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Colonoscopy and Timing of Sedation

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Colonoscopy and Timing of Sedation

by

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Abstract

Adequate sedation of patients for endoscopic procedures has been associated with increased tolerance and acceptability of the procedures. The study aim is to determine if the timing of sedation in relation to the procedure start time is related to patient comfort scores for adult patients undergoing a screening colonoscopy at the Colon Cancer Screening Center (CCSC).

A review of 176 randomly selected charts from completed procedures was conducted at the CCSC. Nine data points and comfort scores that are routinely collected during admission and colonoscopy procedures were compiled and analyzed to discover any existing relationships. No significant relationship was discovered between the timing of the sedation, procedure length and patient comfort during colonoscopy procedures at the CCSC.

Although no significant relationship was discovered, important baseline data was the result of this study. Further study is needed to understand the factors associated with patient discomfort during colonoscopy procedures.

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I would like to dedicate this work to my family. I feel that this graduate program has truly been a group effort. Without their ongoing support when I was stressed and their encouragement when I succeeded in this program, I never would have continued. Thank you and I love you.

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Epigraph

“The aim of colonoscopy is to achieve a thorough examination of the colon in the safest, most comfortable manner” (Kravochuck, Gao, & Church, 2014, p.1593).

Chapter One: Introduction

Colon cancer is one of the most treatable types of cancer if detected at early stages and may be prevented altogether if pre–cancerous growths (polyps) are removed before they have the opportunity to develop into cancer (Sewitch et al., 2013; Telford, Levy, Sambrook, Zou, & Enns, 2010). Screening colonoscopy procedures are used to diagnose and remove polyps in the colon (Chartier, Arthurs, & Sewitch, 2009; Ekkelenkamp, Dowler, Valori, & Dunckley, 2013; Loftus et al., 2013; McLachlan, Clements, & Austoker, 2012; Riss et al., 2009). The colonoscopy procedure involves inserting a flexible camera into the rectum and advancing the camera approximately three feet to visualize the entire colon. This procedure is invasive and can be uncomfortable both physically and psychologically (Aisenberg & Cohen, 2006; Cohen et al., 2006; Ekkelenkamp et al., 2013; Hawkey, Bosch, Richter, Garcia-Tsao, & Chan, 2012; Kuganeswaran et al., 1999; Liacouras, Mascarenhas, Poon, & Wenner, 1998; Morgan, Roufeil, Kaushik, & Bassett, 1998; Mui et al., 2005; Ng, Kong, & Nyam, 2001; Putinati, Ballerin, Corbetta, Trevisani, & Potenta, 1999; Rex & Khalfan, 2005; Speroni, Hannah, Atherton, & Corriher, 2005; Thomson, Andrew, & Jones, 2010). Although the Canadian Partnership Against Cancer ([CPAC], 2010) had identified that Canadians are more likely to get screened for colorectal cancer as they age, many Canadians are unaware of the screening tests available. Furthermore, CPAC (2010) discovered that some Canadians who were aware of the screening methods available found them to be unacceptable. In the literature, fear of discomfort has been identified as a barrier for screening colonoscopy procedures (Aisenberg & Cohen, 2006; Cohen et al., 2006; Ekkelenkamp et al., 2013; Hawkey et al., 2012; Kuganeswaran et al., 1999; Liacouras, et al., 1998; Morgan et al., 1998; Mui et al., 2005; Ng et al., 2001; Putinati et al.,

1999; Rex & Khalfan, 2005; Speroni et al., 2005; Thomson et al., 2010) and Canadian uptake rates for colorectal screening have been low (CPAC, 2010). Canadian literature about colonoscopy is limited and further study to better understand the barriers and the patient experience may result in more effective Canadian screening programs.

Background

One in every six Albertans will be diagnosed with colon cancer in their lifetime; it is the second leading cause of cancer death for men, and the third cause of cancer death for women (Alberta Cancer Foundation, 2009; Canadian Cancer Society, 2014). Screening colonoscopy procedures are a crucial component in the early detection and successful treatment of colorectal cancers. Individuals may be discouraged from seeking screening for colorectal cancer because of fear and anxiety surrounding the thought of having a rectal examination and the perceived discomfort of having a colonoscopy procedure (Aisenberg & Cohen, 2006; Cohen et al., 2006; Hawkey et al., 2012; Kuganeswaran et al., 1999; Liacouras et al., 1998; Morgan et al., 1998; Mui et al., 2005; Ng et al., 2001; Putinati et al., 1999; Rex & Khalfan, 2005; Speroni et al., 2005; Thomson et al., 2010). To promote patient tolerance and perceived acceptability of the procedure, conscious sedation (in the form of fentanyl citrate and midazolam) is offered to patients in endoscopy centres throughout Alberta Health Services (AHS) prior to screening colonoscopies (AHS, n.d.a). Conscious sedation refers to pharmaceutical agents used to moderate discomfort and to lessen awareness and recall during medical procedures such as colonoscopies. Misinformation concerning the extent of the sedation is frequently observed by nurses despite the fact that patients must attend an information session prior to consenting to undergo a colonoscopy at the Colon Cancer Screening Centre ([CCSC] AHS, n.d.a). For

example, nurses have described that patients often believe they may be asleep for the entire colonoscopy procedure and that they will have no physical sensation (Dittmer, 2014a) despite the information provided in the session explaining that they will be awake and should expect some gas-like cramping and feel the scope at the rectum (AHS, n.d.b). Nurses who have corrected this misinformation at the time of the procedure stated that they felt their patients experienced increased anxiety, longer procedures, and the nurses expressed that they had more difficulty maintaining patient comfort during the procedure (Dittmer, 2014a). The drug monographs for fentanyl citrate and midazolam indicate that the peak effects of the medications are three to five minutes after direct intravenous administration to allow time for the sedative medications to be circulated through the body (McGraw-Hill, 2013). Anecdotally, this recommendation of a time delay is not followed consistently in endoscopic practice, and the timing is left to the discretion of the physician. Currently, no AHS guidelines exist regarding the timing of the sedation in relation to the colonoscopy procedure start time (AHS, n.d.b).

Definitions

- A screening colonoscopy is a preventative examination of the colon with a flexible camera. The intent of this procedure is to find polyps and colorectal cancers at early and treatable stages before symptoms of cancer are present (ACF, 2009; AHS, n.d.a; Leddin et al., 2004).
- Cecal intubation time refers to the time that it takes for the colonoscopy to be completed to the point of the cecum, where the small bowel meets the colon (Hawkey et al., 2012). Anecdotally, this is the most uncomfortable portion of the procedure and it is at the cecum that nurses assess patient comfort scores at the CCSC.

- Patient comfort at the CCSC is assessed using the Nurse Assessed Patient Comfort Score ([NAPCOMS] Rostom et al., 2013) system. This system utilizes three identified domains of pain (frequency, duration, and intensity) to measure discomfort. Optimal comfort using this scale is characterized by fewer than two episodes of mild pain or discomfort with insertion of the colonoscope that last less than 30 seconds each, which equals a comfort score of zero or three (Appendix A).

Problem Statement

If sedation practices for screening colonoscopies remain unchanged, some patients may have procedures that are more uncomfortable than necessary. This discomfort may potentially result in ongoing frustration for the nurses as they are typically charged with attending to patient comfort at the CCSC and patients' unmet expectations. The effectiveness of screening programs can also be compromised if patient comfort is not addressed (Aisenberg & Cohen, 2006; Valori, Nicolaas, & de Jonge, 2010; Wolosin, 2003). Patients who have negative colonoscopy experiences are less likely to continue with preventative health activities such as recommended screening schedules and treatment, and are also less likely to encourage screening procedures for family and friends (Aisenberg & Cohen, 2006; Sakraida, 2010; Valori et al, 2010; Wolosin, 2003).

Significance

Colon cancer is one of the most preventable forms of cancer (Sewitch et al., 2013; Telford et al., 2010). Colonoscopy is considered the optimal form of screening for colorectal cancers because the entire colon is visualized and if polyps, the precursors to cancers, are detected during the procedure, they can be removed immediately, effectively diminishing the

subsequent development of colorectal cancers (Chartier et al., 2009; Ekkelenkamp et al., 2013; Loftus et al., 2013; McLachlan et al., 2012; Riss et al., 2009). In addition, cancers that are diagnosed and treated in a timely manner are related to improved survival rates as opposed to those cancers not found until patients are symptomatic (Chartier et al., 2009; Telford et al., 2010). The incidence of colorectal cancer can be decreased as much as 81% when screening colonoscopies are performed every ten years (Telford et al., 2010).

Although many patients tolerate screening colonoscopy procedures well (Chartier et al., 2009; Eckardt et al, 2008; Loftus et al., 2013; Speroni et al., 2005), some may experience discomfort because the sedation has not been allowed to circulate through the body and take effect. The discomfort experienced may dissuade patients from following screening and treatment recommendations, and/or encouraging family and friends to get screened, and therefore negatively impact the effectiveness of screening programs (Sewitch et al., 2013; Valori et al., 2010). There is a lack of Canadian guidelines addressing sedation of patients and consequently the patient experience is dependent on local policies and procedures (Loftus et al., 2013). However, given the increasing emphasis on providing patient centered care, attending to satisfaction and comfort are important considerations (Loftus et al., 2013).

The AHS procedural sedation policy currently does not address waiting for the sedation to take effect; it primarily focuses on choosing the appropriate depth of sedation (minimal to deep), and the required monitoring (AHS, n.d.b). At the CCSC, there is pressure to perform screening colonoscopies quickly and efficiently; up to 96 procedures per day are performed in the centre's six endoscopy suites. Typically, physicians work half days (morning or afternoon) and in their allotted time each physician performs eight procedures along with one procedure nurse; one procedure scheduled every half an hour. In this half hour time spot there are numerous

tasks that must be performed accurately and quickly in order to keep the pace and flow of patients through the centre.

The patient experience may be overlooked when screening colonoscopies are initiated before the patient is adequately sedated. Uptake rates for colorectal cancer (CRC) screening procedures are low in Canada, with only 32% of eligible Canadians undergoing colorectal screening measures of any kind in 2008, and only a small proportion choosing colonoscopy (CPAC, 2010). Because colorectal cancers are largely preventable if discovered early (Sewitch et al., 2013; Telford et al., 2010), it is important to encourage more people to have voluntary screening.

Colonoscopy procedures are invasive (Kravochuck et al., 2014; Ylinen, Vehvilainen-Julkunen, & Pietila, 2007). The thought of having a rectal examination (Hawkey et al., 2012) and the preparation necessary to complete the test (i.e., fasting, and powerful laxatives to remove stool from the colon) can be prohibitive enough, without adding the potential pain and discomfort that may be experienced during the test (Chartier et al., 2009; Ekkelenkamp et al., 2013; Sewitch et al., 2013). Indeed, a negative experience in one area of health care can negatively impact the way in which patients access health care in the future (Baudet & Aguirre-Jaime, 2012), and health care providers should strive to provide positive patient experiences to encourage ongoing health promoting behaviours (Sakraida, 2010). A positive patient experience helps to ensure the best use of finite resources (Rasool et al., 2010).

In February of 2016, Health Canada issued new guidelines for colon cancer screening. The new recommendations suggest that adults at low risk for colon cancer undergo screening for colorectal cancer with fecal immunochemical tests (FIT) every two years, or with a flexible sigmoidoscopy every 10 years starting at age 60 (Canadian Task Force on Preventative Health

Care [CTFOPHC], 2016). The FIT test is designed to detect blood within the colon, not necessarily polyps. The Colorectal Cancer Association of Canada ([CCAC] n.d.) reported that the accuracy of this test was only 65% (as opposed to 95% detection rate with colonoscopy). While it is true that the stool tests are much more cost efficient and less invasive than screening colonoscopies (Telford et al., 2010) stool tests are largely used to detect cancers as opposed to preventing them (CCAC, n.d.). This recommendation is because the limited resources available in our health care institutions cannot handle the burden of the provision of screening for all (Telford et al., 2010). The FIT test may seem like a reasonable alternative when CPAC (2010) reported that the screening rates were low (approximately 32% for asymptomatic adults). It is important to note that these recommendations have not yet been implemented in Alberta and do not apply to those who are at higher risk for developing CRC. If a person has a positive FIT test they will still need to undergo a colonoscopy to find the source of bleeding in the colon (CTFOPHC, 2016). The motivation for patients to endure the invasive colonoscopy procedure may be different if they are at higher risk for cancer or have had a positive FIT test. The need to assuage their anxiety would still exist and may be even more important if colonoscopies are not used for primary screening but for known cancer detection. It is the role of the advanced practice nurse (APN) to consider and critique such new evidence to inform practice as part of the competency of nursing judgement (University of Calgary [UC], n.d.a).

In this study, it was hypothesized that any time taken to wait for the sedation to take effect would result in more comfortable patients as evidenced by better (lower) patient comfort scores. The research question for this study was: Does the timing of sedation administration in relation to procedure start time affect the patient comfort scores for adult patients undergoing a screening colonoscopy procedure at the CCSC?

Faculty of Nursing Core Competencies

The successful completion of a graduate program may be demonstrated in the completion of research that accounts for outlined goals. The Faculty of Nursing (FON) at the University of Calgary has developed a curricular framework (Appendix B) with five nursing practice program outcomes that the Master of Nursing student is expected to meet upon completion of his/her program (UC, n.d.b.). The FON stated:

> Graduates should be prepared to: 1) promote and enhance *human flourishing* for patients, families, communities, and themselves; 2) show sound *nursing judgment*; 3) continually develop their professional identity; 4) maintain a *spirit of inquiry*; and 5) develop *leadership and innovation* as they move into the world of nursing practice and beyond," (UC, n.d.b, p.1)

The FON (UC, n.d.a) has described these outcomes as "discrete and measurable skills that are essential for advanced practice" (p.1). The accomplishment of these outcomes is a result of the integrated learning that has occurred throughout the Nursing Graduate program. The way the outcomes were met will be interwoven throughout this thesis. For example, the critical examination of current health care systems and practices to identify gaps and changes that may promote the wellness of individuals and communities is evidence that the core competencies of *Human Flourishing* and *Nursing Judgement* have been addressed (UC, n.d.a).

Research Topic

The topic for this project was raised through personal practice and experientially, a greater ability to promote and advocate for patients' comfort during endoscopic procedures was

gained with practice. The research question emerged as a "researchable" aspect of quality of care and was explored through the required course work of the Master of Nursing program at the University of Calgary. The core competencies of *Professional Identity* and the *Spirit of Inquiry* were achieved through the development of a research question and study protocol aimed at providing evidence to inform practice (UC, n.d.a). Through personal inquiry and a combination of scholarly review and current nursing practice, an aspect of quality of care that could be studied at the graduate level was determined. Donabedian (1990) described several domains that encompass quality care and included in these domains was the patient experience and acceptability of the health service. This project aims to provide evidence to improve not only the patient experience but also to address the perceived acceptability of this procedure. In addressing these domains, the health care provider may be able to positively influence individuals' health promoting behaviours (Sakraida, 2010).

The Health Promotion Model

The health promotion model proposed by Pender (Sakraida, 2010) has provided a relevant theoretical framework for this research project. "Health promoting behaviours should result in improved health, enhanced functional ability, and better quality of life at all stages of development" (Sakraida, 2010, p. 435). A central tenet of this model is that people are unique and the ways in which they perceive the world influences their choices and actions which in turn may affect their long-term wellbeing. Health promoting behaviours are the desired outcome of this model, and to achieve them, health professionals may exert influence over a person's decision making. Also, real and perceived barriers may influence a person's commitment to undertaking health promoting behaviours. In relation to this study, screening colonoscopies are

preventative measures to promote long-term wellbeing (Chartier et al., 2009). The refusal of screening measures due to fear, embarrassment, and anxiety can have significant negative health outcomes (Chartier et al., 2009; Hawkey et al., 2012). Therefore, encouraging people to be screened for colon cancer by enhancing the patient experience is encouraging them to be involved in health promoting behaviours (Dittmer, 2014a). The ability of health care providers to assure patients that their comfort will be attended to is important to address barriers (e.g., fear) and may provide a positive influence on their decision-making.

Quality in Health Care

Donabedian (1990) outlined seven characteristics that he attributed to quality in health care: efficacy; effectiveness; efficiency; optimality; acceptability; legitimacy; and equity. Acceptability, or the degree to which the colonoscopy procedure meets patient preferences, and legitimacy, the degree to which the procedure meets societal expectations, were the most relevant characteristics to this study. The thought of this invasive procedure (colonoscopy) can be anxiety provoking (Aisenberg & Cohen, 2006; Cohen et al., 2006; Hawkey et al., 2012; Kuganeswaran et al., 1999; Liacouras et al., 1998; Morgan et al., 1998; Mui et al., 2005; Ng et al., 2001; Putinati et al., 1999; Rex & Khalfan, 2005; Speroni et al., 2005; Thomson et al., 2010), and the perception of acceptability was related to effectiveness of screening programs (Aisenberg & Cohen, 2006; Valori et al., 2010; Wolosin, 2003). While Donabedian's (1990) work was mainly directed at physicians as decision makers, it is possible that his work can be expanded to the health care team. Donabedian (1990) identified that it can be a challenge to balance patient preferences, social context or acceptability, and the identified attributes, and this work was influential to the development of this project. Through the examination of the relationship

between comfort scores and the timing of sedation was the hope that the evidence would be used to change practice to improve the tolerance or acceptability of the screening colonoscopy procedure without drastic changes to the way the procedures are currently offered.

Summary

Screening colonoscopy procedures are an important component of early cancer detection. While considered the gold standard of screening procedures (Chartier et al., 2009; Loftus et al., 2013; McLachlan et al., 2012; Riss et al., 2009), colonoscopies can be perceived as intolerable because of the anxiety they provoke and the discomfort that is experienced (Aisenberg & Cohen, 2006; Cohen et al., 2006; Hawkey et al., 2012; Kuganeswaran et al., 1999; Liacouras et al., 1998; Morgan et al., 1998; Mui et al., 2005; Ng et al., 2001; Putinati et al., 1999; Rex & Khalfan, 2005; Speroni et al., 2005; Thomson et al., 2010). The timing of sedation in relation to comfort may prove to be useful information when attending to the comfort of patients undergoing colonoscopy procedures. Research about this aspect of the procedure may provide useful information to promote tolerance and acceptability of this invasive procedure. If comfort could be better assured during screening procedures, the uptake rates of screening programs may be increased and the number of people who develop and/or die from preventable cancers may be reduced (Sewitch et al., 2013; Telford et al., 2010).

Chapter Two: Literature Review

An initial search via the Google Scholar database was used primarily to determine relevant search terms to be entered into other databases; pertinent terms were also selected from the reference lists of articles read for other courses that pertained to this topic. Once commonly used terms were identified, more in depth searches in the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Excerpta Medica Database (EMBASE), the Medical Literature Analysis and Retrieval System Online (MEDLINE), and the Cochrane Database of Systematic Reviews (CDSR) were conducted. This search strategy was developed in consultation with the Faculty of Nursing librarian at the University of Calgary. The Medical Subheadings (MeSH terms) used in this search were *adult, anxiety, colonoscopy, comfort, conscious, conscious sedation, endoscopy, hypnotics, sedatives, midazolam, patient, patient comfort, patient satisfaction, pre–anesthetic medication, premedication,* and *satisfaction*. The search terms were combined with "or" and "and" to limit the findings to relevant research. The strategy of backwards tracking by looking through reference lists of studies was also used to identify pertinent studies. Fourteen articles were retrieved from CINAHL, 53 from EMBASE, 47 from MEDLINE, and 8 from the CDSR, totaling 122 articles. After duplicates were removed 64 studies remained (Appendix C).

The time span was not limited for the searches as the approved use of conscious sedation was introduced in the 1980s (Cohen et al., 2006), nor was the search limited to the discipline of nursing. The filter of peer–reviewed journals published in the English language was added. After reviewing abstracts, 26 records were excluded, as they did not pertain to colonoscopy procedures and midazolam sedation. Thirty–eight records were selected for this review and included 16 randomized controlled trials, two literature reviews, one large sample national

survey, seven surveys and 12 observational studies.

Themes

After reading through the selected articles for this review, several themes became apparent: nature of the procedure; anxiety and discomfort; tolerance and satisfaction; context sedation costs; and risks. Tables of the included studies were developed and can be found in Appendix D.

Nature of the procedure. Colonoscopy, by nature, is an uncomfortable procedure (Baudet & Aguirre-Jaime, 2012; Dere et al., 2010; Hutson, 2009; Kravochuck et al., 2014; Ristikankare, Hartikainen, Heikkinen, Janatuinen, & Julkunen, 1999). Dere et al. (2010) described the procedure as distressful, and Ylinen, et al. (2007) called the procedure "intimate, unpleasant, and painful" (p.1126). Universally, authors outlined colonoscopy procedures as uncomfortable but the reasons for the discomfort were implied. In only two articles were the specific reasons for physical discomfort during colonoscopy detailed. Insertion of the colonoscope can cause stretching of the mesentery surrounding the colon and may result in pain (Wood, et al., 2012), and opening the lumen of the colon with air to both visualize the colon and insert the instrument, elongated the colon with air, can increase the difficulty of the procedure and discomfort for the patient (Hsieh, Koo, & Leung, 2014).

Other reasons for discomfort during colonoscopy procedures were discussed throughout the literature. Gender was found to be a consideration as women have more tortuous sigmoid colons, which made the colonoscopy procedure technically more difficult (Ma, Mahadeva, Quek, & Goh, 2007; Macken, Gevers, Hendrickx, & Rutgeerts, 1998; Morrow et al., 2000; Speroni et al., 2005; Subramanian, Liangpunsakul, & Rex, 2005; Takahashi, Tanaka, Kinjo, & Sakumoto,

2005). Prior abdominal surgery was discussed as problematic as scarring created from the healing process in the abdomen may prevent the advancement of the colonoscope (Takahashi et al., 2005). Ma et al. (2007) found that prolonged procedures contributed to discomfort, and Schutz, Lee, Schmitt, Almon, and Bailie (1994) discovered that longer procedures were associated with reported dissatisfaction with the conscious sedation given. Sedation is often administered to improve the comfort of patients during screening colonoscopies and to enhance the acceptability of this invasive procedure (Bal et al., 2012; Baudet & Aguirre-Jaime, 2012; Crepeau et al., 2005; Dere et al., 2010; Macken et al., 1998; Morao, Ratilal, Santos, & Sampaio, 2011; Morrow et al., 2000; Petrini, Egan, & Hahn, 2009; Speroni et al., 2005; Subramanian et al., 2005; Takahashi et al., 2005). Pain management is an important aspect in the successful completion of colonoscopy procedures, and can greatly influence patients' perceptions and acceptability of the procedure (Sewitch et al., 2013).

Anxiety and discomfort, tolerance and satisfaction. In addition to physical discomfort, patients admitted having psychological distress while undergoing colonoscopy procedures (Baudet & Aguirre-Jaime, 2012; Speroni et al., 2005; Ylinen et al., 2007). This psychological distress was largely described as anxiety in the literature. Anxiety and fear regarding anticipated discomfort can keep people from getting screened or following treatment and screening recommendations (Bal et al., 2012; Baudet & Aguirre-Jaime, 2012; Chartier et al., 2009; McLaughlan et al., 2012; Sewitch et al., 2013; Schutz et al., 1994; Telford et al., 2010). Anxiety was often cited as a reason why colonoscopy procedures were poorly tolerated, and why sedation was needed (Bal et al., 2012; Baudet & Aguirre-Jaime, 2012; Crepeau et al., 2005; Dere et al., 2010; Elphick, Donnelly, Smith, & Riley, 2009; Macken et al., 1998; Morao et al., 2011; Morrow et al., 2000; Petrini et al., 2009; Speroni et al., 2005; Subramanian et al., 2005;

Takahashi et al., 2005). Elphick et al. (2009) found patient anxiety to be statistically significant ($p<0.01$) in relation to how well the procedure was tolerated (i.e., lower anxiety related to better tolerance). Bal et al. (2012) determined that that the use of sedation reduced procedure related anxiety and pain for patients, while Morao et al. (2011) described that midazolam was useful for unpleasant procedures such as colonoscopy because of its anxiolytic nature and amnesic effect that resulted in more relaxed and tolerant patients.

In their large study of 2016 patients, Baudet and Aguirre-Jaime (2012) found administering sedation was associated with tolerance and satisfaction with colonoscopy procedures. Fear of discomfort during the procedure was shown to be statistically significant ($p<0.01$) as the most commonly reported barrier to having a colonoscopy procedure. The ability to deliver high quality care during endoscopic procedures to alleviate distress, assure comfort, and promote adherence to ongoing care recommendations was identified as important (Rasool et al., 2010). Satisfaction with colonoscopy procedures and willingness to return for subsequent care under similar circumstances was related to the provision of adequate sedation ($p<0.001$ [Loftus et al., 2013]). In this study, it was also noted that the focus on the patient experience during endoscopic procedures led to improved practice. Of the 529 survey respondents, 56% of patients were willing to undergo a repeat procedure under similar circumstances if the pain they experienced during their initial screening procedure was rated as low. In their large sample study ($n=17,027$) Ekkelenkamp et al. (2013) found that sedation was helpful in the tolerance of colonoscopy procedures. However, it was also discovered that higher doses of sedation were not correlated with overall success of the procedure or patient comfort. It was concluded that patient comfort was considered an important indicator of procedure quality.

In their prospective study of 100 patients, Speroni et al. (2005) discovered that 41% of

patients complained of moderate to severe pain during their colonoscopy procedure, and more than 65% admitted anxiety pre-procedure. Furthermore, 50% of patients surveyed rated their pre-procedure anxiety as moderate to severe, but because of the moderate sedation given during the procedure, their pain recall was minimal post procedure. Overall, none of the patients surveyed reported being dissatisfied with their procedure on a four-point visual analog scale, and 87% of patients reported being satisfied with their colonoscopy experience.

Elphick et al. (2009) identified statistically significant ($p<0.01$) inconsistencies in how patients rated pain during colonoscopy procedures. Patients in this study rated their pain lower at regular intervals during procedures and higher at the end of procedures when an overall score was given. Although the scores during and after the procedure were in conflict, the overall impression of the procedure did not change when patients were surveyed two to three months post procedure. The patients' overall perspective of the colonoscopy procedure was important as it was this impression the researchers believed would encourage or deter patients from continuing with treatment recommendations.

In addition to sedation, patient satisfaction with colonoscopy may be related to pre-existing patient factors (e.g., anxiety), organizational factors (e.g., procedure wait times), and physician characteristics (e.g., experience, bedside manner [Eckardt et al., 2008]). Thomson et al., (2010) also described that patient satisfaction may be related to the depth of sedation. This finding may be contextual in nature as Eckardt et al. (2008) maintained that most patients were satisfied with their procedures despite reporting experiencing some episodes of discomfort during their procedure; this was substantiated by Ekkelenkamp et al.'s (2013) finding that higher doses of sedation did not correlate to increased comfort levels.

Context. Context is defined as the set of circumstances that establish the background and form the setting under which an event occurs, while providing the terms under which the event can be understood (Merriam-Webster, n.d.). It is important to consider the local context and other associated factors such as politics, budgets, and patient expectations regarding how sedation is, or is not, offered to patients (Chartier et al., 2009; Crepeau et al., 2005; Eckardt et al., 2008; Ekkelenkamp et al., 2013; Subramanian et al., 2005; Takahashi et al., 2005; Thomson et al., 2010; Triantafillidis, Merikas, Nikolakis, & Papalois, 2013; Ylinen et al., 2007). Patient expectations, prior personal experiences, and experiences of family and friends were influential on the reported satisfaction with colonoscopy procedures (Paspatis et al., 2011). Sedation practices vary worldwide and have led to inconsistent accounts of patient experiences (Chartier et al., 2009; Ekkelenkamp et al., 2013).

Some patients may tolerate colonoscopy procedures with no sedation, however the procedure can be distressing, and conscious sedation is frequently administered to address this (Bal et al., 2012; Baudet et al., 2012; Dere et al., 2010; Hutson, 2009; Kravochuck et al., 2014; Macken et al., 1998; Morrow et al., 2000; Speroni et al., 2005; Subramanian et al., 2005; Thomson et al., 2010). In the United States, Subramanian et al. (2005) wrote that patients placed high value on being completely sedated and pain free during colonoscopy procedures. Similarly, in France, over 90% of colonoscopies are conducted under general anaesthesia as patients expect to have no sensation or recollection of their procedures (Crepeau, 2005). Conversely, in Japan and Finland, sedation was not routinely needed or expected by patients (Ekkelenkamp et al., 2013; Ristikankare et al., 1999; Takahashi et al., 2005). Thomson et al. (2010) recommended that colonoscopy procedures without sedation should not be routine practice in Australia, but should be performed based on patient preference, and only when the patient is made fully aware

of what to expect during the procedure. Context was an important consideration to the acceptability of the procedure and how sedation was offered, and was also used to explain why comparisons of patient experience can be difficult (Ekkelenkamp et al., 2013).

Sedation. In the body of literature related to colonoscopies, "standard" sedation commonly includes the use of the anxiolytic agent midazolam, and the short acting opioid agent fentanyl (Baudet & Aguirre-Jaime, 2012; Dere et al., 2010; Dong, Kalmaz, & Savides, 2011; Cohen et al., 2006; Crepeau et al., 2005; Ekkelenkamp et al., 2013; Hutson, 2009; Petrini et al., 2009; Porostocky Chiba, Colacino, Sadowski, & Singh, 2011; Speroni et al, 2005; Thomson et al., 2010; Triantafillidis et al., 2013). The standard level of sedation is called moderate sedation, and promotes amnesia of the procedure (Loftus et al., 2013; Morao et al., 2011) and pain control (Bal et al., 2012). The reported doses of sedation given to achieve this level are variable, but with moderate sedation the patient can maintain his or her own airway, and remain responsive and open to suggestions (Crepeau et al., 2005). Monitoring of heart rate, respiration rate and pulse oxygen is necessary, and it is within the nursing scope of practice to administer this combination of drugs (Hutson, 2009; Loftus et al., 2013; Porostocky et al., 2011; Thomson et al., 2010; Triantafillidis et al., 2013).

In Cohen et al.'s (2006) national survey of sedation practices in the United States, 75% of gastroenterologists (n=1343) reported routinely using a combination of midazolam and fentanyl during endoscopic procedures with satisfactory levels of sedation achieved for their patients. In Porostocky et al.'s (2011) survey of Canadian gastroenterologists and surgeons, it was discovered that sedation was used in over 90% of procedures, and the most common combination of sedation administered was midazolam and fentanyl. In addition to Canada and the Unites States, this "standard" type of sedation was used in many other countries (e.g.,

Australia, Austria, Belgium, Croatia, Finland, Ireland, Kuala Lumpur, Spain, Germany, Greece, Pakistan, Portugal, Taiwan, Turkey, and the United Kingdom). Despite the common use of this type of sedation, there is no of consensus on how to measure comfort during procedures (Elphick et al., 2009; Triantafillidis et al., 2013), and specific guidelines or protocols for use of this type of sedation were absent in the literature. Of the 38 studies reviewed, none included the time between sedation administration and the start of the procedure. The drug monographs for both fentanyl and midazolam state that the onset of the medication is three to five minutes after administration (McGraw-Hill, 2013). Arguably, if sedative medication is not allowed to circulate through the body and take effect before colonoscopy procedures are commenced, the patient will likely not have received the entire benefit of the sedation, and may experience discomfort leading to dissatisfaction with the colonoscopy procedure.

When American physicians were asked what sedation they would prefer for their own procedure, 47.8% of survey respondents indicated a preference for propofol (deep sedation) over the moderate sedative effects of midazolam and fentanyl, which they routinely used for their patients (Cohen et al., 2006). This finding was interesting as Schutz et al. (1994) wrote that educated persons (those with a minimum of one year of post-secondary education) were more likely to be dissatisfied with conscious sedation, and they further speculated that this finding may be related to the educated patient's need for control. Canadian physicians responded differently than American physicians as one third of respondents indicated a willingness to try the procedure with no sedation, and only one third of respondents reported they would like propofol for their own procedures (Porostocky et al., 2011). This lower preference for propofol may be attributed to the fact that propofol is not routinely used or endorsed for adult screening colonoscopies in Canada related to the increased costs and risks associated with its use (Romagnuolo et al., 2008).

Several authors discussed the use of alternate sedatives and levels of sedation because satisfaction with the standard sedation was rated as poor amongst some patients and physicians (Cohen et al., 2006; Gasparovic, Rustemovic, Opacic, Bates, & Petrovecki, 2003; Maslekar, Gardiner, Hughes, Culbert, & Duthie, 2009; Thomson et al., 2010; Triantafillidis et al., 2013). Creating meaningful comparisons between various sedatives and patient experiences has been difficult (Ekkelenkamp et al., 2013). Context, patient expectations, and not following the drug monographs may account for some of this reported dissatisfaction.

Costs and risks. Colonoscopy was found to be a cost-effective screening measure for colorectal cancers, and the cost of performing a screening colonoscopy every ten years (for average risk individuals) outweighed the health care costs associated with no screening at all (Telford et al., 2010). However, the administration of sedation of any kind increased both the costs and risks of the procedure (Cohen et al., 2006; Ekkelenkamp et al., 2013; Hutson, 2009; Loftus et al., 2013; Porostocky et al., 2011; Thomson et al., 2010; Triantafillidis et al., 2013). Costs associated with administration of the sedation included staff training, monitoring of the patient during the procedure, monitoring of the patient during the recovery period, adequate space, and equipment. Deep sedation was cited as more expensive to administer than moderate sedation due to the necessity of an anaesthetist to administer the sedatives, and the patient incurred greater risks (Porostocky, et al., 2011; Thomson et al., 2010; Triantafillidis et al., 2013).

From an economic standpoint, the administration of moderate sedation by nurses has been associated with efficient utilization of limited resources. In countries where nurses administered the sedation, procedural costs associated with sedation administration were reduced as compared to procedures where an additional physician administered the sedation (Porostocky et al., 2013; Thomson et al., 2010; Triantafillidis et al., 2013). Additionally, the provision of

sedation assisted with the overall success of the procedure (e.g., detecting polyps and completing the procedure to cecum) (Paspatis et al., 2010; Porostocky et al., 2013). Researchers often cited cost as an issue (physician costs, staffing, and nurses) but no specific cost figures were mentioned in the selected literature (Porostocky et al., 2013; Thomson et al., 2010; Triantafillidis et al., 2013). Canadian costs associated with colonoscopy were difficult to find, with most information out of date (older than five years) and from one province only (Ontario) (Sharara, Adam, Crott, & Barkun, 2008).

Secondary costs were also associated with the administration of sedation. The inability to drive, lost time off work, and the fact that additional family members also took time off to care for sedated patients were cited as reasons for the secondary costs (Dere et al., 2010; Dong et al., 2011; McLaughlan et al., 2012; Paspatis et al., 2011; Petrini et al., 2009; Ristikankare et al., 1999; Takahashi et al., 2005). In their retrospective survey of 68 patients, Dong et al. (2011) determined that 34% of respondents took more than the procedure day off work, and 46% of respondents also had a family member who took time off work to drive the patient home. The indirect financial repercussions of sedation use are not routinely considered or captured in the costs of colonoscopy procedures or in the patient experience, and the inconvenience of secondary costs has been identified as a barrier to patients getting screened for colorectal cancer (Dong et al., 2011; Eckardt et al., 2008; McLaughlan et al., 2012).

Lastly, negative colonoscopy experiences were found to be transferable to other areas of health care. Patients who had a negative experience during their colonoscopy were less likely to access health care of any kind, and more likely to attribute bad experiences to the health care system (Baudet & Aguirre-Jaime, 2012; Rasool et al., 2010). Dissatisfied patients were reported to be less likely to be compliant with medical recommendations, and more likely to seek multiple

medical opinions (Baudet & Aguirre-Jaime, 2012; Schutz et al., 1994; Valori et al., 2010). Developing a trusting relationship with patients by ensuring a positive colonoscopy experience may have system wide impacts, not only for the patient in question but also for everyone with whom they share their experiences.

Gaps

The narrative critique of this body of knowledge and the subsequent identification of gaps may be considered as the achievement of the core competencies identified in the FON graduate curriculum framework, of the *Spirit of Inquiry* and *Nursing Judgment* (UC, n.d.a). Colonoscopy related studies conducted from the nursing perspective were scarce in the literature. The FON (UC, n.d.a) stated that contributing to the nursing knowledge base and providing evidence on which to base practice constitutes advanced practice. Wood et al. (2012) discussed how nurses are ideally positioned to assess the patient's comfort during colonoscopy procedures. Nursing care can have a significant impact on the patient experience during colonoscopy (Loftus et al, 2013; Sewitch et al., 2013; Ylinen et al., 2007). Nurses conducted only three studies in this review (Hutson, 2009; Speroni et al., 2005; Ylinen et al., 2007). More evidence from the nursing perspective may enhance the patient experience. Nurses, as health care providers may have influence over the way people make health care decisions, and providing evidence from a nursing perspective may subsequently encourage people to be screened and to continue with screening recommendations (Sakraida, 2010).

Several other gaps were identified through the review of the selected literature, most notably related to when to give sedation in relation to the procedure start time. Evidence regarding waiting for sedation to take effect prior to initiating a colonoscopy is absent in the

literature and may provide useful information regarding the use of conscious sedation. Transferable baseline data on which to substantiate the need for different medications and /or colonoscopy procedure interventions and techniques was absent. Data that specified the percentage of people that would benefit from any change implemented was also deficient. The provision of current and more comprehensive information regarding the costs of colonoscopy procedures would make a cost analysis and comparison easier. There was a lack of information regarding the standards of care for individual endoscopic centers, and if certain drug monographs or sedation policies were followed. Anecdotally, it has been observed that when time is allowed for the medication to take effect, patients are more relaxed at the initiation of the procedure. When patients are comfortable from the start, they may be better able to maintain that level of comfort throughout the entire procedure, consistent with Morgan et al.'s (1998) finding of higher levels of pre-colonoscopy stress being associated with reduced tolerance of the procedure. There was a lack of agreement on the method of assessing patient comfort, as some studies performed a pre-post-test evaluation, and others used comfort–scoring tools. This difference in style may be due to the variance in contextual importance of comfort amongst countries and endoscopic practices.

Lastly, missing from this body of evidence were data from the patients' perspective, especially from a qualitative approach that could elicit depth of information versus pre-determined, limited questionnaires where answers are restricted. Colonoscopy screening programs have been implemented in over 50 countries worldwide (Ekkelenkamp et al., 2013; McLaughlan et al., 2012), however Canadian literature regarding colonoscopy and sedation is limited (Porostocky et al., 2011). More data from a Canadian perspective could provide direction for the use of sedation to enhance the patient experience. As patient expectations and

values are contextual in nature (Paspatis et al., 2011), not all data from other countries is generalizable to Canadian settings.

Summary

"The aim of colonoscopy is to achieve a thorough examination of the colon in the safest, most comfortable manner" (Kravochuck et al., 2014, p.1593). The successful completion and tolerance of colonoscopy procedures was based on many factors including context and sedation. Ensuring a reasonable colonoscopy experience was linked to the success of screening programs (Bal et al., 2012; Baudet & Aguirre-Jaime, 2012; Ekkelenkamp et al., 2013; Maslekar et al., 2009; Paspatis et al., 2011; Schutz et al., 1994; Shaikh et al., 2010; Valori et al., 2010). There were several gaps in the literature such as the lack of transferable baseline data on which to substantiate the need for different approaches to patient comfort, cost figures, standard comfort assessment tools, context, and patient expectations. These gaps may result in an insufficient depth of understanding of this clinical practice and the inability to make meaningful comparisons of sedation practices and patient comfort.

Chapter Three: Method

Using statistical analysis, the research question was answered using information that was routinely collected at the CCSC, and analyzed in a way that corresponded to the question. It has often been said throughout this graduate program that the research question drives the method. In this study, the relationships between seven data points and the outcome variable (patient comfort) were examined. A benefit of quantitative research is that with a large enough sample, the research findings may be seen to be representative of the population and findings may be generalizable (Polit & Lake, 2010).

Research Question

Does the timing of sedation administration in relation to procedure start time affect the patient comfort score for adult patients undergoing a screening colonoscopy procedure at the CCSC? In this study, it was hypothesized that the timing of sedation is correlated to the comfort scores for patient undergoing screening colonoscopies at the CCSC.

Design

For this study, a retrospective cohort using a chart review was used. Widely used in health care investigations, the retrospective chart review is an unobtrusive research practice that can be used to gather evidence (Bonnel & Smith, 2013; Matt & Matthew, 2013). When compiled and analyzed, routinely collected data may reveal important information about patient experiences and areas for improvement at the CCSC.

Site selection. The setting for this study was the Forzani and MacPhail Colon Cancer Screening Centre (CCSC). This centre is unique in that it is the only publicly supported Canadian

facility with a dedicated focus on colon cancer screening (AHS, n.d.a). Approximately 20,000 procedures per year are performed on individuals considered to be at low risk for complications while undergoing a screening colonoscopy under conscious sedation. The CCSC operates within AHS and is considered a non–hospital facility located on the campus of the Foothills Hospital in Calgary, Alberta.

Recruitment. As this study was a chart review, traditional recruitment of participants was not necessary. The *Conjoint Health Research Ethics Board (*REB15-2117*)* granted a waiver of consent and as such it was possible to obtain necessary information for this study without the need to individually approach patients and obtain their consent. Per the *Health Information Act* (Province of Alberta, 2014) section 50(1), a waiver may be granted when obtaining consent is considered "unreasonable, impractical or not feasible" (p.37). Obtaining consent to access the outlined personal health information necessary for this study was deemed unreasonable because if participants believed they may not be adequately sedated for this procedure, they may have experienced increased anxiety and apprehension undergoing the procedure. In addition, 176 participants were needed for this study, and given that this was an unfunded graduate level research project, it was not feasible for one researcher to be able to recruit this many participants. Finally, including the consent in the chart (where consents are normally kept at CCSC) for this study may have alerted personnel involved in performing the procedures, and they may have altered the way they administered sedation, knowing that the patient's chart would be reviewed after the procedure. Any changes from the routine administration of sedation may have skewed the data collected thus accurate correlations would not have been assured. *In addition,* an agreement with the custodian of the charts (through AHS) was signed to gain access to the necessary charts (Appendix E). A custodian that discloses health information must ensure that

proper ethics board approval has been obtained and the researcher must make an agreement in which he/she agrees to comply with the rules and regulations outlined in the *Health Information Act* (Province of Alberta, 2014). In this agreement, the data collection strategy that was initially proposed was carefully followed, and the custodian was informed in writing of both the beginning and the end of the data collection period.

Population. At the CCSC, thousands of colonoscopies are performed every year and the eligibility criteria for the centre (e.g., asymptomatic for gastrointestinal disease, adult between the ages of 18-74 with no underlying medical conditions that might increase the risk of sedation), ensures a relatively homogenous population from which a sample could be drawn and data extracted (AHS, n.d.a). In this retrospective chart review, a random sample of charts for patients who had undergone screening colonoscopy at the CCSC were included. Exclusion criteria consisted of charts from incomplete colonoscopy procedures, missing data elements, and patients with prior colectomy surgeries (their colons have been partially removed and thus their procedures shorter than those patients without surgery). Patient charts where masses (growths larger than polyps) were identified during procedures were also excluded as the procedure is drastically changed with such findings (e.g., multiple other tasks such as biopsies and tattooing to identify the site are carried out and may affect the study parameters). Lastly, the charts of patients who chose to have colonoscopies without sedation were excluded as it is the timing of sedation that was studied in this chart review.

Data collection. Pre-screening documentation at the CCSC was found in paper format and data elements such as body mass index (BMI), prior surgery, and prior sedative use were collected from the pre-screening documents. Procedural documentation was done in an electronic format and the procedure notes are printed by the nurses and included in the patient chart prior to

their discharge after their colonoscopy procedure. This data was routinely collected and required no extra effort or instruction from the researcher or any of the staff at the CCSC. A data collection tool was developed to collect data for this study with the input of key stakeholders (Appendix F). The data elements selected for this study were chosen not only to answer the research question but also to examine the validity of various assumptions in practice at the CCSC. Data elements used in this study, along with the reason for inclusion are listed below:

- Sedation administration time: The difference between sedation administration time and procedure start time was of primary interest in this study, along with the subsequent effect on the nurse–assessed comfort score to answer the research question;
- Age: At the CCSC, older patients are often thought to tolerate the procedure better and experience less discomfort. To be considered eligible for a colonoscopy at the CCSC, patients must be between the ages of 18-74 (AHS, n.d.a);
- Body Mass Index: There is a common belief at the CCSC that heavier people (those with a higher BMI) tolerate the procedure better than those with a lower BMI, with the rationale being the extra abdominal fat may cushion the colon and provide some protective effect against the pain commonly experienced during colonoscopy procedures. At the CCSC there is no maximum or minimum BMI outlined in the eligibility criteria (AHA, n.d.a);
- Gender: Anecdotally, there is a common belief that more women than men seek screening colonoscopies. The rationale discussed was that women are often thought to be more proactive with their health, and are more accustomed to invasive procedures (e.g., Papanicolaou [Pap] tests);

- Total procedure time: The difference, measured in minutes/seconds, between the procedure start time and procedure end time. On withdrawal of the colonoscope was when polyps were typically removed at the CCSC and may account for any variation noted;
- Time the cecum is reached: This portion of the procedure is anecdotally the most uncomfortable and it is when the cecum was reached that the comfort score was assessed at the CCSC;
- Dose of sedation: Routinely when patients complain of discomfort during colonoscopy procedures, more sedation is offered. The ability to correlate the dose of sedation to the comfort score could indicate if comfort was dependent on the dose of sedation administered;
- Prior surgery: It is an assumption at the CCSC that the colonoscopy procedure will be more difficult and will not well-tolerated by patients who have had prior abdominal surgery;
- Prior sedative use: At the CCSC, there is an assumption that patients who use sedatives will have built up a tolerance for the sedation and will not tolerate the colonoscopy procedure well;
- Patient comfort score during the procedure: The comfort score was the dependent variable of interest in this study.

Nurse assessed comfort scores. The nurse assessed comfort scores used at the CCSC is the first multicenter, internationally validated tool of its kind (Rostom et al., 2013). Whereas no standard for comfort measurement exists and patient comfort is not typically used as a quality

indicator for colonoscopy procedures, it is noteworthy that this tool was developed in part at the CCSC to measure patient comfort. The reliability and validity of this tool was measured by using intraclass correlations (ICC) between nurse ratings, endoscopist ratings, and patient ratings of comfort during colonoscopy procedures. The tool was tested on a total of three hundred patients from the CCSC and two endoscopy centers in the United Kingdom. There is a high level of agreement between the NAPCOMS and endoscopist ratings of comfort (ICC = 0.77; 95% CI, 0.72-0.81), a moderate level of agreement between the NAPCOMS and patient ratings (ICC = 0.61; 95% CI, 0.53-0.67), and a moderate level of agreement between the endoscopist and patient ratings (ICC = 0.52; 95% CI, 0.43-0.60). It was suggested by Rostom et al. (2013) that comfort might be considered for use as a quality indicator in the future, as patient comfort was described as an important measure of the patient experience. This is currently a controversial issue as it is considered unethical to collect data with no purpose. The comfort score data is used to describe the patient experience at the CCSC, but the NAPCOMS score is not currently considered a quality measure (R. Hilsden, personal communication, October 24, 2016).

This comfort score is measured using three identified domains of pain (frequency, duration, and intensity). Optimal comfort using this scale is characterized by fewer than two episodes of mild pain or discomfort with insertion of the colonoscope that last less than 30 seconds each, which equals a comfort score of zero or three (Appendix A). An identified strength of this tool is that nurses, sometimes viewed as being more objective at rating pain than physicians during colonoscopy procedures, are the ones to assign the NAPCOMS rating. Endoscopy nurses have also witnessed numerous procedures and are described by Rostom et al. (2013) as having perspective on the patient experience. The critique of this tool is that nurses

may be perceived as having a bias for or against certain endoscopists which may be reflected in the comfort scores.

Inter-rater reliability. It is important to demonstrate that the data used in a study was collected accurately as the question of consistency may arise due to human error (McHugh, 2012). In this study, there was only one researcher/data collector; a second data collector (a member of the CCSC research team) was used on approximately 10% of the charts to demonstrate that the researcher was collecting data consistently. Calculating the percent agreement amongst data collectors can be directly interpreted as the number of items that are considered correct (McHugh, 2012). In this study, there was 100% agreement between data collectors.

Data analysis. The Statistical Package for the Social Sciences 22.0.0 (SPSS) was used to analyze the data. Descriptive data were used to describe the sample characteristics based on the data collection points (mean dose of sedation given, mean time between sedation administration and procedure start time, mean procedure length, percentage of males and females in the sample, and frequency of comfort scores in the sample). Pearson's correlation coefficient and t-tests were used in the analysis of the data, as the outcome variable was categorical in nature, to examine the relationship between identified independent variables and patient comfort scores at the CCSC. The level of significance (p) used was 0.05.

The Pearson product-moment correlation coefficient is a standardized measure of the strength of a linear relationship between two variables and is symbolized by *r* (Field, 2013). Essentially, a Pearson product-moment correlation attempts to draw a line of best fit through the data of two variables, and the Pearson correlation coefficient (*r)* indicates how far away all these data points are to this line of best fit (i.e., how well the data points fit this new model/line of best

fit). To demonstrate how well the data points fit this line of best fit, data is often displayed in a scatter plot to provide a visual representation. The Pearson coefficient can be any value between -1 and +1. The stronger the association of the two variables, the closer *r*, will be to either +1 or -1 depending on whether the relationship is positive or negative, respectively. The closer the value of *r* is to 0, the greater the variation around the line of best fit and the less statistically significant the relationship.

The independent t-test is used to determine whether there is a statistically significant difference between the means in two unrelated groups (Field, 2013). The t-test is used to ascertain whether any difference observed between the groups is representative of a real difference or whether the difference is due to chance.

Pilot project. Twenty charts were reviewed as a pilot project as per the protocol outlined in the proposal of the study (Dittmer, 2014a). This pilot project was used to ascertain the amount of time it took to collect the data, assess the completeness of the records reviewed, and review the way in which the rest of the data were to be collected for this study. Because of this pilot project the way the rest of the study data was collected was altered. It was discovered that the CCSC had changed the way in which the charts were compiled. Instead of being sent to an administrative office to be completed, the charts were being sent to the CCSC chart room. Rather than sending off the procedure reports to the family physicians each day, the reports were being sent one to two times per week in larger batches. These changes allowed for multiple days of data to be collected at one time; it was possible to review approximately 20-30 charts at once, and it took approximately one and one half hours to collect the required data. The chart room, where the charts were kept, was locked after 1745h therefore it was necessary to collect the data at an earlier time than was first anticipated, to avoid interrupting unit operations. Most charts

reviewed in this pilot phase contained all the data elements specified in the protocol; only one was missing the colonoscopy procedure printout and was deemed incomplete for this study. Lastly, during this pilot period, it was discovered that data about patients reported alcohol consumption was not consistently or completely documented, and although initially proposed as a data collection point in the proposal for this project (Dittmer, 2014a), was eliminated as a variable for this study because of this finding.

Ethical considerations. Approval for the study was obtained on October 5, 2015 from the Conjoint Health Research Ethics Board (CHREB) at the University of Calgary (REB15-2117*).* As this was a retrospective chart review, there was little to no anticipated risk to patients beyond what they would normally encounter during a screening colonoscopy procedure. Only routinely collected data from colonoscopy procedures were analyzed. Personal and identifiable information such as names, birth dates, or health numbers was not collected. A waiver of consent was sought and granted, and therefore specific consents from each participant were not required.

Safeguards to protect patients' privacy were built into the study design of this project. For example, the data collected did not include any identifying information. A master list of encounter numbers was kept on a separate document from the data collection sheets to have as a key to be able to verify the data collected.

Data were collected on paper copies of the data collection tool, and stored in a locked cabinet in the locked research office of the study principal investigator (supervisor) located at the Faculty of Nursing at the University of Calgary. The master list was also collected on a paper document to be kept in the same manner. Once data collection was complete, data was transferred to an excel file and all electronic files were kept on a password–protected computer and backed up on a password protected external device only accessible by the student researcher.

Chapter Four: Results

The participants in this study ranged in age from 41-75 years, with the mean age of 58.98 years (Table 1). The BMIs of the participants ranged from 17-49 with a mean BMI of 27.26 (Table 1). The sample consisted of 44% males and 56% females (Table 2). The range of time differences between sedation administration and procedure start time was negative three minutes to six minutes, with a mean time of 1.26 minutes (Table 1). The time for the procedure to be completed to the cecum ranged from one to 34 minutes with a mean time of five minutes (Table 1). Twenty-seven percent of patients reported having had prior abdominal surgery (Table 3). Only eight percent of patients reported the prior use of sedative medications (Table 2).

The frequency of comfort scores (range 0= no discomfort to 9=maximum discomfort) was as follows: 65 participants in this study (36.9%) scored zero, 62 (35.22%) scored three, 21 (11.9%) scored four, 17 (9.65%) scored five, nine participants (5.11%) scored six, one (0.56%) scored seven and eight and zero participants in this study scored a nine on the NAPCOMs comfort scale (Table 2).

Little to no correlation (Table 4) was discovered between the timing of the sedation and the comfort score (r=.108, n=176, p=.154) (Tables 5 and 6). Little to no correlation was discovered between age and comfort (r=-0.021, n=176, p=0.778) and BMI and comfort (r=-0.027, n=176, p=0.092) (Table 6). A fair correlation was discovered between the procedure length to cecum and comfort score (r=0.341, n=176, p=0.000) and total procedure time and patient comfort (r=0.260, n=176, p=0.000) (Table 6). A moderate correlation was discovered between the dose of sedation and the comfort score (r=0.523, n=176, p=0.000) (Table 6).

An independent-samples t-test was conducted to compare patient comfort scores in males and females. There was no significant difference in the scores for males (M=2.30, SD=1.836) and females (M=2.49, SD=2.206) conditions; t (173.171) = 0.644, p= 0.521 (Table 7).

An independent-samples t-test was also conducted to compare patient comfort scores in patients who had prior abdominal surgery and those who had not. There was no significant difference in the scores for those who did have surgery (M=2.45, SD=1.932) and those who did not (M=2.40, SD=2.097); t (174) = 0.147, p = 0.883 (Table 8). Lastly, an independent-samples t-test was conducted to compare patient comfort scores in patients who reported prior sedative use and those that did not. There was no significant difference in the scores for the patients who reported prior sedative use (M=3.43, SD=2.311) and those who did not (M=2.32, SD=2.008) conditions; t (174) =1.956, p = 0.052 (Table 9). The independent-samples t-tests conducted indicated that no statistical difference was discovered between comfort scores and gender, prior surgery, or prior sedative use.

Table 1

Sample Characteristics

	AGE	BMI	Time diff % sedation admin and start	Minutes to cecum	Total procedure length (in minutes)
Mean	58.98	27.26	1.26	6.73	18.04
Median	58	26	1.0	5.0	16.5
Mode	53	24	1	5	11
Minimum value	41	17	-3	1	8
Maximum value	75	49	6	34	55

Table 2

Frequency of Sample Characteristics

	n (%)
Gender	
1 Male	77 (43.75%)
2 Female	99 (56.25%)
Prior Surgery	
1 Yes	47 (26.71%)
2 No	129 (73.29%)
Prior Sedative Medication	
1 Yes	14 (0.79%)
2 No	162 (92%)
Total Dose Sedation	
1 Less	31 (17.61%)
2 Average	103 (58.52%)
3 More	42 (23.86%)

Table 3

Frequency of Comfort Score

Comfort Score	n (%)
0	65 (36.9%)
3	62 (35.22%)
4	21 (11.9%)
5	17 (9.65%)
6	9 (5.11%)
7	1 (0.56%)
8	1 (0.56%)
9	0 (0%)

Table 4

Interpretation of Pearson's Coefficient (Colton, 1974)

	Coefficient, *r*	
Strength of Association	Positive	Negative
Little to none	0 to 0.25	0 to -0.25
Fair	0.25 to 0.5	-0.25 to -0.5
Moderate to good	0.5 to 0.75	-0.5 to -.075
Very good to excellent	0.75 to 1.0	-0.75 to -1.0

Table 5

Scatter Plot of Time vs. Comfort Score

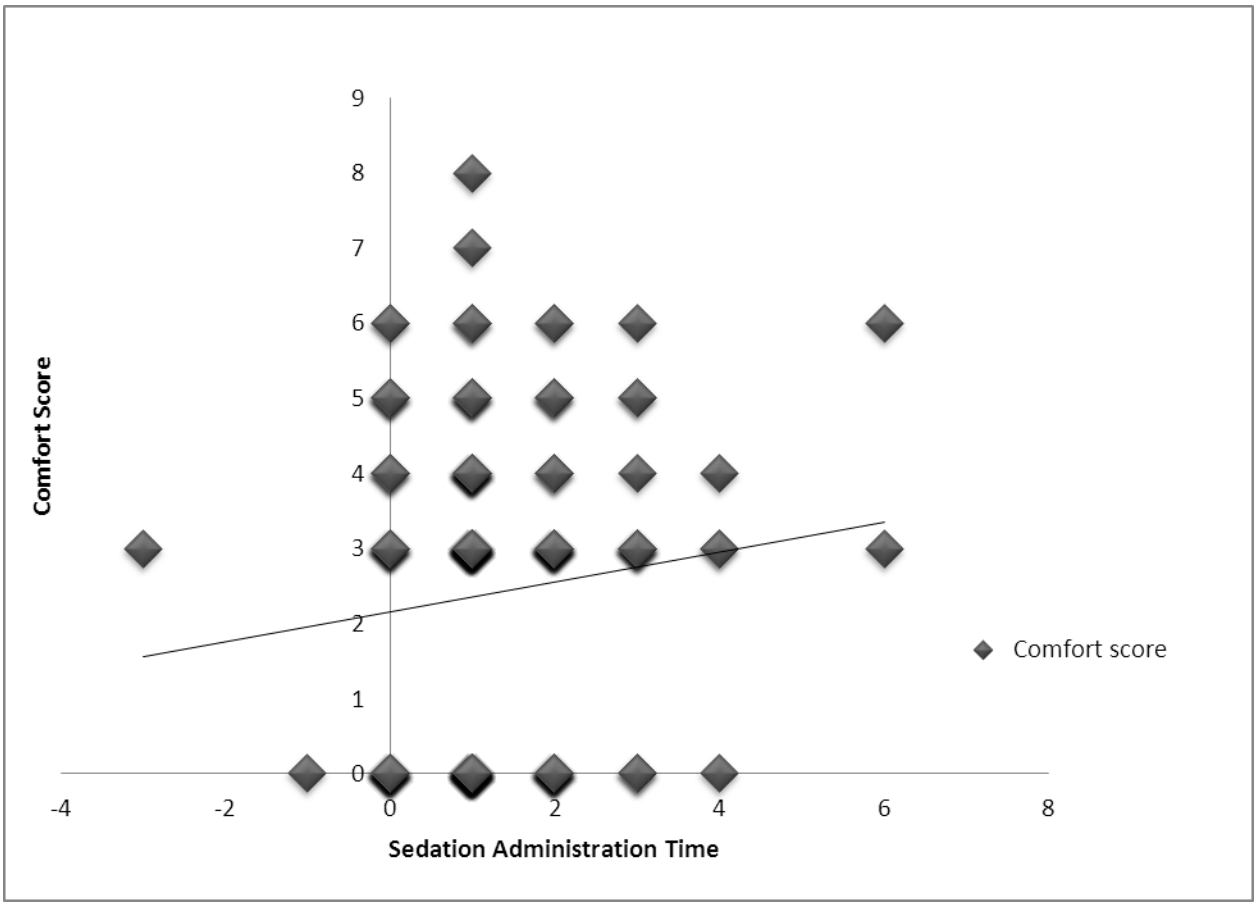

Table 6

Pearson's Correlations

		comfort_score	significance
Age	Pearson Correlation	-.021	little or none
	Sig. (2-tailed)	.778	
	N	176	
BMI	Pearson Correlation	-.127	little or none
	Sig. (2-tailed)	.092	
	N	176	
Time_difference	Pearson Correlation	.108	little or none
	Sig. (2-tailed)	.154	
	N	176	
Mins_to_cecum	Pearson Correlation	.341	fair
	Sig. (2-tailed)	.000	
	N	176	
Total_procedure time	Pearson Correlation	.260	fair
	Sig. (2-tailed)	.000	
	N	176	
Dose_sedation	Pearson Correlation	.523	moderate to good
	Sig. (2-tailed)	.000	
	N	176	

Table 7

t-test Results Comparing Comfort Scores in Males and Females

Comfort Score	n	Mean	SD	t-cal	t-crit	df	p
Male	77	2.30	1.836	-0.644	2.576	173.171	.521
Female	99	2.49	2.206				

Table 8

t-test Results Comparing Comfort Scores in Patients with Prior Surgery Yes or No

Comfort Score	n	Mean	SD	t-cal	t-crit	df	p
Yes	47	2.45	1.932	.147	2.576	174	.883
No	129	2.40	2.097				

Table 9

t-test Results Comparing Comfort Scores in Patients with Prior Sedative Use Yes or No

Comfort Score	n	Mean	SD	t-cal	t-crit	df	p
Yes	14	3.43	2.311	1.956	2.576	174	.052
No	162	2.32	2.008				

Summary

The data analysis for this study revealed that the researcher's hypothesis was not supported; the timing of the sedation was not significantly related to patient comfort scores.

While a moderate relationship was discovered between the dose of sedation and patient comfort, no additional significant relationships were discovered between the timing of sedation and the other variables included in this study. The results from this study demonstrate that timing of sedation is not a significant factor with respect to patient comfort scores.

Chapter Five: Discussion

The data generated from this study did not support the hypothesis that patient comfort is affected by the timing of sedation; little to no correlation between the timing of sedation and the patient comfort score was detected (r=.108, n=176, p=.154, Table 6). It was the hope that a "quick win" (AHS, n.d.d) could be achieved to improve patient comfort during colonoscopy procedures with only a small adjustment to current practice. The fact that 27.84% of this sample experienced a comfort score of four or greater during their colonoscopy procedure begs the questions of what other factors influence patient comfort, and how can patient comfort be better addressed. What was discovered is that more information is needed on how to better address patient comfort. Current colonoscopy procedure data from a Canadian context was the result of this study and may be useful to inform future studies.

Other Findings

Other findings resulting from this study provide valuable data to dispel current assumptions at the CCSC, and also provide a basis for future study.

Age. There was little to no correlation (r=-.021, n=176, p=.778, Table 6) between patient age and comfort score, thus the assumption that age may be a factor in how the procedure was tolerated was not supported. This was inconsistent with findings in the literature which suggest that younger patients experience more reported discomfort during colonoscopy procedures (Elphick et al., 2009; Takahashi et al., 2005; Thomson et al., 2010). This finding may inform practice at the CCSC, to dispel the current assumption that older patients tolerate colonoscopy procedures better.

Body mass index. Body mass index was also not correlated to patient comfort at the CCSC (*r*=-.127, n=176, p=.092). This was consistent with Speroni et al. (2005), who found that BMI did not influence the reported pain perception during a colonoscopy procedure. This finding is contrary to an assumption at the CCSC, also supported by Elphick et al. (2009) and Takahashi et al. (2005), that patients with lower BMIs tolerated the procedure more poorly because of the lack of visceral fat to cushion their colon and prevent stretching.

Gender. The assumption that more females than males seek screening procedures was supported in this study, but the difference may not be a great as was thought. The sample for this study consisted of 44% males and 56% females. As well, no significant relationship was revealed between gender and patient comfort and this was consistent with a study conducted by Bal et al. (2012). There was disagreement in the literature about how gender was related to the tolerance of colonoscopy procedures. Female gender was cited as a predictor for discomfort during colonoscopy procedures (Ma et al., 2007; Morrow et al., 2000) and females reported more procedure related discomfort (Elphick et al., 2009; Takahashi et al., 2005). Female gender was also a factor in the reported dissatisfaction with the colonoscopy experience (Thomson et al., 2010).

Time cecum reached and total procedure time. Only a fair correlation existed between the times the procedure was completed to the cecum and the patient comfort scores (*r*=.341, n=176, p=.000), or between total procedure time and comfort score (*r*=.260, n=176, p=000). At the CCSC the comfort score is only assessed once when the cecum is reached. It is possible that this finding would be different if comfort scores were measured again at the end of the procedure. In the literature, prolonged procedures were associated with increased reported

discomfort during colonoscopy procedures (Elphick et al., 2009; Ma et al., 2007; Morrow et al., 2000; Takahashi et al., 2005).

Total dose of sedation. As the total dose of sedation increased, so did patient comfort as reflected in the moderate relationship between dose of sedation and patient comfort in this study (*r*=.523, n=176, p=.000). Wood et al. (2012) found that as the dose of sedation increased so did the reported discomfort score and it was explained that extra sedation is offered when patients are already demonstrating signs of discomfort. The way comfort scores are captured may need to be examined to make the results broadly applicable and comparable. The answer to patient comfort is not as simple as giving extra sedation due to the risk associated with increased doses of sedation (Cohen et al., 2006; Ekkelenkamp et al., 2013; Hutson, 2009; Loftus et al., 2013; Porostocky et al., 2011; Thomson et al., 2010; Triantafillidis et al., 2013). The approach at the CCSC is to give the lowest possible dose of sedation necessary to keep patients as comfortable as possible. The decision to provide more sedation needs to be considered carefully.

Prior surgery. No significant relationship was discovered between patient comfort and prior abdominal surgery. This finding was not substantiated in the literature where hysterectomy surgery was identified as a factor in how colonoscopy procedures were tolerated (Elphick et al., 2009; Takahashi et al., 2005). Takahashi et al. (2005) further explained that the extra abdominal space left in the abdomen as a result of removing an organ (e.g., uterus) allowed for more movement and looping of the scope, which may cause more stretching of the mesentery and increased reports of pain. Conversely, Morrow et al. (2000) determined that prior surgery was not a factor in how colonoscopy procedures were tolerated.

Prior sedative use. Prior sedative use was not significantly related to patient comfort at the CCSC. Other researchers have found conflicting results. Bal et al. (2012) also found no

association between patient comfort and prior benzodiazepine (BZE) use, whereas in a review of the literature, Thomson et al. (2010) found that the reported prior use of BZEs resulted in increased reported pain and a need for increased doses of sedation. For this study, prior sedative use was interpreted as the reported use of any type of sedative prior to the procedure, and was not specific to the reported use of BZEs alone.

Comfort score. At the CCSC, most patients were rated as comfortable although 27.84% of patients in this study were assessed as experiencing more than minimal discomfort. While this finding was substantially greater than in other studies, this assessment was absent in most of the literature reviewed. However, Ma et al. (2007) stated 14.4% of patients tolerated the procedure poorly and Paspatis et al. (2011) reported that only 1.1% of the patients in their study rated tolerance of the procedure as fair, the rest reportedly had no or only slight discomfort. Rasool et al. (2010) reported that only 4% of participants in their study experienced moderate pain and none reported experiencing severe pain.

At the CCSC nurses assess patient comfort, and because the patient is the nurse's primary concern, nurses are ideally situated to do this (Rostom et al., 2013; Wood et al., 2012). There was no consensus in the way comfort scores were assessed throughout the literature and this made it difficult to compare various findings. Many studies in the literature used visual analogue scales (VAS) to measure patient comfort; others used questionnaires. Some studies used self-reporting strategies to collect data on how the procedure was tolerated whereas others relied on nurse or physician assessments. Many hospitals did not assess patient comfort using scales of any kind (Ylinen et al., 2006). While it would be a lofty goal to find one standard method of assessing comfort that would be applicable to every context, it would make the comparison of findings much more meaningful (McLachlan et al., 2012).

Donabedian (1990) outlined several quality indicators that can be attributed to health care, however comfort was not included as one of them. Rostom et al. (2013) maintained that comfort was not necessarily a quality indicator; they described that comfort was at present, only a measure of the patient experience because evidence-based standards in terms of patient comfort during colonoscopy procedures of practice do not exist. Local policy and American and British colonoscopy guidelines are what most inform Canadian practice, and Canadian endoscopy units could benefit from more standardization of care (Porostocky et al., 2011).

Comfort Score Limitations

Capturing data and attempting to make improvements to care based on evidence may satisfy organizational initiatives. Measuring comfort using a validated tool (e.g., NAPCOMS) is not considered standard practice in endoscopy units (Rostom et al., 2013). Consistently capturing this data could provide the evidence on which to substantiate changes to practice. A limitation of the NAPCOMS is that the middle scores of four or five are not well defined. According to Rostom et al. (2013), a score of zero meant the patient experienced no discomfort and a score of three meant minimal discomfort was experienced; it was explained that when a comfort score of six or greater was observed the physician should consider whether or not to discontinue the procedure.

Arguably, if a nurse assesses that a patient experienced more than minimal discomfort but not so much to consider discontinuing the procedure, this may be an indication that more could have been done to address the comfort levels for that patient (with a score of four or five). This is where the APN uses critical thinking to assess the potential to improve the patient experience (UC, n.d.a). It has been observed in practice that patients with comfort scores of four or five have

asked for extra sedation, move around the procedure table, have asked the nurse "can we just take a break," require the nurse to intervene, and are observably not comfortable. Since the introduction of this comfort score at the CCSC in 2013, additional documentation and expected associated actions have been implemented depending on the assessed comfort score. For example, to provide evidence that the patient's comfort was addressed nurses at the CCSC are currently directed to document on the patient record the interventions performed when a patient has a higher than minimal comfort score. When a comfort score of six or greater is assigned, the nurse is often directed to fill out a safety learning report as it has been considered an adverse event (AHS, n.d.c). The disparity in what was reported by Rostom et al. (2013) and what is currently practiced in the CCSC may be a result of the tool being in use for a longer period on a larger cohort of patients.

Some have asked if the patient does not remember the procedure then why does attending to comfort matter? Ethically, it is important to provide care that is respectful and acceptable both for the patient and the caregiver (Donabedian, 1990). Additionally, per the Health Promotion Model (Sakraida, 2010), failing to attend to the patient experience may result in individuals having the perception that a barrier to engaging in health promoting behaviours exists.

Patient Expectations

McLachlan et al. (2012) stated that understanding patient perceptions of the colonoscopy procedure, and the barriers that deterred them from undergoing one, were the keys to improving the acceptability of this test. This concept is mirrored in the Health Promotion Model where perceived or real barriers may prevent individuals from engaging in health promoting activities (Sakraida, 2010). Misinformation concerning the extent of the sedation to be received is

frequently observed even though patients must attend an information session prior to consenting to undergo a colonoscopy at the CCSC (Dittmer, 2014a). Anecdotally, patient expectations that they may be asleep for the entire colonoscopy procedure and that they will have no physical sensation during the colonoscopy may contribute to their anxiety and discomfort. Nurses who correct this misinformation at the time of the procedure have expressed an increased concern for patient and more difficulty maintaining the patient's comfort (Dittmer, 2014b).

Sedative medication can alter the perception and recollection of the colonoscopy procedure and as such, the patient is not consistently able to provide accurate information regarding when and where pain was experienced throughout the procedure (Ekkelenkamp et al., 2013). This altered perception has made it difficult for nurses to address patient comfort. Additional research that not only identifies patient expectations but also looks at ways of addressing them may help ensure a tolerable and comfortable procedure. Ensuring that comfort (during colonoscopy procedures) is measured accurately would enable health professionals to better understand and improve upon the patient experience (Rostom et al., 2013). Improved quality of care may be demonstrated if people increasingly seek health care (e.g., colonoscopies) based on how services are provided (e.g., assuring patient comfort) and based on how these services are informed by current evidence-informed practices (Donabedian, 1990). Porostocky et al. (2011) agreed that qualitative studies may yield important information about patient experiences and preferences that surveys are unable to capture. Such information may highlight aspects of the colonoscopy experience that could be improved to enhance the acceptability and public perception of screening colonoscopies.

One physician at the CCSC explained that he informally tested the hypothesis of this study by waiting for three minutes after sedation was administered before starting his procedures.

He stated at the end of the procedure day that he felt his patients were more comfortable (R. Mohamed, personal communication, May 13, 2015). Because no correlation between the timing of the sedation and patient comfort was discovered as part of this research, the question still exists as to what other factors influenced the patient comfort that he observed. It is possible that the environment in the procedure room was affected by waiting for three minutes and that the pace of the procedure was slower and more relaxed. It is also possible that the nurse was not as rushed in the necessary tasks and that the patient felt better attended to potentially reducing patient anxiety (which may well be a variable to study in future research). Additional study regarding the patient experience in colonoscopy procedures may assist in the identification of factors that could be addressed to promote patient comfort and improve the patient experience.

Current Health Initiatives: The Patient First Strategy

Current health initiatives at AHS have focussed on the patient experience throughout the health care system (AHS, n.d.e). Examining quality from the patient perspective has not been well studied (Sewitch et al., 2012). Encouraging health care practitioners to investigate the patient experience may result in practice changes. The evidence from this study demonstrated that while comfort scores were not statistically related to the timing of sedation, 28% –almost one third– experienced more than minimal discomfort during their colonoscopy procedures; the need for improvement related to patient comfort at the CCSC still exists. Using this evidence to inform practice at the CCSC could demonstrate patient centred care and address AHS's commitment to quality (AHS, n.d.e). In addition, further study in this area may help discover other factors related to patient comfort during colonoscopy procedures.

The *Patient First* strategy at AHS is an initiative intended to create a culture shift where patients' needs are central to how care is provided (AHS, n.d.e). The ability to provide patient and family centred care has been identified as important, and with this strategy the patient and family are integral members of the health care team. Alberta Health Services received recommendations from the Patient and Family Advisory Group, developed in 2010, to bring the patient voice to policy development and to increase patient engagement (AHS, n.d.e). This broad initiative is intended to promote trust and transparency with the health care providers, and applies in all ways that patients access the health care system. Two of the main tenets of this strategy, promoting respect and supporting people in staying healthy, are central to this researcher's area of interest. Promoting patient comfort during colonoscopy procedures and addressing patients' and families' anxiety related to colonoscopy are examples of how this strategy might be implemented. Encouraging people to stay well and be proactive about their health (e.g., screening) was a goal identified in the Health Promotion Model (Sakraida, 2010). These goals were also identified by the CCSC and by AHS (AHS, n.d.e).

Implications

The data from this study could be useful as a foundation on which to base future inquiries. It was identified that a significant number of people experienced more than minimal discomfort during their procedures at the CCSC and thus the opportunity for improvement has been presented. The identification of this problem satisfies the FON core competency of the *Spirit of Inquiry* (UC, n.d.a). The solution to improved patient comfort does not appear to be as simple as waiting for sedative drugs to circulate through the body. Further research may be beneficial to examine not only the factors associated with patient discomfort but ways to address

the identified factors to improve the patient experience. Much literature was discovered that discussed the use of alternate sedative medications and colonoscopy techniques, but very little was from a Canadian context, with scant supporting data to demonstrate the need for new measures. The data from this study can be used as a basis in a Canadian context to provide substantiation and support for future research.

To address patient comfort, leadership at both the unit level and organizational level could elicit the expertise of the nursing staff in the development and adoption of new and innovative ways to improve care, to ensure important ideas will not be missed (Porter-O'Grady, 2003). Physicians and staff may not welcome the data gained from this research. Physician resistance to changes in practice has been identified as a significant issue (Reinertsen, Bisognano, & Pugh, 2008; Suter, Oelke, Adair, & Armitage, 2009) and improving patient comfort may require a change in practice on their part. Physicians, as a group, are in a powerful position to block change if they are not engaged in the research process. "Their knowledge, enthusiasm, cultural clout, and personal leadership" is a requirement for the successful implementation of any change (Reinertsen et al., 2008, p.23). Frontline staff at the CCSC will also need ongoing support and communication from administrators and unit leaders in the implementation of any changes informed by the results of this research.

Limitations and Recommendations for Future Research

Several limitations of this study were identified that may impact the generalizability and the applicability of the findings. The first limitation was identified in the pilot project. The researcher found that data about patients' alcohol consumption was not consistently collected in the charts reviewed for this study and was therefore excluded as a variable. Patient pre-procedure

anxiety was not assessed or measured in any way to determine how it related to patient comfort at the CCSC. Anxiety was noted in the literature to impact the tolerance of colonoscopy procedures (Bal et al., 2012; Baudet & Aguirre-Jaime, 2012; Crepeau et al., 2005; Dere et al., 2010; Elphick et al., 2009; Macken et al., 1998; Morao et al., 2011; Morrow et al., 2000; Petrini et al., 2009; Speroni et al., 2005; Subramanian et al., 2005; Takahashi et al., 2005). Further study that accounts for patient anxiety may assist with not only identifying which patients are most anxious, but may also reveal strategies to address anxiety in a way that would assist colonoscopy procedures to be better tolerated.

The study design made it difficult to address what affects patient comfort. The multiple variables studied could not be considered in isolation. A study design that controlled more of the variables would have provided stronger evidence. For example, a study that included only procedures conducted by one nurse and one endoscopist would have minimized any style differences that were not accounted for in this study. Additionally, the sample size for this project may have been insufficient to show a significant statistical relationship. Studying a greater number of charts may have resulted in different results. There was also no accounting for which physician performed the colonoscopy procedure or the level of experience of the physician. Ekkelenkamp et al. (2013) identified that physicians who performed more colonoscopies per year also had more patients who tolerated the procedure well. Many physicians work at the CCSC and their colonoscopy practices and techniques vary which was not captured in the data collection.

Similarly, nurses' experience and capacity to attend to the patient's comfort varies and was not measured in any way. Nursing interventions commonly used during colonoscopy procedures (e.g., coaching breathing, verbal reassurance, and applying abdominal pressure) may

affect patient comfort scores and could be worthy of future study. Not all nurses and doctors create the same environment in the procedure room. The pace of the procedure, and the use of music, talking, and distraction techniques vary amongst all staff. The ability to put patients at ease and create a calm environment was not gauged, but may have had a significant impact on how the procedure was tolerated.

Patients' prior colonoscopy experience was also not accounted for in this study. No information was collected about patients' prior colonoscopy procedures. No information was gathered about patient's perception of the procedure or their expectations regarding the procedure, physicians, nurses, or sedation. This information may provide valuable insight to how colonoscopy procedures are tolerated, and may be foundational in future research.
In this research the total dose of drugs was related to the patient comfort score but not how the drugs were given. For example, whether the drugs were given in one bolus or if there were any extra doses provided was not accounted for. The total dose of sedation was moderately related to the patient comfort (.523, Table 6) but the effect of how the doses were administered was not considered.

The technical difficulty of the procedure was not correlated with patient comfort. The researcher did not gather information about the size or number of polyps removed or any other complicating finding such as diverticulosis or tortuous bowels. The technical difficulty of the procedure may have impacted the environment in the room, the attentiveness of the staff on patient comfort versus their focus on other tasks, and may have also impacted the patient's anxiety regarding the procedure.

Strengths

An identified strength of this study was the uniqueness in examining the timing of sedation as it relates to patient comfort. This study provided much needed procedural data from a Canadian context. It was identified in the literature review that data from a Canadian context was almost absent. Although the outcome of this study demonstrated no correlation between the timing of sedation and patient comfort it is still important to share the information learned. Disseminating negative results may help future researchers so they can avoid repeating the same study and to serve to add to knowledge about what is known about a topic (Dickersin & Chalmers, 2011; Fanelli, 2011; Gelling, 2013). For example, it was discussed that the staff at the CCSC felt that patients with a higher BMI tolerated the procedure better than those with a lower BMI. Evidence in this study revealed that no significant relationship existed between comfort score and BMI. Although this was not the variable of interest, other findings (such as BMI and comfort correlation) would be missed if this study is not disseminated, and the assumption would persist. Not all scientific inquiries result in positive outcomes and failing to report negative findings overlooks the value of negative results. Reporting only positive outcomes may result in preconceptions and reduces the validity of scientific study. The ability to exclude the timing of sedation during colonoscopy procedures as it appears unrelated to patient comfort will help direct future study into what aspects of the colonoscopy procedure do affect patient comfort.

Faculty of Nursing Core Competencies

The demonstrated accomplishment of program outcomes and core competencies have been highlighted throughout this thesis to demonstrate that the criteria for completion of the

Nursing Graduate program have been met (UC, n.d.a) (Appendix B). It would be remiss to plan a project without consideration of such competencies. To summarize, evidence that the program outcomes have been accomplished can be found in the completion of this research project. The outcome of *Leadership and Innovation* was demonstrated through the development of the research question. The idea that the patient comfort could be improved and in effect could improve the effectiveness of the screening program challenged the way in which the colon cancer screening program was developed and also challenged the practices and norms of the unit. A way in which practice may be improved to benefit the patient experience was identified. The research question was derived from previous employment experiences, clinical experiences, discussions with nursing and physician colleagues, as well as from consideration of concepts learned through the FON graduate program The aim of this research was to provide empirical evidence that would support the need for change in a way that was meaningful to the care providers (physicians and nurses) and would diminish resistance that can come with the suggestion that change is needed (Reinertsen et al., 2008).

The *Spirit of inquiry* was evidenced through the literature review that was conducted as part of this project. The existing literature was identified and analyzed to expose gaps and substantiate the need for this research project. Through the literature it was discovered that there were no studies that investigated the timing of sedation in relation to patient comfort. There were numerous studies that looked at alternative sedatives and analgesics, however it is important to ensure the proper use of the standard sedation before concluding that alternatives are needed. By querying this relationship, it was discovered that evidence is lacking and the purpose of this research project was to contribute to the field of knowledge (UC, n.d.a).

Professional Identity was evidenced in this research project by integrating the core values that are vital to the "art and science of nursing" (UC, n.d.a., p.3). The purpose of conducting this research project was to provide evidence that would contribute positively to the patient experience during colonoscopies, thus demonstrating the values of people-centeredness, human dignity, compassion, health and excellence. Striving to ensure that patients are comfortable can only happen when all the providers (doctors, nurses, and leaders) work together toward the common goal of providing the best possible care for patients.

Human Flourishing is a complex outcome to describe, but can be seen in this research project in the examination and questioning of the accepted practice to better address the needs of the patients, and to promote their comfort and willingness to be proactive with their health. Screening can be perceived as a preventative measure and can have impacts on not only the individual but their families and communities as well (Sewitch et al., 2013; Telford et al., 2010). Promoting health is a vital component to human flourishing; when people are healthy they can spend their energy and effort on success and contentment in other areas of their lives (Sakraida, 2010).

Nursing Judgement is evidenced in four processes, as outlined in the FON core competencies: critical thinking, clinical judgement, ethics, and integration of evidence in informed practice (UC, n.d.a). Through this research project, evidence was provided about patient comfort and the timing of sedation (which was observably nonexistent in the literature) on which to base clinical practice. Critical thinking was used to determine that there was a need to first identify a possible problem in practice, and second to identify a possible solution. According to the FON core competencies (UC, n.d.a) this solution should be based on sound evidence, and this project was designed to use the scientific method to achieve this. Being

mindful of ethical considerations while conducting this research was important; during this study measures to protect the participants' privacy were followed.

These program outcomes cannot be met solely in isolation from each other and the research project satisfies these requirements in more ways that those identified (UC, n.d.b). The culmination of the knowledge and skills acquired through this graduate program has resulted in the successful completion of this study. The successful achievement of the outcomes as identifies in the framework at the graduate level have been evidenced in the completion of this research project.

Knowledge Translation

Research that does not engage those who will benefit from its use lacks purpose (Bowen & Graham, 2013). Knowledge translation (KT) is described as the process of developing and disseminating evidence with the purpose of improving health outcomes (Canadian Institutes of Health Research [CIHR], 2016). Two approaches to knowledge translation has been described at CIHR (2016); integrated and end of grant. Integrated KT is the degree to which stakeholders have been engaged throughout the research process. In this study, collaboration with stakeholders started from the beginning as engagement was important to ensure that the research project was useful and meaningful. By addressing an issue that many nurses have expressed as a concern at the CCSC, interest was garnered in this project (Dittmer, 2014b). From the beginning, key stakeholders were engaged from the CCSC and from the FON to develop the data collection tool used for this study.

End of grant KT can include planned activities to disseminate the research findings (CIHR, 2016). To this end, results of this study will be shared with the stakeholders and staff at

the CCSC education day once the research is complete. In addition, a poster presentation of this study was accepted and presented at the 2016 AHS Quality Summit, and the literature review and study will be submitted for publication in the peer reviewed journal, *Gastroenterology Nursing*. Dissemination of the results in terms of publications and presentations at conferences could be powerful ways to share the results. Disseminating changes that could improve patient comfort requires that context be considered as each endoscopy unit is different with their own priorities, budgets, and concerns (Reinertsen, Bisognano, & Pugh, 2008). As research can be highly contextual (Bowen & Graham, 2013; CIHR, 2016), the immediate usefulness of the data from this project may be limited to the CCSC. Continued engagement with stakeholders will be necessary at the CCSC to investigate other aspects that may improve patient comfort during colonoscopy at the CCSC.

Summary

Although the hypothesis was rejected, valuable data from a Canadian perspective resulted from this research project. No correlation was discovered between the comfort score and the timing of sedation. The problem of how to better address patient comfort during colonoscopy procedures is complex and requires further investigation, ideally from the patient perspective. The dissemination of results from this study has already been initiated through the poster presentation at the 2016 Quality Summit and will continue with publication in a peer reviewed journal, and a staff education presentation at the CCSC.

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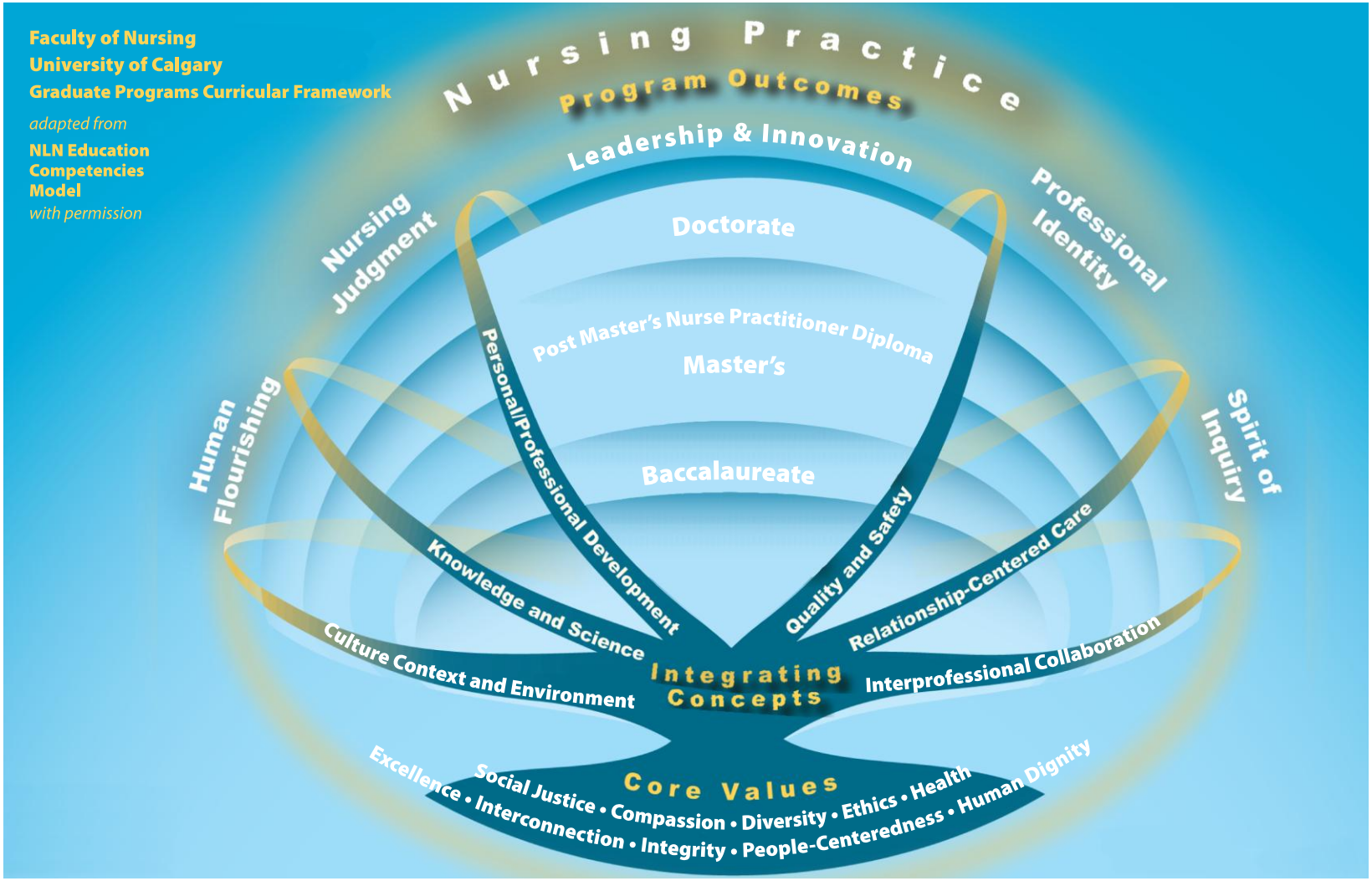
Appendix A

Nurse Assessed Patient Comfort Score (NAPCOMS)

Domain	Item	0	1	2	3	Score
Pain	1 - Intensity	None or minimal	Mild	Moderate	Severe	
	2 - Frequency	none	Few 1 or 2 episodes	Several times (3-4 episodes)	Frequent (> 4 episodes)	
	3 - Duration	none	Short duration (episode <30) seconds)	Moderate Duration (30 sec – 1 minute)	Long duration (episode lasts > 1min)	
	Total Pain score (Intensity + Frequency + Duration)					
Sedation	Level of consciousness*	Alert	Sleepy but initiates conversation	Responds only when asked or stimulated	Unresponsive or only responds with pronounced stimulation	
Global	Tolerability*	Very well Tolerated	Reasonably Well tolerated	Just tolerated	Poorly tolerated	

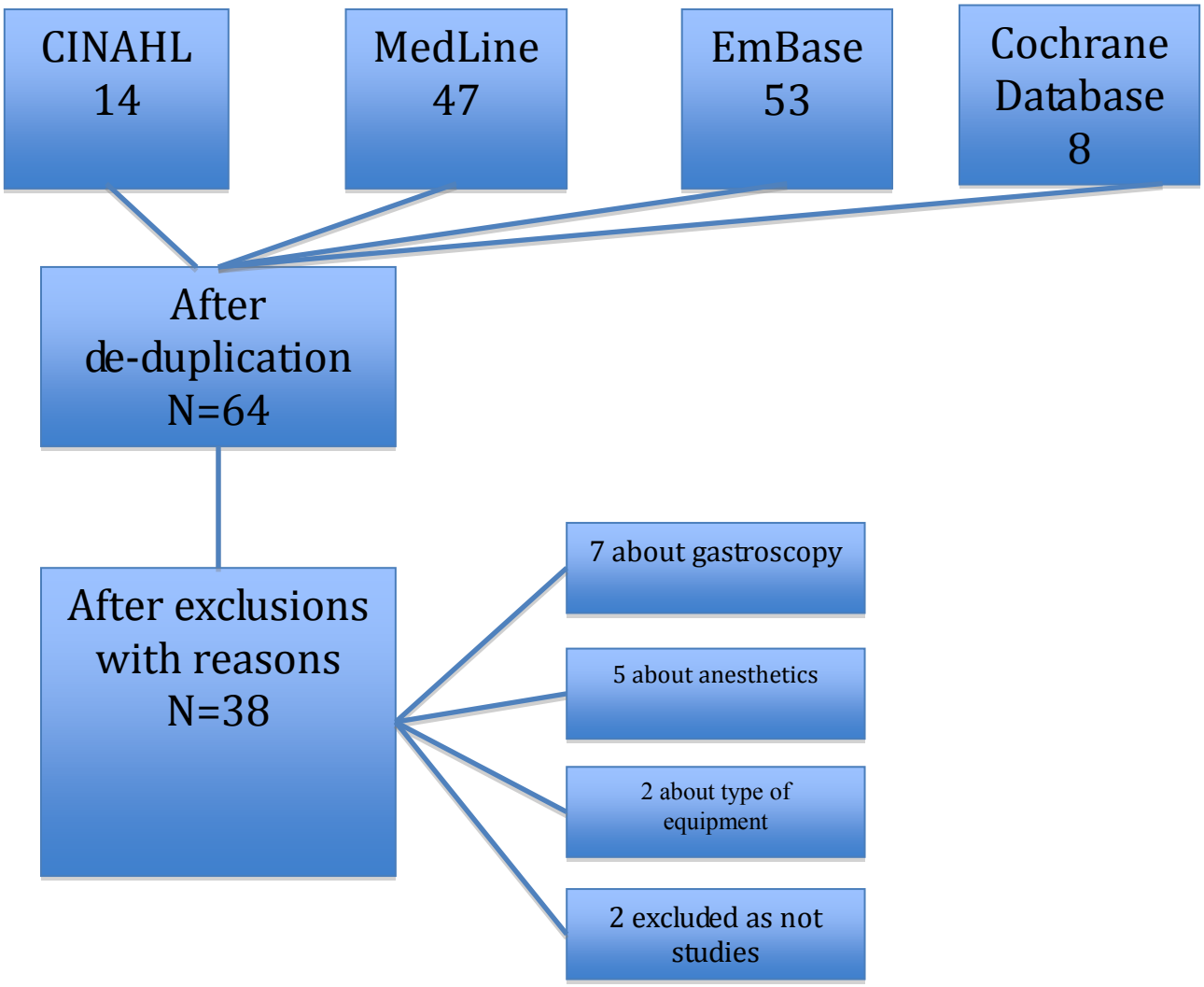
Appendix B

Faculty of Nursing Curricular Framework



Appendix C

Prisma Diagram



Appendix D

Literature Review Tables

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
1. Bal, B. S., et al. (2012). "What factors are associated with the difficult-to-sedate endoscopy patient?" Digestive Diseases and Sciences 57(10): 2527-2534. - Washington Hospital Center 920 bed tertiary care hospital inner city Washington, DC, USA	Subjects completed 3 questionnaires at time of enrolment and then 24 post procedure subjects were called to complete a 4 point likert scale rating their experience (scores of 3 or 4 were classified as dissatisfied) staff at the clinic filled out a 5 point scale rating the difficulty to sedate	n=180 but 143 completed study	Scales completed on enrolment, phone call follow up, staff filled out likert scale regarding sedation, no mention of who collected data	Prospective cohort study likert scale	For staff scales inter–rater reliability was mentioned as good for questionnaires validity was mentioned for all instruments used	CONCLUSION: Pre-procedural state or trait anxiety is associated with difficult sedation during endoscopy. In this study neither alcohol abuse nor chronic opiate/BDZ use was associated with difficult sedation	Did not take into consideration total dose of medication, simply sedation level as assessed by staff it was mentioned that the population was limited to the one inner city center and the population has multiple medical issues r/t poor medical access

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
2. Baudet, J. S. and A. Aguirre-Jaime (2012). "The sedation increases the acceptance of repeat colonoscopies." European Journal of Gastroenterology and Hepatology 24(7): 775-780. Canary Island, Spain	Compared patients who had undergone previous colonoscopies with sedation (cases) with patients who had undergone previous colonoscopies without sedation and patients who had never had a colonoscopy before. Following the examination, patients answered a satisfaction survey and were asked whether they would be willing to undergo future colonoscopies	n=2016	Pre–procedure staff collected data, and patient filled out 2 questionnaires, 30 days after procedure patients were contacted by call center and asked 2 more questionnaires by phone	A prospective case–control study quantifying the anxiety and fears of patients appointed for colonoscopy	Fears surveys had face validity and then were subsequently validated, all other surveys validity was mentioned	"Sedation reduces the anxiety and fear of undergoing a repeat colonoscopy and improves both patient satisfaction and the acceptability of future procedures (p.775)".	Bias was stated that sedation was available on demand- so that the patient who were the most feared the procedure requested sedation Because of large sample size conclusions are more generalizable

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
3. Chartier et al. (2009) Montreal, QC Canada "Patient satisfaction with colonoscopy: A literature review and pilot study" Can Journal of Gastroenterology Vol 23 No 3 March 2009	A systematic review of the literature and pilot study of patient satisfaction with the colonoscopy experience.	n=15	Search strategy well outlined on p.204	Systematic review	Study portion was a pilot, review was systematic and stringent adherence to method was followed	Patients were very satisfied with colonoscopy. The majority were willing to return for repeat testing under the same con-ditions, and colonoscopy was not preferred over other modalities. However, studies were limited by methodological shortcomings. Providing patients with a positive colonoscopy experience is essential to encourage repeat screening.	Canadian context, results generalizable (p.207). A major limitation of is that patients may have gone elsewhere for care. Had to combines satisfaction results of screening vs. diagnostic colonoscopies.

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
4. Cohen, L. B., et al. (2006). "Endoscopic sedation in the United States: results from a nationwide survey." The American Journal of Gastroenterology 101(5): 967-974. USA national survey	Dependent variable was sedation administration Independent variable was physician demographics	n=5000, 1353 surveys were returned Cluster sampling with randomization within clusters. Authors chose their sample proportionally related to geographic representation	Data were collected, but specified by whom. Survey with 22 items was analyzed. Response rate was 27.1% Data were analyzed using Student's t-test, Wilcoxon rank sum test and Chi square tests	A 22-item survey regarding current practices of endoscopy and sedation was mailed to 5,000 American College of Gastroenterology physician members nationwide	Survey was developed by authors (face validity) and refined by a marketing agency stated unable to validate	The use of various types of sedation was related to the physician demographics across six regions in the US	Retrospective data-may be subject to recall bias

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
5. Crepeau et al. (2005) Paris, France "Significance of patient-controlled sedation during colonoscopy" Gastroenterologie Clinique et Biologique, 29(11), 1090-1096.	Patients were randomized into two groups- control with standard anesthetic, and PCA group. Satisfaction was measured in both groups post procedure	n=72	Questionnaires were mailed, physicians collected data about procedures	RCT	Visual analog scale used to measure satisfaction. Satisfaction with PCA vs. standard anaestheic was significant (0.003)	Results demonstrate that need of sedation is widely overestimated in France. Some patients are willing to consider colonoscopy without general anesthesia.	Only two gastroenterologists performed all the procedures, results may vary with technique. Satisfaction questionnaires were mailed only 61% response. Recall bias may be an issue. No blinding as to which arm of study

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
6. Dere, K., et al. (2010). "A comparison of dexmedetomidine versus midazolam for sedation, pain and hemodynamic control, during colonoscopy under conscious sedation." European Journal of Anaesthesiology 27(7): 648-652. Istanbul, Turkey	Midazolam and fentanyl citrate were administered intravenously to cases in Group I (n = 30). An initial loading dose dexmedetomidine was administered intravenously in 10 min to cases in Group II (n = 30	n=60	unsure	RCT, prospective, randomized, double-blinded study	none mentioned	CONCLUSION: Dexmedetomidine provides more efficient hemodynamic stability, higher Ramsay sedation scale scores, higher satisfaction scores and lower NRS scores in colonoscopies. According to our results we believe that dexmedetomidine can be used safely as a sedo–analgesic agent in colonoscopies.	To give anaesthetic agents, there must be staff availability and this drastically increases the cost of the procedures, in North America this medication is typically limited to OR and ICU

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
7. Dong, M. H., et al. (2011). "Missed work related to mid-week screening colonoscopy." Digestive Diseases and Sciences 56(7): 2114-2119. University of California at San Diego USA	Patients were interviewed by telephone regarding missed work time and the reasons for doing so.	n=68	Telephone interviews	This was a retrospective study	none mentioned	One third of working patients who undergo mid-week screening colonoscopies miss work on additional days to the procedure day. Unanticipated time missed from work could increase the indirect costs of screening colonoscopy.	Due to the retrospective nature of the study, subjects may be influenced by recall bias. Also, our study cohort consisted of individuals who had chosen to undergo colonoscopy procedure, and may not represent all individuals eligible for screening or surveillance exams

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
8. Eckardt et al. (2008) "Open access colonoscopy in the training setting: Which factors affect patient satisfaction and pain" Endoscopy, *40*(2), Germany and USA	Patients were randomized into trainee and experienced endoscopist groups. Satisfaction with experience was measured.	n=368	Well outlined on p.99, pre–test post test questionnaires, no mention of who analyzed or collected data	RCT	80% power, with alpha value of 0.05	Many factors affected patient satisfaction organizational factors such as wait times, Patient characteristics such as anxiety and gender, and procedural factors long vs. short procedures, level of sedation) Trainees performing procedure had no effect on satisfaction	Only partial blinding Only 75% of patient responded to questionnaires, Recall bias

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
9. Ekkelenkamp, V.E., Dowler, K., Valori, R.M., Dunckley, P Rotterdam, The Netherlands	All colonoscopies performed in our four endoscopy centres are recorded in two reporting sys-tems that log key performance indicators	17027	No mention of who collected data	Chart Review	Comfort score not validated	The best colonoscopists have a higher CIR, use less sedation, cause less discomfort and find more polyps. Measuring patient comfort is valuable in monitoring performance.	VAS used for comfort Large sample size

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
10. Elphick, D. A., et al. (2009). "Factors associated with abdominal discomfort during colonoscopy: a prospective analysis." European Journal of Gastroenterology and Hepatology 21(9): 1076-1082. United Kingdom	The aim was to determine factors associated with higher levels of patient discomfort during colonoscopy performed without, or with low-dose, midazolam sedation.	n=109	Discomfort scores were recorded every 2 min during the procedure and during peaks of discomfort. An overall discomfort score was recorded.	Prospectively recruited patients were asked to grade anticipated discomfort on a Numeric Rating Scale ranging from 0 to 10. Discomfort scores were recorded every 2 min during the procedure and during peaks of discomfort. An overall discomfort score was recorded.	Anxiety and discomfort scales validated	Patient factors independently associated with discomfort during colonoscopy are female sex, high anxiety and anticipation of discomfort. These factors are easily determined and therefore we suggest that selected patients with a combination of these factors may benefit from analgesic, with or without sedative, use during colonoscopy.	However, it may be that, as in irritable bowel syndrome, patients with visceral hypersensitivity have an increased tendency to report abdominal pain resulting from luminal distension, rather than have an increased neurosensory sensitivity. There is selection bias in that it is likely that anxious patients, or those who anticipated discomfort, would be administered midazolam.

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
11.Gasparovic, S., et al. (2003). "Comparison of colonoscopies performed under sedation with propofol or with midazolam or without sedation." Acta Medica Austriaca 30(1): 13-16. Croatia	Comparison of 3 groups, propofol, midazolam, no sedation	n=147	ANOVA, Tukey post-hoc test, t-test, Friedman test for repeated measures and chi-square	Prospective study RCT, Anaesthetist monitored VS at 3 min intervals throughout procedure, anaesthetist rated pain during procedure and patients rated pain 30 mins after procedure using 4 point scale	None mentioned in text	Our results showed that propofol provided good sedation with excellent pain control, a short recovery time (20 mins faster than BZE) and no significant hemodynamic side effects.	small sample size, 3 groups uneven

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
12. Hsieh et al. (2014) "A Patient-Blinded Randomized, Controlled Trial Comparing Air Insufflation, Water Immersion, and Water Exchange During Minimally Sedated Colonoscopy" The American Journal of GASTROENTEROLOGY Taiwan (USA/Canada)	An assessment of comparative effectiveness of three methods of conducting colonoscopy, water immersion vs water exchange vs. air insufflation	n=270	Research assistant administered questionnaires to assess satisfaction	RCT	Alpha level 0.05 with a power of 0.99%	Methods with less insertion pain could enhance application of minimal sedation colonoscopy	Patients blinded only Study was at a single center One endoscopist performed all procedures, -does not account for variances in technique Findings consistent with previous systematic review

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
13. Hutson, P. (2009). "Is the use of intravenous opioids essential to control pain during colonoscopy?" Gastrointestinal Nursing 7(3): 15-23. United Kingdom	Review Aim: To consider the necessity for using an opioid during colonoscopy investigation and whether omission reduces patient satisfaction and perception of pain	n=16	Method: A comprehensive search process was employed and 16 studies were reviewed in-depth using a piloted quality appraisal tool.	Review of non-randomized and randomized controlled trials were included within the review and results focused on the patient's perception of pain and cardiopulmonary side- effects.		Cardiopulmonary risks are significantly reduced without compromising patient satisfaction and tolerance of colonoscopy if opioid administration is considered for selected patients and not given as a routine regime.	Small sample

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
14. Kravochuck, S., et al. (2014). "Differences in colonoscopy technique impact quality." Surgical Endoscopy 28(5): 1588-1593. Cleveland, Ohio, USA	Individual endoscopists in outpatient endoscopy clinics were studied. Consecutive elective colonoscopy patients were included. Examinations were observed, and techniques used in procedures were recorded. The type and dose of medication, the pain score recorded by the endoscopy nurses and the incidence of hypotension and hypoxia were noted.	n= 245, 116 women, 129 men	Nurses and two study observers collected data. Linear regression was used to explore relationships between the mean number of techniques used and the mean pain score, the mean dose of narcotics, and the mean incidences of hypoxia and hypotension	Prospective, comparative study	Data were gathered during the examination on a scannable form and then scanned into the database. Quality control checks were performed regularly	Use of ancillary techniques for colonoscope insertion minimizes pain, narcotic use, and hypoxia/hypotension. The product of benzodiazepine dose and narcotic dose is a good way of assessing sedative effect. BZE and narcotic combination good for procedure, technique was good at diminishing discomfort but dosing was not r/t diminished pain	A limitation was small # of procedures performed by each of 10 endoscopists, they did not use polyp detection rate as a quality indicator, they did not note the use of the variable stiffness dial on the scopes

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
15. Loftus et al. (2013) "Patient satisfaction with the endoscopy experience and willingness to return in a central Canadian health region" Canadian Journal of Gastroenterology Winnipeg, MB	1200 surveys were sent to patients from 6 facilities to assess patients satisfaction and willingness to return	N=529	Survey questionnaire	Large sample survey	Power .05	It is important to assess willingness to return because behavioural intent is based on more than simply satisfaction with the last visit/procedure ** Pain control was a major factor in the willingness to return Willingness to return was also correlated to recommending treatment to a friend Lower education was related to decrease willingness to return	Self report, Recall bias Only 44% of the 1200 surveys were returned despite large sample, experiences may be missed

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
16. Ma, W.T Mahadeva, S.F Quek, K. Goh ,L.(2007) Tolerance and Safety to Colonoscopy with Conscious Sedation in Malaysian Adults University Malaya Medical Centre, Kuala Lumpur	To determine the local population tolerance to colonoscopy and identify risk factors for poor tolerance. To examine the safety of the current practice of conscious sedation and identify risk factors for cardio-respiratory depression during colonoscopy.	n=208	Pre–test demographic HAD scale completed, total dose of drugs, quality of prep and tolerance of procedure recorded. Also post test to document willingness to repeat procedure performed	Prospective RCT study.	HAD and VAS all validated scales	14.4 % of patients tolerated procedure poorly; female gender and longer procedures were correlated to poor tolerance. Poor prep and "looping" /anatomical difficulties also contributed to poor tolerance	Data collectors were blinded to dosage of sedation procedure were completed by trainees, may not reflect senior endoscopists practice

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
17. Macken, E., et al. (1998). "Midazolam versus diazepam in lipid emulsion as conscious sedation for colonoscopy with or without reversal of sedation with flumazenil." Gastrointestinal Endoscopy 47(1): 57-61. Belgium	The efficacy and tolerance of midazolam versus diazepam in lipid emulsion was evaluated in patients undergoing total colonoscopy.	n=200, 3 excluded n=197	Data collectors blinded to group allocation, PARS score recorded pain score recorded and willingness to repeat procedure all at certain intervals	Randomized controlled, double-blind trial	PARS score, The results were evaluated statistically using the analysis of variance test for continuous variables and the Kruskal-Wallis test for non–continuous numeric variables. A logistic regression model was used to evaluate the effect of drug and gender on pain score. A p value of less than 0.05 was considered as statistically significant.	Midazolam induced significantly more amnesia, and the score for recall of the pain score was significantly less after 14 days in the midazolam group. Women more likely to need analgesia, especially if previous hysterectomy	12 endoscopists performed procedures, variations existed in technique and procedure length

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
18. Maslekar, S., et al. (2009). "Randomized clinical trial of Entonox versus midazolam-fentanyl sedation for colonoscopy." British Journal of Surgery 96(4): 361-368. United Kingdom	Patients undergoing elective colonoscopy were included. Patients completed a Hospital Anxiety and Depression questionnaire, letter cancellation tests and pain scores on a 100-mm visual analogue scale before, immediately after the procedure and at discharge. They also completed a satisfaction survey at discharge and 24 h after the procedure.	n=131	Data collector blinded to group allocation, HAD and VAS scales used to record pain, patients also filled another VAS 24 hours post procedure, patient satisfaction measured at d/c and at 24 hours post procedure, endoscopist and nurse satisfaction with procedures were all recorded	Prospective RCT, with partial blinding only	HAD and VAS, Differences in proportions were tested using the $\chi 2$ test or Fisher's exact test for smaller samples. VAS scores, sedation scores, postoperative time to discharge and results of the letter cancellation test were evaluated using the Mann – Whitney U test. All P values are two tailed.	Entonox provides better pain relief and faster recovery than midazolam–fentanyl and so is more effective for colonoscopy.	Partial blinding only, data collectors blinded but patient s and endoscopists not blinded, no absolute pain scoring systems are available for colonoscopy

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
19. McLachlan et al. (2012) "Patients' experiences and reported barriers to colonoscopy in the screening context—A systematic review of the literature" Patient education and counseling 86 (2012) 137-146 Melbourne, Australia	A systematic review of the literature was conducted to characterize patients' own experience of colonoscopy in the screening context.	N=56	Data collection/selection strategy well outline on page 138	Systematic review	Themes were identified and extracted to form a comprehensive picture of participants' collective experiences. Conclusions were drawn based on common elements. A narrative summary technique was used to aid interpretation of study results	Colonoscopy is an important element in the early detection of colorectal cancers. Several barriers impact the uptake rates, and public acceptability of the test. Barriers include lack of understanding of the importance of the test, feelings of vulnerability, and the necessary preparation	Systematic review had large sample It was not possible to synthesize the results or carry out a meta-analysis as the studies identified by the search were clearly heterogeneous. Evidence of validity was not consistently provided in the sample Distinctly different criteria were used to select the study samples

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
20. Morao, S., Ratilal, B. O., Santos, H., & Sampaio, C. (2011). Midazolam for sedation before procedures [Protocol]. *Cochrane Database of Systematic Reviews,* Lisboa, Portugal	Protocol for Midazolam review	Not known	They propose to screen eligible titles and abstracts for eligibility. Two authors (SM and BR) will independently perform this screening. We will resolve any disagreements by consulting with a third author (CS) who will decide on inclusion or not.	Cochrane review protocol/proposal	Study parameters well defined per Cochrane protocol	Study not completed, protocol only	Topic is relevant, this review is not completed at present

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
21. Morgan, J. Roufeil, L., Kaushik, S., Bassett, M. Canberra and Bathurst, Australia	Information provided differently to two groups of patients, 1 control 1 based on preference	80	Not mentioned Self-report, physiologic, and behavioral indices of anxiety and pain were measured.	RCT	Anxiety scale validated	Patients given information congruent with coping style experienced significantly less self-report anxiety immediately after the information intervention and spent less time in recovery	Self reported anxiety scale used

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
22. Morrow, J. B., et al. (2000). "Sedation for colonoscopy using a single bolus is safe, effective, and efficient: a prospective, randomized, double-blind trial." American Journal of Gastroenterology 95(9): 2242-2247. USA	The safety and efficacy of a single bolus of sedatives before colonoscopy by directly comparing it to the recommended method of titration. Total physician time was calculated from the first injection of sedatives to the removal of the colonoscope. Patient assessments of pain and tolerance were obtained at the time of discharge using visual analog scales	n=101	Data collector physician was blinded. Blood pressure was closely monitored. Episodes of hypotension or hyper-tension were recorded. Initial sedation time, insertion time to the cecum, total procedure time, and total physician time were recorded. The independent investigator assessed the depth of sedation. A blinded nurse assessed readiness for home discharge using standard recovery room protocol. Additional aspects of the procedure were also recorded	Prospective, randomized double-blind trial	Pain and tolerance were assessed in a double-blind fashion with validated visual analog scales.	Rapid bolus sedation for colonoscopy saves significant endoscopist time, is associated with less O2 desaturation, and provides equivalent levels of patient com-fort. A revision of the guidelines for sedation and analgesia during endoscopy should be considered.	None mentioned within the study, sample size was small, 5 physicians participated and therefore differences in practice/techniq ue not accounted for

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
23. Paspatis, G. A., et al. (2011). "Deep sedation compared with moderate sedation in polyp detection during colonoscopy: a randomized controlled trial." Colorectal Disease 13(6): e137-144. United Kingdom/Ireland	The detection rate of adenomas is one of the current quality indicators in high-quality colonoscopy. We compared the performance of colonoscopy for the detection of polyps in patients sedated with deep and moderate sedation. Secondary objectives included the patient's and the endoscopists' satisfaction, recovery time and the adverse events related to sedation between the two groups.	n=520	Patients were prospectively randomized into a deep sedation group and a moderate sedation group. In both, sedation and analgesia were performed using midazolam with pethidine. The independent research nurse who performed all procedural assessments was blind to the randomization scheme. With the assistance of the endoscopy nurse, the endoscopist administered the sedative agents and carried out the sedation protocol.	RCT, 2 groups deep sedation vs. moderate sedation, medications given were the same except for dosing	Statistical power of 80 %, Distributions of the number of polyps were skewed, the Mann–Whitney test was used in all comparisons between the two groups. Categorical variables were tested using corrected v2 or two sided Fisher's exact tests. Criterion for statistical significance was $p<0.05$. The statistical computer package SPSS 17 was used.	The study demonstrated no difference in the detection of polyps by colonoscopy using deep or moderate sedation. There was a higher level of endoscopist satisfaction and longer recovery time in patients with deep sedation.	One center, one endoscopist, patient satisfaction with colonoscopy is largely influenced by both expectation and prior experience, endoscopist not blinded

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
24. Petrini, J. L., et al. (2009). "Unsedated colonoscopy: patient characteristics and satisfaction in a community-based endoscopy unit." Gastrointestinal Endoscopy 69(3 Pt 1): 567-572. USA	A total of 2091 patients underwent colonoscopy in our ambulatory endoscopy unit and were offered their procedure with sedation or no sedation. Time to cecum, extent of examination, pain level experienced, and willingness to have the procedure with the same, more, or less medication in the future were evaluated.	n=2091	All patients were asked by nurses who were not involved in the colonoscopy to fill out a short questionnaire asking whether they were satisfied with their decision about the medications used, about the maximum level of pain experienced at any point during the procedure, and whether they would have future procedures with the same, more, or less medication.	Prospective, comparative study	None mentioned	Un–sedated colonoscopy is feasible and successful in 22% of our patients, with 97.4% of this group willing to have the procedure without sedation in the future. Polyp detection rates and cecal intubation rates are comparable to currently reported quality measures, and complication rates are lower with un–sedated colonoscopy.	The study is not randomized or blinded.

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
25.Porostocky et al. (2011) A survey of sedation practices for colonoscopy in Canada Canadian Journal of Gastroenterology Vol 25 No 5 May 2011 Canada	A survey was mailed to 445 clinician members of the Canadian Association of Gastroenterology and 80 members of the Canadian Society of Colon and Rectal Surgeons in May and June 2009.	Sixty five per cent of CAG members (n=288) and 69% of CSCRS members (n=55) n-343	Self-report survey	National survey	Content and face validity, and pilot testing discussed p.256	Results of the survey suggest that gastroenterologists in Canada use sedation for colonoscopy in more than 90% of their patients. Further studies are needed to determine optimal staffing of endoscopy units with and without the use of propofol.	Recall bias is no have access to a database of general surgeons performing endoscopy in Canada and, therefore, did not survey most general surgeons, who are the primary providers of colonoscopy in rural Canada

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
26. Rasool, S., et al. (2010). "Evaluation of quality and patient satisfaction during endoscopic procedure: a cross sectional study from south Asian country." JPMA - Journal of the Pakistan Medical Association 60(12): 990-995. Pakistan	To assess the quality of gastrointestinal (GI) endoscopic procedures and patient satisfaction in endoscopy suite of South Asian country.	n=323	Patients coming to the endoscopic suite of Aga Khan University Hospital (AKUH) were interviewed and assessed in this cross-sectional study. Quality of GI endoscopic procedures was evaluated using assessment tools as suggested by The American Society of Gastroenterology. Patient satisfaction after the procedure was assessed using a modified GHAA-9 questionnaire. The questionnaire was statistically evaluated using Pareto analysis and Spearman rank correlation.	Prospective questionnaire cross sectional study	Valid questionnaire used	Discussed colonoscopy satisfaction	Single centre study. The use of Likert scale in the mGHAA-9 questionnaire also has its limitations due to the fact that patients were unable to differentiate between responses like excellent and very good or fair and poor (r/t educational level)

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
27. Riss, S., et al. (2009). "CO2 insufflation during colonoscopy decreases post-interventional pain in deeply sedated patients: a randomized controlled trial." Wiener Klinische Wochenschrift 121(13-14): 464-468. Vienna, Austria	The present study was designed to assess the efficacy of CO2 insufflation after colonoscopy in moderately and deeply sedated patients. We also evaluated whether CO2 insufflation increases patients' compliance for colorectal cancer screening.	n=300, 143 +157	Pain was assessed in all patients at 15 min, 30 min and 6 hours post test on a 10 pt analog scale	Study was designed as a patient-blinded randomized controlled trial	Despite the lack of blinding the results are very comparable to other double-blinded studies, they are most likely valuable and "true".	CO2 insufflation in deeply and moderately sedated patients during colonoscopy has no impact on patients' satisfaction with the procedure or on their attitude to voluntary colorectal cancer screening. However, the use of CO2 insufflation significantly diminishes abdominal pain after colonoscopy.	Only patients were blinded to gas used (air vs. CO2)

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
28. Ristikankare, M., et al. (1999). "Is routinely given conscious sedation of benefit during colonoscopy?" Gastrointestinal Endoscopy 49(5): 566-572. Finland	Patients scheduled for diagnostic colonoscopy divided into 3 groups: (1) sedation with intravenous midazolam (midazolam group); (2) sedation with intravenous saline (placebo group); and (3) no intravenous cannula (control group). The endoscopist assessed the procedure immediately after the examination. The patients completed a VAS questionnaire before leaving the endoscopy unit. Another VAS questionnaire was sent to the patients 2 weeks after the examination.	n=180	Questionnaires VAS at d/c and 2 weeks post test. Also the endoscopist evaluated the technical difficulty of the examination, patient cooperation and the degree of pain experienced by the patient immediately after the procedure	Randomized, placebo-controlled prospective study	It has been claimed that completion of a VAS is difficult for many patients and this may diminish the validity of the method. Verbal reliability checking was done and if inconsistency was found question was, question was excluded	Shortly after the procedure, the patients in the midazolam group rated the examination less difficult than those in the placebo group routinely administered sedation does not markedly increase patient tolerance or make colonoscopy technically easier	The study was performed in a country where sedation before colonoscopy is not routine. It may be argued that results merely reflect cultural expectations of Finnish patients, and that as such these results cannot be globalized

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
29. Sewitch et al. (2013) Patient-identified quality indicators for colonoscopy services Canadian Journal of Gastroenterology Vol 27 No 1 January 2013 Canada	To identify quality indicators for colonoscopy services from the patient perspective; to rate indicators of importance; to deter- mine factors that influence indicator ratings; and to compare the identified indicators with those of the GRS.	n= 66 in 12 focus groups, n=402 for surveys	Strategy for data collection outlined on p.26	A two-phase mixed methods study was undertaken in Montreal	Findings provided partial validation for the GRS as a measure of patient-defined quality and suggest that endoscopy staff and patients value some of the same aspects of colonoscopy services because 12 of the 29 (41.4%) indicators overlapped	66 participants in 12 focus groups identified three quality indicator themes: communication, comfort, and service environment. Patients identified 17 novel quality indicators, suggesting that patients and health professionals differ in their perspectives with respect to quality in colonoscopy services	Both qualitative and quantitative methodologies were used to identify and rate patient-derived colonoscopy quality indicators. Selection bias was identified as a limitation for the survey. Focus group moderators differed by city and discrepancies in the conduct of the focus group discussions may have led to information bias

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
30. Schutz, S., Lee, J., Scmitt, C., Almon, M., Baillie, J. North Carolina USA	A number of variables were assessed to determine if they were related to Patient satisfaction	328	Independent data collector conducted phone interviews, Self - administered questionnaires	Pre-test post test	No mention if partial validation for the GRS as a measure of patient-defined quality and suggest that endoscopy staff and patients value some of the same aspects of colonoscopy services because 12 of the 29 (41.4%) indicators overlapped	A thorough discussion of expectations assists with satisfaction. Female gender , long procedures and education were associated with dissatisfaction	Large Sample

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
31. Speroni, K. G., et al. (2005). "Evaluation of demographic, behavioural, and procedural factors on pain perception by patients undergoing colonoscopy and moderate sedation." Gastroenterology Nursing 28(6): 502-508. Virginia, USA	Pain perception was measured among patients undergoing a colonoscopy procedure. From an evidenced-based practice perspective, identification of demographic, behavioural, and procedural factors that increase pain perception during a colonoscopy may afford hospitals with an opportunity to improve their patients' satisfaction with the experience of care.	n=100 convenience sample	Patients were asked to rate pain on a 4-point categorical scale (before the colonoscopy, every 5 minutes during, and after the colonoscopy. Before discharge, patients recorded overall pain control satisfaction on a visual analog scale	This prospective study collected demographic, behavioural, and procedural factors data on the pain perception of 100 patients as they were undergoing colonoscopy and moderate sedation	None mentioned	Women experienced more discomfort than men, increased difficulty of the colonoscopy procedure may result in increased procedure time and higher levels of dis-comfort and thus the need for increased sedation	VAS used, convenience sampling considered weak

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
32. Subramanian, S., et al. (2005). "Preprocedure patient values regarding sedation for colonoscopy." Journal of Clinical Gastroenterology 39(6): 516-519. Indiana, USA	This study sought to investigate pre–procedure patient values and expectations regarding sedation use for colonoscopy. This information might be useful understanding variation between patients in their expectations, in designing sedation regimens that best meet patient expectations.	n=210	Questionnaires were administered to 210 consecutive outpatients presenting for colonoscopy. An un–scaled visual analog scale was used to value each of eight statements relating to sedation.	Survey	All comparisons between groups were performed with unpaired Student's t tests. All tests of significance were two-sided, and P values less than 0.05 were considered statistically significant.	American patients place the highest valuation on experiencing no pain during colonoscopy, waking up promptly after the procedure, and for going to sleep and not waking up until the procedure is over. However, un–sedated colonoscopy does appeal to a small minority of patients, primarily men with graduate educations.	A limitation of our study is that we did not correlate pre–procedure expectations and choice of sedation with post-procedure satisfaction with colonoscopy and choice of sedation

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity	Outcomes	Strengths and weaknesses
33. Takahashi, Y. M.D., Hideaki Tanaka, M.D., Mitsuyo Kinjo, M.D., Ken Sakumoto, M.D. Prospective Evaluation of Factors Predicting Difficulty and Pain During Sedation-Free Colonoscopy Dis Colon Rectum 2005; 48: 1295–1300 DOI: 10.1007/s10350 -004-0940-1 Okinawa, Japan	A total of 848 consecutive sedation-free colonoscopies were evaluated in a prospective manner. Factors were recorded, including patient pain, intubation time, demographic data, history of abdominal surgery, bowel preparation status, diverticular disease, bowel habits, anxiety level, and number of previous colonoscopies. Factors were analyzed to determine their association with pain &difficulty	n= 848	The assisting endoscopy nurses and patients independently assessed the pain level immediately after the procedure by use of a four-point pain scale. Intubation time presence or absence of intubation to the cecum, demographic info, indications for colonoscopy, his- tory of abdominal surgery, history of surgery (hysterectomy and others), bowel preparation status, diverticular disease, bowel habits, anxiety level and number of previous colonoscopies were all recorded in a prospective manner.	Prospective study	None mentioned in text	BMI, younger age, first time, cecal intubation time, poor preparation, antispasmodic use, and previous hysterectomy were associated with patient pain, and lower BMI, female gender, constipation, poor preparation, and previous hysterectomy were associated with difficulty of intubation constipation, especially those with a history of abdominal hysterectomy, may require more time for colonoscopy.	All procedure performed by one endoscopist. Sedation not offered

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
34.Telford et al. (2010) The cost-effectiveness of screening for colorectal cancer CMAJ 2010 Canada	Costs were estimated using a probabilistic Markov model and quality-adjusted life expectancy of 50- year-old average-risk Canadians without screening and with screening by each test. We populated the model with data from the published literature. We calculated costs from the perspective of a third-party payer, with inflation to 2007 Canadian dollars	This article focuses on the comparison of no screening and three screening strategies: fecal occult blood test, performed annually; FIT performed annually; and colonoscopy performed every 10 years	Outlined on page 2	Cost analysis comparison	N/A	Screening for colorectal cancer is cost effective over conventional levels of willingness to pay. Annual fecal immunochemical test, or colonoscopy performed every 10 years offer the best value for the money in Canada.	Model-based economic evaluation depends on the data available in the medical literature, which is constantly evolving. The natural history of colorectal cancer is based on assumptions regarding the progression from adenoma to carcinoma and the transition time from a low-risk polyp to a malignant neoplasm. We did not include the possibility of regression of polyps

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
35. Thomson, A., et al. (2010). "Optimal sedation for gastrointestinal endoscopy: review and recommendations." Journal of Gastroenterology and Hepatology 25(3): 469-478. Australia	The present review focuses on the commonly used regimens in endoscopic sedation and the associated risks and benefits together with the appropriate safety measures and monitoring practices. In addition, alternatives and additions to intravenous sedation are discussed. Personnel requirements for endoscopic sedation are reviewed sedative drugs.	Sample size not declared in text but reference list has 77 items	Not defined	Review	Not mentioned	1.Endoscopy without intravenous sedation is not recommended as a routine practice, Pre–procedure music may help to reduce anxiety. 2. Pre–procedure assessment is essential to assess risks.3. All endoscopic patients should have IV, also reversal agents and properly trained staff 4. Propofol was seen as a superior sedative agent for endoscopy 5. Sedatives may be given by non -anaesthetists within certain parameters and dosages	This "review" did not mention search strategy and number of articles reviewed

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
36. John K Triantafillidis, Emmanuel Merikas, Dimitrios Nikolakis, Apostolos E Papalois (2013) Sedation in gastrointestinal endoscopy: Current issues *World Journal of Gastroenterology* 2013; Greece	In this review, an overview of the current knowledge concerning sedation during digestive endoscopy will be provided based on the data in the current literature.	Not disclosed	Not disclosed	Review	n/a	Thoroughly outlined many different drugs used for sedation, and special situations e.g. pregnancy and cirrhosis, chronic lung disease Also discussed legal issues and safety issues of administering sedation	Many items in ref list Data collection omitted

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
37. Wood, J. J., et al. (2012). "Does use of a colonoscopy imaging device improve performance? A cohort study." Surgical Endoscopy 26(12): 3616-3621. United Kingdom	Patients underwent colonoscopy with or without the use of a magnetic endoscopic imager.	A total of 5,879 colonoscopies were performed. A magnetic endoscopic imager was used for 4,873	Routinely collected data was used for this study	Cohort study observational study	STROBE guidelines followed	Magnetic endoscopic imager use improves patient comfort during colonoscopy but has not been shown to improve completion.	This was a nonrandomized trial although improved with logistic regression analysis.

Author, date, location	Intervention	Sample size	Data collection methods	Type of study	Validity if mentioned	Outcomes	Strengths and weaknesses
38.Ylinen et al. (2007). "Nurses' knowledge and skills in colonoscopy patients' pain management." Journal of Clinical Nursing 16(6): 1125-1133. Finland	This study aimed to describe the knowledge and skills of nurses in managing pain during colonoscopy procedures.	n = 116	Three questionnaires were mailed to the ward sister of each unit for subsequent distribution to the nurses. An instruction letter explaining the nature of the study was enclosed, and the filled-in questionnaires were returned directly to the researcher in prepaid return envelopes	A quantitative survey design was used. The data were collected from colonoscopy nurses with a self-completed semi-structured questionnaire developed for the study.	The questionnaire was pilot-tested in order to improve its content and construct validity. It is essential how reliably the researcher is able to analyse the questions and to find categories that soundly correspond to content. The material was typed out, and mutually similar expressions were categorized and ranked based their frequency of occurrence. Based on the responses to the open-ended questions, the themes were formulated inductively.	The study showed that colonoscopy nurses used numerous non–pharmacologi cal methods, but only rarely acquired professional knowledge. There was a lack of pain scales and ethical conversation in the participating endoscopy units.	Anonymity may have given the respondents an opportunity to describe their actions realistically, but they might also have described ideal actions rather than reality. The fast pace and pressure of work might have disturbed the circumstances of filling out this questionnaire and also shifted the respondents' focus and affected the quality of their answers.

Appendix E

Signed Custodian Agreement

Marg Lachance, Manager Colon Cancer Screening Centre
Foothills Medical Centre – Teaching Research and Wellness Building
3280 Hospital Drive, 6th floor
403-944-3822

October 7, 2015

As the custodian of the charts to be reviewed for the study REB15-2117, I give my permission for the charts to be accessed for this purpose. As outlined in the study, the charts will be accessed on the premises of the Forzani and McPhail Colon Cancer Screening Centre and only within the parameters outlined within the study protocol. Once the study is complete, the access to the charts will conclude. This letter will serve as the custodian agreement as required by the Health Information Act.

Marg Lachance

Appendix F

Data Collection Tool

Randomly Selected Chart	Age	BMI	Gender	Prior Surgery	Prior Sedative use	Time Sedative Given	Procedure Start time	Time Cecum Reached	Procedure End Time	Total Dose of Sedation	Comfort Score
#1	53	32	F	Y	N	1055	1055	1109	1119	50 F 4 M	5
#2	57	25	M	N	Y	1235	1236	1246	1257	50 F 3 M	3
#3	66	36	F	Y	Y	1230	1232	1248	1254	50 F 5 M	4
…											