some biases.

The use of proxy assessments is not the ideal situation in conducting palliative care
research but at times cannot be avoided as in the case of Mr. A. Based on the studies by
Nelolaichuk et al., (1999a; 1999b) I believe that by using the ESAS measurement tool,
consistency in the interview process and checking in with the patient on two occasions, that
the proxy assessments obtained from Mrs. A were a close approximation to the symptoms
experienced by Mr. A and therefore could be considered reliable. Mrs. A, as the proxy
assessor was familiar with, and demonstrated a good understanding of how to use the BPI
and ESAS measurement tools for daily pain and symptom assessments. The patient, nurse
and the physician all concurred with the pain ratings. The physician, however, stated that the
level of anxiety could have been a reflection of Mrs. A’s anxiety around the progression of
the disease and not an accurate reflection of Mr. A’s. In future studies when proxy
assessments become necessary it may be prudent for the researcher to rely on multiple
assessments that include the nurse, the caregiver and whenever possible, the patient.

Vulnerability and Intrusiveness

Two significant areas of concern within palliative care research became evident
throughout this pilot study. The first was the vulnerability of Mr. A’s condition that elicited
protectiveness on the part of Mrs. A, and the second was the concern of intrusion on the
patient’s and family’s limited time that I felt as the researcher.
Palliative or terminally ill patients are particularly vulnerable. Illness often deprives the patient of physical strength resulting in increased fatigue and decreased independent capabilities necessitating an increased reliance on caregivers and family (Addington-Hall, 2002; Casarett & Karlawish, 2000; Dean & McClement, 2002). The vulnerability of this patient population raises the ethical question of whether or not they should be subjected to research (Addington-Hall, 2002; Casarett & Karlawish, 2000; Dean & McClement, 2002).

However, it has been found that although given the patient’s prognosis he/she will not likely benefit from the research, many patients participate for altruistic reasons. The literature presents rationale for patient participation that includes giving meaning to their illness, providing value to the community, leaving a legacy of helping others, providing an opportunity to be heard and benefiting other patients with similar circumstances in the future (Addington-Hall, 2002; Dean & McClement, 2000; Kristjanson, Hanson & Balneaves, 1994).

Mr. and Mrs. A agreed to participate with the hope that their contribution would help to benefit others with similar circumstances. Mrs. A, however, was very protective of Mr. A ensuring that personal contact was kept to a minimum by acting as a spokesperson for Mr. A since he had difficulty vocalizing and became very anxious when asked too many questions. Mrs. A’s instinct to protect Mr. A at a vulnerable point in his life is understandable.

The literature concurs that families are often very protective of the patient, acting as ‘gatekeepers’, not wanting the patient to be ‘bothered’ by questions, often resenting the time it takes to participate in research (Addington-Hall, 2002). The concern, for palliative care researchers, is that research questions deprive patients of energy and valuable time that they could use on strengthening relationships and addressing “unfinished business” with family and friends (Addington-Hall, 2002; Casarett & Karlawish, 2000). The success of palliative
care research, relies on the acceptance of the research on the part of the participants and the
insurance that the planned research is in keeping with the patient's preferences and
expectations (Casarett & Karlawish, 2000). To continue to have Mr. A participate in the
study, I agreed to have Mrs. A act as his spokesperson.

In this study, I was very aware of the intrusive nature of daily questionnaires. To
ensure that Mrs. A was willing to participate in the study I followed the concept of
'process consent' (Addington-Hall, 2002) whereby Mrs. A was asked daily for her consent
to continue and to identify a suitable time for the interview. By having Mrs. A establish a
suitable time each day I felt that the intrusiveness of the daily interviews was minimized. I
made a point of confirming, when I called, that she had a few minutes to talk. There was only
one occasion during the two weeks that Mrs. A requested that I call back later, which I did.

Conducting research with the terminally ill should adhere to the palliative care
philosophy that aspires to provide "family-centred" care embracing the needs of both the
patients and those close to them (Addington-Hall, 2002; Casarett & Karlawish, 2000). It is
prudent of the researcher to include the family's perceptions and those of involved health
care providers in assessments and interventions within the research study (Addington-Hall,
2002; Casarett & Karlawish, 2000). In keeping with the philosophy of 'family-centred'
palliative care, this study sought consent from, not only the patient, but also the patient's wife
to provide information on her perception of the effectiveness and manageability of the pain
management strategy. Further clinical information on the use of the syringe driver was
sought from the general physician and community health care nurse, once informed consent
was obtained.
Summary

In this Chapter, the findings, for Mr. A, were discussed in relation to the literature pertaining to the effectiveness of CSCI in pain and symptom management and the impact of pain on Mr. A’s activities of daily living. Factors considered in the decision making process to initiate CSCI via the syringe driver were also discussed in relation to Mr. A. The decision making process that took a systematic approach was outlined and an illustrated decision-making tree was presented based on the discussions held with the physician. The comfort and ease of use of CSCI via syringe driver was then described with particular attention to Mrs. A’s willingness and ability to manage it effectively.

In terms of pain management, a continuous infusion augmented with bolus doses attained and maintained a plasma concentration of hydromorphone in the blood stream that generally provided Mr. A with sustained pain relief. As his disease progressed, the continual dose of hydromorphone also increased to a point where the physician suggested switching the opioid from hydromorphone to methadone to avoid opioid tolerance. This option was not pursued since Mr. A did not wish to be hospitalized for the adjustment period. Other than anxiety and tiredness, Mr. A experienced minimal pain-related symptoms and was comfortable receiving CSCI of hydromorphone via syringe driver at home until he died shortly after completion of this study.

In terms of the decision-making process, the physician’s choice of using a transdermal fentanyl patch and then CSCI hydromorphone and then suggesting methadone followed a logical systematic process. Mr. A’s individual needs, the availability of the device, resources, and the capability and willingness of Mrs. A to manage the syringe driver, constituted the contributing factors considered prior to initiating CSCI via syringe driver.
The feasibility of conducting the research using a case study approach was discussed in terms of recruitment, the appropriateness and usefulness of the measurement methods and tools, voluntary consent, using proxy assessments, intrusiveness and the vulnerability of the palliative population. A case study approach was appropriate for this study, but the recruitment was problematic. Only one patient participated in the study. However, the case did provide relevant information regarding the decision making process, the effectiveness and manageability of using the syringe driver. The vulnerability of the patient and the researcher's concern about burdening the patient with questionnaires prompted the use of daily proxy assessments provided by the patient's wife. The proxy pain assessments were validated with the patient on two occasions and were considered a close approximation of the patient's pain by the physician and the CHNs involved in Mr. A's care.
CHAPTER SIX
SUMMARY, LIMITATIONS, CONCLUSIONS AND IMPLICATIONS

Summary

One of the main symptoms that terminally ill patients seek to control is chronic malignant pain and its management continues to pose a challenge for health care providers (D'Olimpio, 2001; Heller, 2000; Stjernsward, 1997). Although the oral route is preferred, it sometimes becomes necessary to use an alternative route for medication. This pilot study was designed to provide insight into the effectiveness of continuous subcutaneous infusion via syringe driver with a small group of cancer patients and to help determine the feasibility of carrying out such a study. In the review of the literature, the widely accepted definitions of pain, pain mechanisms and pain terminology were described as were theories on pain with an emphasis on the Multidimensional Model of Pain, designed specifically for cancer patients, that evolved from the Gate Control Theory. An overview of treatment modalities, both non-pharmacological and pharmacological was presented with particular attention given to pharmacological strategies. Alternative modalities to the oral route were described and included rectal suppositories, transdermal fentanyl patch, intermittent subcutaneous injections and continuous subcutaneous infusions (CSCI). Two predominant theoretical approaches to clinical decision-making were described as a systematic-positivist approach and an intuitive-humanist approach.

This study was considered a pilot study and used as preliminary investigative research in assessing the study’s appropriateness, design, methodology, instrumentation and feasibility. The purpose of this study was to explore whether using a continuous subcutaneous infusion via syringe driver was an effective and easy to use modality for the
management of chronic malignant pain in patients who could not tolerate oral analgesics. For this reason a case study approach was chosen using both quantitative and qualitative techniques because a case study approach is useful in linking clinical practice to research by increasing knowledge of treatment effects, such as CSCI via syringe driver in a real life context as with a patient experiencing chronic malignant pain. Inclusion criteria were restricted to cancer patients with a Palliative Performance Scale of greater than or equal to 40%, indicating that the focus is on patients who are cognitively aware and capable of decision-making but may have periods of drowsiness and/or confusion. Data pertaining to levels of pain and pain-related symptoms were collected daily for two weeks and at a follow up point two weeks later using the Brief Pain Inventory and the Edmonton Symptom Assessment Scale. For those time periods, data were also collected on the dosage and frequency by which medication and breakthrough doses were administered. Information pertaining to the comfort and ease of use of the syringe driver was collected at four points during the one month period of the study.

Unfortunately, only one person met the criteria during the allotted time frame and the use of proxy assessments by the wife became necessary to respect the patient and family preferences. Despite this recruitment, however, findings for that person, Mr. A, are helpful in informing us about the efficacy of CSCI and the feasibility of the research methods.

Several factors were considered in making the decision to initiate CSCI via syringe driver for Mr. A. They included that he was not able to tolerate oral medications, other modalities had been found ineffective or labour intensive, the syringe driver was available, the physician and nurses were knowledgeable and competent with its use, and the patient and family were receptive and supportive to using it. Mrs. A was able to assess her husband's
pain and with instruction, able to manage the equipment with ease.

The findings suggest that Mr. A’s pain was generally well controlled using the syringe driver for continual subcutaneous infusion and bolus doses of hydromorphone. Within the first two weeks, as the disease progressed, the total daily dose of hydromorphone with additional breakthrough bolus doses increased from 114 mg to 204 mg to maintain Mr. A’s average daily pain rating between 1.0 and 3.5 using a 0 – 10 numeric scale. Breakthrough doses were given when the pain reached 4.0. Generally, Mr. A required 3 to 7 breakthrough bolus doses except for one occasion when 9 breakthrough bolus doses were required for pain relief. The literature describes probable causes for not attaining relief as a malfunction of the device, a change in the type of pain, disease progression and/or opioid tolerance. On this occasion a device malfunction was noted and once the community health care nurse changed the needle and location of the infusion site to provide effective administration of hydromorphone, pain relief was obtained.

Two weeks later his pain had increased considerably and the total hydromorphone dose had also increased to 378 mg (180 mg/24 hrs plus 11 breakthrough doses of 18 mg) to maintain his average pain rating at 4.5. The need for elevated doses of opioids can be an indication of opioid tolerance and on this occasion the physician suggested switching the opioid from hydromorphone to methadone, however, hospitalization is generally required for methadone adjustment. Respectful of Mr. A’s wishes to remain at home, it was decided in this case to remain with CSCI via syringe driver and to increase the dose of hydromorphone accordingly to attain adequate pain relief for Mr. A at home.

The main pain-related symptoms that Mr. A experienced during the course of the study were elevated levels of anxiety and tiredness. Elevated levels of anxiety can be
associated with unrelieved pain interpreted as a sign of disease progression. Elevated levels of tiredness can be associated with a change in opioid administration and in this case coincided with increased doses of hydromorphone during the course of the study.

In terms of comfort and ease of use both Mr. And Mrs. A consistently rated a 5 on a five point scales indicating that it was ‘easy to use’, that they were ‘very pleased’, that they found it ‘very comfortable’ and that they were ‘willing to continue’ with its use.

Through a case study approach, a better understanding of how effective and manageable it was to use CSCI via syringe driver was attained and the factors influencing the decision to initiate its use for Mr. A were clarified. In terms of effectiveness, a continuous infusion augmented with bolus doses attained and maintained a plasma concentration of hydromorphone in the blood stream that generally provided Mr. A with sustained pain relief. As his disease progressed, the dose of hydromorphone increased from 90 mg/24 hrs with 4 mg breakthrough bolus doses to 120 mg/24 hrs with 12 mg breakthrough bolus doses during the first two weeks then to 180 mg/hr with 18 mg breakthrough bolus doses two weeks later. The need to increase the opioid to attain pain relief can be indicative of opioid tolerance. Switching the opioid from hydromorphone to methadone to avoid opioid tolerance was an option, but Mr. A declined not wishing to be hospitalized. Mr. A remained at home using CSCI via syringe driver.

In terms of manageability, the patient’s wife, once instructed by the community health care nurse, managed CSCI via syringe driver with relative ease and comfort, changing the syringes and batteries as needed and administrating breakthrough bolus doses based on her ongoing assessments. It was important that Mrs. A had the ability and the willingness to do what was needed related to assessment and CSCI via syringe driver management,
otherwise use of the syringe driver would not have been considered an option for Mr. A.

In terms of the decision-making process, the physician's choice of using a transdermal fentanyl patch and then CSCI via syringe driver and then suggesting methadone followed a logical systematic approach. Mr. A's individual needs and the availability of resources constituted the contributing factors to initiate CSCI via syringe driver.

The case study approach was highly relevant to this study as it facilitated a detailed investigation on the use of CSCI via syringe driver on an individual patient experiencing cancer pain. The main problem encountered in the study was only being able to recruit one patient in the allotted time frame who met the criteria. The measurement tools were appropriate in assessing pain and related symptoms and easy to use taking approximately 5 minutes each to complete. Conscious of the vulnerable condition of the patient, it became necessary in order to limit the burden and intrusiveness of questionnaires to use proxy assessments obtained from the patient's wife. However, Mrs. A's assessment can be considered a close approximation of the patient's condition and were useful in providing valuable information for the purpose of this study. A case study approach was appropriate and feasible.

Limitations of this Case Study Research

The main limitations to this study relate to internal validity and external validity or generalizability. In terms of internal validity, the main threats relate to the use of proxy assessments and the small sample size of only one case study. Although the preference is to have patients report their own pain assessment, there are situations when proxy assessments become necessary. In this study, the patient's wife provided a proxy assessment because Mr. A was unable to provide verbal reports of his pain due to the location of his tumor pressing
on his larynx. Another reason was based on Mrs. A’s concern to prevent any additional stress to Mr. A that might arise from his direct involvement in the study. Although the use of proxy assessments seemed a reliable approximation of the patient’s pain-related physical symptoms and validation was sought, the assessments were not based on personal accounts of pain as experienced by Mr. A himself. There was, however, agreement in pain ratings on two occasions when Mr. A was interviewed specifically to determine if he agreed or disagreed to the pain ratings provided by Mrs. A on his behalf.

Although having a single case cannot sufficiently address potential threats to internal validity, it nonetheless provided a microscopic view of the study phenomenon and the context. The case study was effective in answering all questions posed, and in doing so, it enriched understanding and it provides the basis for subsequent investigation. In terms of external validity, generalizability is limited because of the small sample size that is typical of the single case approach (Polit & Hungler, 1999). As noted, however, the intent of this study, was to generate detailed findings to enrich understanding rather than to generate findings for the purposes of generalizability. Whereas, generalization is based on a traditional sampling theory that has the ability to make inferences about a population, the case selection is based on a focused observation of an entity in context. The fundamental aims of the case approach, thus raises the question as to whether the concept of generalizability is applicable or even relevant to this context (Bergen & While, 2000). As it pertained to this study, the use of a case study approach may not establish a generalizability, but it has the potential to provide increased insight into the efficacy of CSCI via syringe driver within the context of terminally ill patients who are suffering from cancer related pain.
Conclusions

Recognizing the limitations of having only one case and using pain assessment and treatment data obtained by proxy, the following conclusions can be drawn from this study:

1. The low-tech syringe driver can be effective in attaining and maintaining adequate pain relief. Breakthrough bolus doses can be easily administered and medication doses can be readily adjusted to meet the individual needs of the patient.

2. Several factors influence a decision to initiate CSCI via syringe driver such as whether the patient can tolerate oral medications, the effectiveness in controlling pain with other alternative modalities, knowledge and competency of the health care providers, accessibility of the modality within the community, and the willingness of the patient and family to provide assessments, administer the bolus doses as required and maintain the equipment appropriately.

3. The syringe driver can be easily learned and managed in the home by family members.

4. A case study approach is conducive to exploring the effectiveness and manageability of CSCI via syringe driver with a terminally ill individual.

Implications

Implications for Theory

This study shed light on the theoretical perspective and its usefulness. Study outcomes support the theoretical perspective that pain is multidimensional in nature as described in the Multidimensional Model of Pain (Ahles et al., 1983). It can be assumed, based on proxy assessments of his pain, that Mr. A’s pain was interactively influenced by his emotional state, his cognitive ability, his familial support and his desire to remain at home to
retain a sense of normalcy. Cancer related pain as a total pain experience comprised of a myriad of factors whereby the physical pain the patient experiences is only one dimension of the suffering the patient endures (Saunders, 2000). The Multidimensional Model of Pain is therefore useful in guiding a thorough assessment of the total pain experience related specifically to cancer pain. This can guide the decision-making process for an individualized pain management strategy. Because of this, pain management strategies should not simply focus on the physiological dimensions but must also consider the affective, cognitive, behavioural and sociocultural dimensions of the total pain experience.

Implications for Practice and Education

The study suggests several implications for practice and education. As indicated above, it is imperative that the patient’s assessment include the total pain experience and not simply focus on one dimension. A challenge for health care providers is choosing the best alternative treatment modality when the patient is unable to tolerate the oral route. It is clear from this study, that palliative care communities need to be more aware of the advantages of the syringe driver in the delivery of CSCI and consider using it more often, especially in terms of the ultimate benefit it affords the patient and family. The syringe driver can be generally effective in providing adequate pain relief, is “user friendly”, light-weight and portable and relatively inexpensive when compared to other infusion devices. Accessibility of the device and the availability of health care providers competent in its use are essential factors in the decision to initiate the use of CSCI via syringe driver. Health care providers, therefore, need to know about the device and how to best support the patient and family in its use.

Accessibility refers to the availability of syringe drivers within the community and to
the necessary resources to manage their use safely and effectively. Unfortunately, CSCI via syringe driver is not widely available in British Columbia for use in the community. Efforts need to be made to increase awareness about the advantages of such a modality and to encourage its use in more communities. To support competent practice, education and standards of practice are required for physicians to identify when to initiate the use of the syringe driver, for nursing to implement and monitor its safe use, for pharmacists to prepare medication and for the family/caregiver to provide ongoing management.

The physician should be knowledgeable regarding the advantages and disadvantages using CSCI via syringe driver as an alternative modality for medication administration when a patient is unable to tolerate oral medications. The physician should also be competent in adjusting the medications and/or dosage to attain adequate pain relief that meets the individual needs of the patient. The pharmacist should be knowledgeable in preparing the appropriate dose in the syringe to accommodate the regular dose and the breakthrough boluses prescribed. Formulas and charts are available to guide the pharmacist in preparing the syringes. Compatibility charts and books provide information and guidelines to administer more than one medication safely. In British Columbia the pharmacist also needs to be familiar with the use of a laminar flow hood when preparing the syringes for use in the syringe driver.

The nurses have the responsibility to implement and ensure the safe use of the syringe driver. They are responsible to monitor the site, the rate of infusion and clearly document their observations. Nurses need to be competent in changing the dressing and resiting the subcutaneous needle as needed. Nurses also have the responsibility to conduct an accurate pain assessment regularly and communicate any changes in the patient’s condition to the
physician to confer whether a dose adjustment is necessary. In the home the CHN is responsible to teach the family/caregiver how to manage the syringe driver safely and administer breakthrough boluses effectively.

The patient and/or the family require direction to manage the syringe driver safely in the home. This includes administering breakthrough boluses, keeping the syringe driver dry, changing the syringes daily and changing the batteries as needed. Reassurance and guidance from the health care providers support the family/caregiver in maintaining safe use of the syringe driver in the home setting. Fundamental to this process is ensuring clear communication between health care providers who decide on the actual treatment regimen and the family who often bear the responsibility of providing accurate pain assessment – often under difficult circumstances and with little preparation for the role. As shown in this case study, Mrs. A’s ability to assess and communicate Mr. A’s pain in a timely manner and the receptiveness of the health care team in responding to those assessments all contributed to shaping Mr. A’s treatment plan and its ultimate effectiveness.

To support competent practice for health care professionals a standardized approach for policies and procedures in using the syringe driver is recommended (C. Oliver, personal correspondence, August 8, 2003; McCormick et al., 2001). In Kelowna, the Palliative Care Program has devised guidelines for health care providers in the use of the syringe driver and provides in service training to community and hospital nurses to promote competency of use (V. Gibault, personal communication, November 7, 2003).

In New Zealand, where the use of the syringe driver is considered common practice for palliative patients, national policies and standards exist around its safe use. A syringe driver competency program for registered nurses has been developed that can be completed
by distance then followed up with a practical competency assessment and a written test (R. Jenkins, personal correspondence, February 17, 2004).

The purpose of polices and procedures is to ensure continuity of care and safe practice. The nurse should be competent and confident in the use of the syringe driver to enable him/her

- to monitor the site for signs of problems
- to have the knowledge and competency to complete accurate pain assessments on an ongoing basis to determine whether the prescribed medication has been effective
- to advise the physician of any changes in pain levels or breakthrough doses
- to adjust the dose according to the physician’s orders
- to educate the family/caregiver in the safe use of the syringe driver
- to advise the family/caregiver of the available resources in the community that they can contact if problems arise day or night

Standardized policies and procedures on the use of the syringe driver are recommended to ensure safety and continuity of practice between the home and hospital settings. Good communication between the nurse, patient, physician, family and pharmacists is also essential for ongoing effective pain management.

Implications for Future Research

The study’s findings also suggest implications for research. A case study approach is appropriate to gain a greater understanding of the use of a syringe driver for a palliative patient. Given the usefulness of the approach for one case, it is highly recommended that additional cases be examined. Some slight changes are suggested however for future work. In
future research it may be advisable to rely on multiple sources for data that include the patient and others for proxy assessments such as the nurse and the caregiver. While outcomes of this study support the use of proxy assessments, it is important to realize that proxy assessments may grossly under- or over-estimate another’s pain and that such inaccuracies may have grave consequences for individual’s placed in vulnerable and dependent positions. Whenever possible, it is important to include the patient to ensure a close approximation of the assessment or to include a standardized means for testing the reliability and validity of the proxy pain assessments. Further work is needed related to the validity of proxy reports since proxies provide a valuable source of information and in some cases are the only source.

In any research the level of intrusiveness must be considered related to the burden of the study. In this study, questionnaires were administered daily for two weeks and then at a two week follow up interview. For future studies it is recommend that assessments be done daily for one week when the device is initiated to establish a base line of the reported levels of pain and pain-related symptoms. Ideally, daily assessment of pain levels for one week prior to beginning CSCI would be helpful for comparison. Following the daily assessments for one week, it would be followed by an assessment at the end of the second week to observe any changes and then again at a two-week follow up interview for further assessment of the effectiveness. It would also be prudent for future researchers to confirm if the patient was at home, in hospital, in a palliative care unit or a hospice when he/she eventually died and what mode of medication administration was being used at the time of death. This approach would provide sufficient relevant data to determine the effectiveness and manageability of the syringe driver over time. It may also address whether the use of the syringe driver enabled the patient to remain at home until the time of death.
This case study reflected the effectiveness and manageability of using CSCI via syringe driver. It did not, however, compare the effectiveness, ease of management, overall cost or medication preparation of the CSCI via syringe driver to other alternative modalities when the oral route is not tolerated, nor to other delivery devices used for CSCI. Future research that compared CSCI, irregardless of the device, to other alternative modalities such as the transdermal fentanyl patch and intermittent subcutaneous injections could provide valuable information that would aid in the decision making process to determine the most appropriate pain management strategy for a palliative patient. A within-patient-crossover design would be appropriate for a comparative study between the modalities. Future research that compares the use of the syringe driver to other delivery devices of CSCI, such as the CAD pump, could provide valuable insight into the advantages and disadvantages of each device. A within-patient-crossover design that compares the delivery devices for CSCI, could provide information that may influence palliative care communities to apply the appropriate ‘health technology that people can use and afford’ for their palliative patients, in keeping with the WHO recommendations on Primary Health Care (1978).

Concluding Remarks.

The management of chronic malignant pain affects over 60% of patients with advanced cancer and continues to provide ongoing challenges to health care providers. Unrelieved pain can demoralize and disturb interpersonal relationships, lead to anxiety, loneliness, depression and fear. The main objective of treatment is to provide effective pain relief, while limiting side effects and promoting independence and freedom of movement. This becomes particularly challenging for health care providers when the patient is unable to tolerate oral medications. Continuous subcutaneous infusion (CSCI) via a low-technology
syringe driver is the accepted modality for medication administration for palliative patients in some countries when the patient is unable to tolerate oral medications. It is designed to allow patients more freedom of movement, to be managed easily in the home or hospital setting and to attain and maintain a plasma concentration that is easily adjusted according to the patient's individual needs. In British Columbia, only two communities have chosen to use CSCI via syringe driver: the Southern Central Interior and Central Vancouver Island.

In this case study, CSCI via syringe driver was a good choice of modality for the case studied because it was generally effective in administering an adequate dose of hydromorphone to promote pain relief and it was easily managed in the home. Other patients would likely benefit from its use and the modality needs to be made more accessible for medication administration in British Columbia. It is easy to use, effective in administering medication that can be easily titrated to meet individual needs and is cost effective compared to other devices used for continuous subcutaneous infusions.
REFERENCES


Virik, G., & Glare, P. (2002). Validation of the Palliative Performance Scale for inpatients


Appendix A

The WHO Three-Step Analgesic Ladder

(Victoria Hospice Society, 1998, p. 176)
### Characteristics of Drug Administration Routes

<table>
<thead>
<tr>
<th>Route</th>
<th>Oral Analgesics</th>
<th>Transdermal Fentanyl</th>
<th>Intermittent Subcutaneous Injections</th>
<th>Continuous Subcutaneous Injections</th>
<th>Intravenous Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for use</td>
<td>First method of choice for analgesic treatment. Meds easily accessible</td>
<td>Used when patients are unable to swallow or tolerate oral opioids due to intractable side effects (Librach &amp; Squires, 1997)</td>
<td>Suitable for patients with dysphagia or intractable nausea and vomiting (Neighbors et al, 2001)</td>
<td>Used in patients with advanced illness who are unable to use oral and rectal medications to relieve symptoms such as pain, nausea and dyspnoea (Gomez, 2000 &amp; Miller et al, 1999).</td>
<td>Used in a hospital setting. Require good venous access.</td>
</tr>
<tr>
<td>Ease of Use</td>
<td>Self administered, reducing the involvement of the caregiver. Around the clock administration.</td>
<td>Convenient, avoiding around the clock medication administration. Less invasive</td>
<td>Subcutaneous butterfly recommended for regular injections (Librach &amp; Squires, 1997)</td>
<td>Training for staff and/or caregiver to change syringes, monitor the site and give additional drug boluses. Syringe generally needs to be reloaded every 24 hours. May be used for prolonged periods in the hospital and at home providing continuity.</td>
<td>Must be administered by an IV certified nurse. Tubing is changed every 72 hours. IV reinserted as necessary. Requires special equipment and maintenance (Librach &amp; Squires, 1997).</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Can change dose easily. Peaks and troughs can occur when analgesics are not taken regularly.</td>
<td>Slower titration than oral CSCI and IV taking 12 to 24 hours to reach a steady plasma level (Librach &amp; Squires, 1997; Neighbors et al, 2001)</td>
<td>Effective for low doses of opioids at high concentration not for large doses of opioids requiring larger volumes (Librach &amp; Squires, 1997)</td>
<td>Plasma drug concentrations are maintained without peaks and troughs providing round the clock comfort (Gomez, 2000 &amp; Lynch et al, 2000).</td>
<td>Same as CSCI.</td>
</tr>
<tr>
<td>Oral Analgesics</td>
<td>Transdermal Fentanyl</td>
<td>Intermittent Subcutaneous Injections</td>
<td>Continuous Subcutaneous Infusion</td>
<td>Intravenous Infusion</td>
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<tr>
<td>Side Effects</td>
<td>Increased dose of opioid required compared to other routes causing increased side effects and increased risk of toxicity.</td>
<td>Difficult to reverse side effects immediately. Patient may experience prolonged side effects after patch removed (Librach &amp; Squires, 1997)</td>
<td>Nausea and sedation related to bolus dosing may be more common than other routes (Librach &amp; Squires, 1997)</td>
<td>Minimizes nausea, vomiting and gastrointestinal tract disorders often experienced after oral administration by allowing drugs to bypass the stomach (Lynch et al, 2000, p. 350)</td>
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<td></td>
<td>Rescue medication is often required within the first 24 hours (Fallon &amp; O'Neill, 2000)</td>
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<td></td>
<td>Same as CSCI but has increased risk of infection at the site of insertion.</td>
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<tr>
<td></td>
<td>Less side effects than oral route (Neighbours et al, 2001)</td>
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<tr>
<td>Symptom Control</td>
<td>Provides multi symptom control if patient is able to swallow and digest medications</td>
<td>Does not allow for adjuvants and multi symptom control. Associated with less chronic constipation (Neighbours et al, 2001)</td>
<td>Does not allow for control of multiple symptoms. Alternative injection site, oral or suppositorie s are required for management of other symptoms</td>
<td>Allows for control of multiple symptoms with a combination of drugs.</td>
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<td></td>
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<td></td>
<td>Allows for administration of different drugs.</td>
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<tr>
<td>Cost effectiveness</td>
<td>Most cost effective mode of administration</td>
<td>More expensive than oral administration. Cost effective when compared to CSCI or IV devices (Neighbours et al, 2001)</td>
<td>Less expensive and less complex than CSCI (Librach &amp; Squires, 1997)</td>
<td>CSCI can cost half as much as an IV infusion (Pasero, 2002)</td>
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<td></td>
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<td></td>
<td>More expensive than CSCI</td>
<td></td>
</tr>
<tr>
<td>Management of Route</td>
<td>Oral Analgesics</td>
<td>Transdermal Fentanyl</td>
<td>Intermittent Subcutaneous Injections</td>
<td>Continuous Subcutaneous Infusion</td>
<td>Intravenous Infusion</td>
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<tr>
<td>Regular Compliance in taking medications required</td>
<td>Less invasive</td>
<td>Subcutaneous butterfly is recommended for regular injections for patient comfort</td>
<td>CSCI supplies are easy to obtain and can be started in the home, office or hospital setting</td>
<td>Requires health care provider to manage delivery of drugs and monitoring of site.</td>
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<tr>
<td>Greater risk of non-compliance with regular administration</td>
<td>Patch is changed every 72 hours (Fallon &amp; O'Neill, 2000)</td>
<td>Injection site changed every 3 to 10 days as needed (Librach &amp; Squires, 1997)</td>
<td>Monitoring of injection site for possible inflammation and pain leading to decreased drug absorption is required.</td>
<td>Site requires changing every 3 to 5 days by a health care professional.</td>
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</tr>
<tr>
<td>Facilitates out patient pain management</td>
<td>Facilitates out patient pain management once the dose titration is established (Neighbors et al., 2001)</td>
<td>Regular injections every 3-4 hours need to be given by family member or health care professional increasing dependence on caregivers</td>
<td>Less need for repeated injections, site changed every 5 to 7-days lessening dependence on caregivers and avoiding need for inpatient IV deliverand of drugs (Lynch et al., 2000)</td>
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129
## Palliative Performance Scale

<table>
<thead>
<tr>
<th>%</th>
<th>Ambulation</th>
<th>Activity &amp; Evidence of Disease</th>
<th>Self-Care</th>
<th>Intake</th>
<th>Conscious Level</th>
</tr>
</thead>
</table>
| 100| Full             | Normal Activity  
No evidence of disease | Full      | Normal       | Full           |
| 90 | Full             | Normal Activity  
Some Evidence of Disease | Full      | Normal       | Full           |
| 80 | Full             | Normal Activity with Effort  
Some Evidence of Disease | Full      | Normal or Reduced | Full |
| 70 | Reduced          | Unable Normal Job/Work  
Some evidence of Disease | Full      | Normal or Reduced | Full |
| 60 | Reduced          | Unable Hobby/House work  
Significant Disease  
Occasional Assistance Necessary | Normal or Reduced | Full +/- Confusion |
| 50 | Mainly Sit/lie   | Unable to do any work  
Extensive Disease  
Considerable Assistance Required | Normal or Reduced | Full +/- Confusion |
| 40 | Mainly in Bed    | As Above  
Mainly Assistance | Normal or Reduced | Full or Drowsy +/- Confusion |
| 30 | Total Bed Bound  | As Above  
Total Care         | Normal or Reduced | Full or Drowsy +/- Confusion |
| 20 | As Above          | As Above  
Total Care         | Minimal Sips | Full or Drowsy +/- Confusion |
| 10 | As Above          | As Above  
Total Care         | Mouth Care Only | Drowsy or Coma |
| 0  | Death            | --            | --               | --            |

Appendix D

KGH Letterhead

Patient Consent Form

Effectiveness and Manageability of Continuous Subcutaneous Infusion Drug Administration for Patients with Chronic Malignant Pain: A Case Study Approach

Principal Investigator/Faculty Advisors: Dr. Ann Hilton, Professor, School of Nursing, University of British Columbia, 604 822-7498 and Dr. Fay Warnock, Assistant Professor, School of Nursing, U.B.C.

Co-Investigator: Elizabeth Beddard-Huber, RN, School of Nursing, University of British Columbia 604-877-6000 local 2012 is a nurse in the Masters of Science in Nursing Program at U.B.C. and this study is part of her Master’s thesis.

Professional Contacts in Kelowna: Dr Gillian Mary Fyles, Medical Leader Pain and Symptom Management/Palliative Care Program – Cancer Centre for the Southern Interior BCCA; Division of Palliative Care, Dept of Family Practice UBC, and Member of Staff Dept of Family Practice Kelowna General Hospital, 250 712 3994 and Vera Gibault, RN, BScN, Clinical Practice Consultant for Community/Palliative Care, Interior Health 250 868 7707.

Purpose: Because of my interest in the management of chronic malignant pain, I want to study the effectiveness and ease of use of the syringe driver in administering continuous subcutaneous infusion (CSCI). You are invited to participate in this study because you are receiving analgesics alone or in combination with other medications continuously via a syringe driver. Your participation will be useful in gaining a better understanding in the factors that influence the decision to use a syringe driver, the effectiveness of this modality for pain and symptom management, and your perceptions about its comfort and ease of use.

Study Procedures: Your involvement will include talking to me about what it is like for you to receive your medication(s) by continuous subcutaneous infusion via syringe driver, your assessment of your pain and symptom levels and how easy or difficult it is for you to use the modality. On the first visit, an initial interview will be done to seek your impressions of this modality and the methods of pain and symptom control you have used in the past for your condition. With your permission, this interview will be audio-taped. Following this interview you will be asked to rate your pain and other symptoms daily for 2 weeks and again two weeks after that. On three occasions over the two-week period and again at the end, you will be asked to rate and comment on your level of comfort and ease in using the CSCI. If your family member is with you, he/she will be asked about their involvement and their level of comfort and ease of use with the modality. I will guide you through the forms in person or by telephone and give you a chance to ask questions or make comments about the study. The initial visit will take about 30 to 40 minutes and the daily assessment will take about 5 – 10 minutes each day. With your permission, a brief summary of the events leading up to the initiation of CSCI via syringe driver will be obtained from overview of your chart and from an interview with your health care providers who are involved in decision and your care. Information from the chart will include diagnosis, onset, your age at diagnosis and the pain management you have used before using the syringe driver.

Page 1 of 2
Confidentiality: All information provided by you, your family and your healthcare providers will be kept confidential. All documents will be identified by a code number and kept in a locked filing cabinet at the British Columbia Cancer Agency in Vancouver. You will not be identified by name in any reports of the completed study. The data collected for this study will only be accessible to the co-investigator and her thesis committee.

Remuneration/Compensation: There is no funding available for participation in this project.

Contact for information about the study: For further questions or would like further information about the study please contact me at the British Columbia Cancer Agency 604-877-6000 local 2012.

Contact for concerns about the rights of research subjects: If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598.

Consent: Your participation in the study is on a voluntary basis. If you refuse to participate or decide to withdraw from the study at any time, your medical or nursing care while in the hospital or in the community will not be altered in any way.

Your signature indicates that you have received a copy of this consent form for your records.

Your signature indicates that you consent to participate in this study.

Subject Signature Date

Printed Name of the Subject

Appendix E

Semi-Structured Interview Guide with Patient

*Initial interview guide with patient re their perception of the initiation of CSCI via syringe driver*

- I am interested in knowing what you think about the initiation of the syringed driver to help manage your pain and related symptoms.
- Could you please describe what your pain was like before using the syringe driver? What about any other symptoms?
- What are your expectations around the use of the syringe driver?
- You started on the syringe driver ____ days ago. Could you describe if there has been any difference in the nature of any other symptoms since you began using the syringe driver?
- What drawbacks or concerns and what benefits do you see in using this modality?
- How do you see using this device and whether it might make any difference to what you are able to do?
- What supports do you have at home to assist you?
- What additional support do you think you will need?
- Do you have any concerns about the safe use of the syringe driver in administering medications?
Appendix F
Demographic Information Form

Participant’s Code ________________
Date ________________ Visit ______

Setting: Home [ ] Hospital [ ]

Gender Female □ Male □

What is your age? ________________

What is your Marital Status ________________

Do you have children? Yes □ No □

If yes how many and what are their ages and gender? ________________

Dwelling Urban □ Rural □

Support No support □; Spousal support only □; Family support □;
Extended support with family and friends □

Please describe your community support

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Please describe your religious affiliation? ________________________________

Do you have any additional comments re your support? Please elaborate
Appendix G

Guide for Chart Review

Patient code________________ Date________________ Time________________

Setting:  Home [ ]  Hospital [ ]

• Diagnosis

• Age at diagnosis

• Presenting symptoms that led to the diagnosis

• Brief overview of the trajectory of the disease to date including a synopsis of the treatments the patient has experienced ie: surgery, chemotherapy and/or radiation.

• PPS score at the present time.

• A review of progress and nursing notes within the 2 weeks prior to initiation of CSCI via syringe driver to identify what type of pain medication and modality the patient was using, the effectiveness of the pain management strategy initially, and what triggered a change in modality.

• Reason for current hospital admission if applicable.
Health Care Provider Consent Form

Effectiveness and Manageability of Continuous Subcutaneous Infusion Drug Administration for Patients with Chronic Malignant Pain: A Case Study Approach

Principal Investigator/Faculty Advisors: Dr. Ann Hilton, Professor, School of Nursing, University of British Columbia, 604 822-7498 and Dr. Fay Warnock, Assistant Professor, School of Nursing, U.B.C.

Co-Investigator: Elizabeth Beddard-Huber, RN, School of Nursing, University of British Columbia 604-877-6000 local 2012 is a nurse in the Masters of Science in Nursing Program at U.B.C. and this study is part of her Master’s thesis.

Professional Contacts in Kelowna: Dr Gillian Mary fyles, Medical Leader Pain and Symptom Management/Palliative Care Program – Cancer Centre for the Southern Interior BCCA; Division of Palliative Care, Dept of Family Practice UBC, and Member of Staff Dept of Family Practice Kelowna General Hospital, 250 712 3994 and Vera Gibault, RN, BScN, Clinical Practice Consultant for Community/Palliative Care, Interior Health 250 868 7707.

Purpose: Because of my interest in the management of chronic malignant pain, I want to study why the decision was made to initiate the use of continuous subcutaneous infusion via a syringe driver and any advantages and/or difficulties encountered in its use. As a health care provider(s) familiar with this individual case, your participation will be useful to gain a better understanding and explanation of the characteristics surrounding the initiation of a continuous subcutaneous infusion via a syringe driver and/or any challenges or difficulties encountered with its use.

Study Procedures: Your involvement would include talking to me about what factors were considered in the decision making process and/or what advantages and/or difficulties you encountered with its use. With your permission the interview identifying contributing factors surrounding the initiation of continuous subcutaneous infusion via syringe driver will be audio-taped. I will take field notes when asking questions pertaining to ongoing advantages and/or difficulties encountered with the use of the syringe driver. You will also be asked to describe any concerns that you might have with the safe use of CSCI via syringe driver.

Confidentiality: All information provided by you, the patient and the patient’s family/caregiver will be kept confidential. All documents will be identified by a code number and kept in a locked filing cabinet at the British Columbia Cancer Agency in Vancouver. You will not be identified by name in any reports of the completed study. The data collected for this study will only be accessible to the co-investigator and her thesis committee.

Remuneration/Compensation: There is no funding available for participation in this project.
Contact for information about the study: For further questions or would like further information about the study please contact me at the British Columbia Cancer Agency 604-877-6000 local 2012.

Contact for concerns about the rights of research subjects: If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598.

Consent: Your participation in the study is on a voluntary basis and will only be required if the patient consents to the study.

Your signature indicates that you have received a copy of this consent form for your records.

Your signature indicates that you consent to participate in this study.

________________________________________

Health Care Provider’s Signature                Date

________________________________________

Printed Name of Health Care Provider
Appendix I

Semi-structured Interview Guide with Health Care Professional

Interview guide for semi-structured interview of the factors considered in the decision making process to initiate CSCI via syringe driver.

Date ______/_______/___________

Health Care Provider Code __________________________

• What factors led you to choosing to use the syringe driver for this patient?
• Tell me more about the contributing factors that led to the decision to initiate CSCI via syringe driver.
• What modalities have been used in the past to administer medications to this individual patient?
• How successful was the medication and/or modality initially?
• What circumstances occurred that perpetuated a change in the medication and/or modality?
• How long do you anticipate this individual patient will receive medication administered by CSCI via a syringe driver?
• Are there any other considerations that influenced the decision to initiated CSCI via syringe driver? Please identify and explain.
• Do you have concerns regarding the accurate and safe administration of medication via the syringe driver? Please explain.
• Do you anticipate any problems that the patient or family/caregiver might encounter with the use of the syringe driver? Please explain.
Appendix J
Semi-Structured Interview Guide for Primary Care Nurse

Code of Patient ____________________________ Date ____________________________ Time ____________________________

Setting: Home [ ] Hospital [ ]

- I am interested in knowing about what you think. How comfortable do you think this patient is with the use of the syringe driver? Please elaborate.

- How typical is this patient to other patients you have nursed that have used or are using a syringe driver?

- What is it like for you as the nurse to use the syringe driver?

- Have you noticed any changes in the patient’s behaviour or mobility since starting on the syringe driver?

- Have you noticed any changes in the patient’s management of pain and related symptoms since being on the syringe driver? Please explain.

- Have you encountered any concerns with the safe use of the syringe driver in the delivery of medications?

- Have you identified any problems or challenges with the use of the syringe driver with this patient?
Appendix K

Brief Pain Inventory

Setting: Home [] Hospital []

Subject Code Date Time

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds 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 last 24 hours.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
8. In the last 24 hours, how much relief have your pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

<table>
<thead>
<tr>
<th>Percentage</th>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
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</thead>
<tbody>
<tr>
<td>Relief</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Complete Relief</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>A</th>
<th>General Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Does not Interfere</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B</th>
<th>Mood</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Does not Interfere</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C</th>
<th>Walking Ability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
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<tr>
<td>Does not Interfere</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D</th>
<th>Normal Work (includes both work outside the home and housework)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Does not Interfere</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>E</th>
<th>Relations with other people</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Does not Interfere</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F</th>
<th>Sleep</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Does not Interfere</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>G</th>
<th>Enjoyment of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Does not Interfere</td>
<td></td>
</tr>
</tbody>
</table>
Appendix L

Edmonton Symptom Assessment Scale

Code _______________________ Date ____________ Time ____________

Setting: Home [ ] Hospital [ ]

Edmonton Symptom Assessment System:
Numerical Scale
Regional Palliative Care Program

Please circle the number that best describes:

<table>
<thead>
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<th>Symptom</th>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
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<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
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<td></td>
<td></td>
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<tr>
<td>Worst possible pain</td>
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<td>Not tired</td>
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<td>Worst possible tiredness</td>
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<tr>
<td>Not nauseated</td>
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<td>Worst possible depression</td>
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<td>Not anxious</td>
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<tr>
<td>Not drowsy</td>
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<tr>
<td>Worst possible drowsiness</td>
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<tr>
<td>Best appetite</td>
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<tr>
<td>Worst possible appetite</td>
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<tr>
<td>Best feeling of wellbeing</td>
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<tr>
<td>Worst possible feeling of wellbeing</td>
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</tr>
<tr>
<td>No shortness of breath</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td>Worst possible shortness of breath</td>
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</tbody>
</table>

used by permission
Appendix M
Ease of Use and Comfort Level for the Patient

Code __________________ Date __________________ - Time __________________

Setting: Home [ ] Hospital [ ]

Semi-structured questions on ease of use and comfort level for the patient

• Could you comment on how easy or difficult the syringe driver has been for you to use?

• Are there things that others do for you related to this modality and if so, what do they do?

• How has using the syringe driver influenced your reliance on others for your pain management?

• Could you comment on how the syringe driver has made a difference or not in your pain management?

• How mobile would you say you were? Has using the syringe driver made a difference to your mobility? If so, please explain.

• Do you have safety concerns with the use of the syringe driver?

• Do you have any additional comments about the ease of use of your administration route?

5-point scales on ease of use and comfort level for the patient

As a patient, how difficult was it to use this way of delivering your medication?

1 2 3 4 5
somewhat somewhat average somewhat very
difficult difficult easy easy

How pleased are you with using the syringe driver to deliver your medication?

1 2 3 4 5
very somewhat neither pleased somewhat very
displeased displeased nor displeased pleased pleased

As a patient, how would you rate your comfort level with this way of delivering medication?

1 2 3 4 5
very somewhat average somewhat very
uncomfortable uncomfortable average comfortable comfortable

How willing are you to continue using your medication administration route?

1 2 3 4 5
very unwilling somewhat neither willing somewhat willing to
to continue unwilling to nor unwilling to willing to continue
Appendix N

Ease of Use and Comfort Level for the Family/Caregiver

Code ____________________ Date ____________________ Time ____________________

Setting: Home [ ] Hospital [ ]

Semi structured questions on ease of use and comfort level for the family/caregiver

• What has it been like for you since the patient has started using the syringe driver?
• What kind of advantages and/or challenges or difficulties have you experienced or noticed with the use of the syringe driver?
• How willing are you, at this point in time, to have the patient continue receiving medication via a syringe driver? Please explain.
• What concerns, if any, do you have about safe administration of the syringe driver?
• Can you describe any changes in the patient’s freedom to move since being on the syringe driver?
• Have you noticed changes in the patient’s behaviour since being on the syringe driver?

5 point scales on ease of use and comfort level for the family/caregiver

How difficult was it to use the syringe driver as a medication administration route?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>somewhat difficult</td>
<td>neither easy nor difficult</td>
<td>average</td>
<td>somewhat easy</td>
<td>very easy</td>
</tr>
</tbody>
</table>

As a family member/caregiver, how pleased are you with the way the patient takes his/her pain medication?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>very displeased</td>
<td>somewhat displeased</td>
<td>neither pleased nor displeased</td>
<td>somewhat pleased</td>
<td>very pleased</td>
</tr>
</tbody>
</table>

As a family member/caregiver, how would you rate your comfort level with the use of the syringe driver to deliver medication?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>very uncomfortable</td>
<td>somewhat uncomfortable</td>
<td>average</td>
<td>somewhat comfortable</td>
<td>very comfortable</td>
</tr>
</tbody>
</table>

How supportive are you for the patient to continue using the syringe driver?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>very unsupportive to continue</td>
<td>somewhat unsupportive to continue</td>
<td>neither supportive nor unsupportive</td>
<td>somewhat supportive to continue</td>
<td>supportive to continue</td>
</tr>
</tbody>
</table>
Appendix O
Breakthrough Pain and Constipation Experience

*Breakthrough pain and constipation experience over a 24 hour period collected daily for 2 weeks*

Subject Code __________________ Date __________________ Time __________________

Setting: Home [ ] Hospital [ ]

- How often within the last 24 hours did you require a breakthrough dose of analgesic for pain management?
- How severe was your pain on each of these occasions over the past 24 hours?

<table>
<thead>
<tr>
<th>No Pain</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Worst possible pain</th>
</tr>
</thead>
</table>

- What was the medication that you received?
- What was the dose?
- How was the breakthrough analgesic administered?
- Are you having any difficulties with constipation over the last 24 hours?