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**DECREASING MORPHINE EQUIVALENT DAILY DOSES OF CHRONIC
NONCANCER PAIN PATIENTS**

CASEY NORRIS

by

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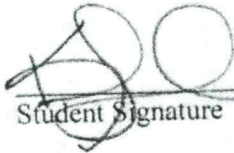
A DNP PROJECT

**Submitted in partial fulfillment of the requirements for the
Degree of Doctor of Nursing Practice
to
The School of Graduate Studies
of
The University of Alabama in Huntsville**

HUNTSVILLE, ALABAMA

2019

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Student Signature

10-9-19
Date

DNP PROJECT APPROVAL FORM

Submitted by Kelly A. Jackson in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

11/4/19 Casey D. Harris Committee Chair
(Date)

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ABSTRACT
The School of Graduate Studies
The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice

College: Nursing

Name of Candidate: Kelly. A Jackson

Decreasing Morphine Equivalent Daily Doses of Chronic Noncancer Pain Patients

Background: The increased use of prescription opioids for chronic pain has contributed to the opioid crisis in the United States. Rising opioid related deaths have prompted the development of chronic pain guidelines. These guidelines suggest opioid tapering however they offer no formal guidance.

Local problem: Nurse practitioners are the primary prescribers in chronic pain clinics and must use proper protocols to taper opioids when necessary. Unfortunately, no evidence of a tapering protocol was found, nor is there a way to assess the nurse practitioners use of a protocol for pain management.

Method: This quality improvement project was completed using the Plan-Do-Study-Act framework. The project took place in a chronic pain clinic consisting of six offices located throughout Middle Tennessee. Patients included in this project were seen for chronic pain management unrelated to recent surgeries, active cancer treatment, or opioid addiction.

Intervention: Nurse practitioners were educated on an opioid tapering protocol. Patients were identified based on elevated morphine equivalent daily doses (MEDD), aberrant behavior, or ineffective pain relief despite high dose treatment. The opioid tapering protocol was implemented by the nurse practitioners over three months with the goal of decreasing MEDD by 20% or more.

Results: Six nurse practitioners successfully tapered opioid use in chronic noncancer pain patients (n=42) by 39%. Using a paired t-test, MEDD's were compared at month one ($\mu = 191.67$, [SD = 198.03]) and after month three ($\mu = 116.35$, [SD = 122.29]), $t(41) = 5.662$. The reduction of 75.31mg was found to be statistically significant ($p = .000$, $\alpha = .05$).

Conclusion: Tapering opioids increases patient safety and compliance with chronic pain guidelines. Alternatively, there are few other options available for the management of chronic pain.

Application to Practice: Implementing a protocol to decrease the MEDD's of appropriate patients helps nurse practitioners better care for their patients while addressing overprescribing. This quality improvement project suggests that tapering opioids can be done safely and effectively while providing meaningful patient care.

Keywords: opioid reduction, tapering protocol, opioid crisis, chronic non-cancer pain, guidelines

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Decreasing Morphine Equivalent Daily Doses of Chronic Noncancer Pain Patients

The increased use of prescription opioids for chronic pain is heavily scrutinized and has contributed to the opioid epidemic in the United States. The opioid crisis was first recognized in the early 1990s with the rise of prescription opioids and the subsequent increase in opioid-related deaths (Center for Disease Control and Prevention [CDC], 2019; Liu, Pei, D., & Soto, 2019).

Before this time, opioid abuse in patients that obtained prescriptions legally was largely downplayed (Ballantyne, 2017). The substantial increase in prescription opioids for chronic non-cancer pain (CNCP) was blamed on well-meaning physicians trying to reduce patient suffering (Ballantyne, 2017; Tolba, Meselhy & Guerra, 2018). It has since been attributed to heavy influence by the pharmaceutical companies, inadequate prescribing education, illicit drug use, and potentially the dismantling of multidisciplinary pain clinics (CDC, 2019; Gatchel, McGeary, McGeary, & Lippe, 2014; Liu, Pei, & Soto, 2019, Tompkins, Hobelmann & Compton, 2017).

From 1999 to 2017, there has been a six-fold increase in drug-related deaths (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019). In 2017, 70,000 people were reported to have died from drug overdoses; 47,000 on those were caused by opioids (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019; Singer, Sullum, & Schatman, 2019; Tennessee Department of Health, 2018). An estimated 36% involving prescription opioids while 75% involved fentanyl and heroin (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019; Singer, Sullum, & Schatman, 2019; Tennessee Department of Health, 2018). This epidemic has influenced laws, the improvement of guidelines, and changed the way pain medicine is practiced.

As opioid-related death rates remain above the national average in Tennessee, the legislative body has published the most restrictive laws governing the prescribing of all controlled substances (National Institute on Drug Abuse [NIH], 2018; Tennessee Department of

Health, 2019). These chronic pain guidelines have specific suggestions including regulating morphine equivalent daily doses (MEDD); the measurement used to compare all opioids to an equivalent dose of morphine. The guidelines suggest single opioid providers, starting MEDD of 40mg, MEDD's greater than 120mg should be referred to a pain specialist, compliance monitoring standards such as urine drug screens and review of the Controlled Substance Monitoring Database (CSMD), and reasons for opioid tapering such as side effects, aberrant behavior, poor efficacy, or financial hardship (Tennessee Department of Health, 2019). According to these guidelines, multiple opioid tapering protocols exist; however, none are referenced, nor is there a protocol that they suggest (Tennessee Department of Health, 2019).

The opioid crisis coupled with tightening of legislation nationwide has caused primary care providers to have reservations about prescribing opioids (Chealte & Savage, 2012; Cicero, 2018; Dineen & Dubois, 2016; Gellard, Good & Shulkin, 2017; NIH, 2018). A lack of evidence proving the efficacy of long-term opioid therapy is also prompting significant opioid tapering by physicians (Berna, Kulich & Rathmell, 2015; Gellard, Good & Shulkin, 2017; Matthias et al., 2017). These physicians are referring more patients with chronic pain to pain management clinics where treatment is often provided by nurse practitioners (NP) (Schneider, 2008).

Nurse practitioners have an opportunity to be part of the solution to the opioid crisis. They must use the appropriate tools and understand their patient's perception of pain (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019). Protocols are used to maintain standardization of care, decrease the variation of care, and are built using evidence-based practice (Baylis, 2013). Multiple opioid tapering protocols have been published. Unfortunately, there is no evidence of use in a chronic pain management setting, nor is there a way to assess the

NP's use of a protocol for pain management. The use of a tapering protocol would allow NP's to address patient concerns while maintaining consistency amongst providers.

The purpose of this quality improvement (QI) project was to improve the use of a protocol in a chronic pain management setting that will help NP's decrease MEDD's while maintaining pain control and reducing the risk of withdrawal or aberrant behavior. The aim of this project was to determine if a tapering protocol would help nurse practitioners lower the MEDD by 20% or more over three months in chronic non-cancer pain patients.

A common factor in opioid overdose is the combined use of benzodiazepines and opioids (Peirce et al. 2019). Studies show that the risk of overdose increases 10-fold in patients using both opioids and benzodiazepines (Dasgupta et al., 2016; Hirschtritt, Delucchi, & Olfson, 2018). With this in mind, a secondary outcome was developed to determine if there was a difference in the total percentage of MEDD decrease in patients who were prescribed benzodiazepines and opioids compared to patients only prescribed opioids.

Synthesis of Evidence

A literature review was conducted using the Cumulative Index to Nursing and Allied Health Index (CINAHL), Education Resources Information Center (ERIC), PubMed, ProQuest, and Science Direct databases using the University of Alabama, in Huntsville's online library with the keywords; opioid reduction, opioid weaning, weaning protocol, taper, nursing protocols, opioid crisis, chronic pain, chronic non-cancer pain, Morphine Equivalent Daily Dose, and benzodiazepines. Additional parameters included articles published between 2013 and 2019, peer-reviewed, available online, and full-text articles. A total of 50,206 articles were identified. After careful review of articles for relativity to the project, 57 were chosen for inclusion. Abstracts were read to determine significance. Articles were discarded based on the age of the

patient population, practice setting, and disease process. Twenty articles were found to be relevant to the topic. Three common themes emerged; insufficient examination of tapering protocols, patients fear of tapering, and insufficient evidence of the benefits of long-term opioid use in CNCP (Berna, Kulich & Rathmell, 2015; Eccleston et al., 2017; Frank et al., 2016; Sullivan et al., 2016; Sundhu et al., 2018). Opioid tapering is often done due to over prescribing, aberrant behavior, or ineffective treatment regardless of elevated doses. Tapering too rapidly or without consideration to the patients' needs can be harmful. Patients can experience withdrawal, unnecessary increases in pain, or feel forced to seek medication illegally. Using an opioid tapering protocol could prevent these unnecessary outcomes.

Insufficient Evidence of Tapering Protocols

There was little evidence to support a particular method of tapering elevated MEDD's of CNCP in chronic pain management clinics (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Sullivan et al., 2016; Sundhu et al., 2018). However, the CDC, Tennessee, and Washington State guidelines advise starting tapering by ten percent of the current MEDD (Agency Medical Directors Group, 2015; Dowell, Haegerich, & Chou, 2016. Tennessee Department of Health, 2019). Noted in the CDC Guidelines for Prescribing Opioids for Chronic Pain, no high-quality studies had been found to compare tapering protocols (Dowell, Haegerich, & Chou, 2016). Multiple Chronic pain guidelines suggested a need to taper opioids but gave no recommendations for a specific protocol or formal guidance (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019; Sundhu et al., 2018).

The lack of formal guidance has left opioid tapering at the discretion of the providers and can be inconsistent (Berna, Kulich & Rathmell, 2015). The CDC guidelines are being implemented in many settings as strict regulations (Dowell, Haegerich & Chou, 2019; Kroenke

et al., 2019). Improper use of the guidelines has caused strict dosage limitations, abrupt tapering of high-dose therapy, and regulations by policymakers that limit or mandate prescription coverage (Dowell, Haegerich & Chou, 2019; Kroenke et al., 2019; Kertesz & Gordon, 2019).

Non-opioid intervention and psychological therapy is an essential aspect of the chronic pain guidelines that are often underutilized or have inadequate reimbursement (Dowell, Haegerich & Chou, 2019). Interventions such as acupuncture, mindfulness, and cognitive-behavioral therapy have been studied, but the data is too small to determine if these interventions decrease opioid use (Eccleston et al., 2017; Sandhu et al., 2018). With multiple reasons why a provider would begin an opioid taper, having a protocol in place will help patients and providers maintain consistent care and avoid frustration (Henry et al., 2019).

Only one study was found in an outpatient pain clinic that evaluated an opioid tapering protocol. Sullivan et al. (2016) conducted a randomized control trial to assess an opioid tapering support protocol in patients that wanted to reduce their MEDD by 50%. The patient's doses were reduced by 10% each week for the first three weeks, then by 10% of the recalculated dose each week after that (Sullivan et al., 2016). Thirty-five patients were randomized into the "usual care" group or the "taper support" group (Sullivan et al., 2016) The "usual care" group continued their usual care with no change whereas the "support" group received weekly visits, motivational interviewing, self-management training, and cognitive-behavioral therapy (Sullivan et al., 2016). Their results show that they were successful in tapering the MEDD's of the patients but yielded no statistical difference between the groups (Sullivan et al., 2016). The small sample size of this study could be attributed to their recruiting method of patient willingness to taper. Of the 144 patients referred, 76 declined because they did not want to or were afraid to taper (Sullivan et al., 2016).

Patients Fear of Opioid Tapering

Patient's fear of opioid tapering is a significant concern to address when beginning a tapering protocol. Multiple studies show fear to be a primary barrier to successfully tapering MEDD's. These fears included a substantial increase in pain, withdrawal, ineffective treatment with non-opioid modalities, decrease in functional ability, and effect on social relationships (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019; Sullivan et al., 2017; Sandhu et al., 2018).

Berna, Kulich & Rathmell (2015), Frank et al. (2016), and Sullivan et al. (2017) found that patients fear an increase in pain during tapering more than the side effects caused by long-term opioid use. Opioid withdrawal was the second most reported concern due to previous experience with withdrawal or fear of the accompanying symptoms (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019; Sandhu et al., 2018). The ineffectiveness of non-opioid treatment such as surgical procedures, injections, and non-opioid medications led patients to believe their pain could not be controlled in the absence of opioids (Frank et al., 2016). Finally, patients were afraid that tapering opioids would cause decreased functional ability and effect social relationships by hindering their ability to work and fulfill family roles (Henry et al., 2019). Interestingly, Ballantyne (2017) found that CNCP patients more often than not self-report pain as 10/10 even on high doses of opioids while maintaining that their opioid treatment is working. Also surprising is that risk of addiction and overdose are not considered relevant to these patients even in light of the current opioid crisis (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019).

Insufficient Evidence of Long-Term Opioid Use

High doses of opioids put patients at increased risk of overdose and death. Due to the lack of evidence of long-term opioid use in CNCP, opioid tapering is suggested and may help reduce these risks in certain patients (Agency Medical Directors Group [AMDG], 2015; Dowell, Haegerich, & Chou, 2016; Tennessee Department of Health, 2019). To better determine the efficacy of long-term opioid use and elevated MEDD's, the Center for Disease Control and Prevention (CDC) commissioned two studies, a systematic review of available studies conducted by Chou et al. (2015) and a contextual analysis of population data (Ballantyne, 2017; Tolba, Meselhy & Guerra, 2018). While both reported strong evidence of increased risk of long-term opioid use, neither effort found evidence to support the efficacy of long-term opioid use for CNCP (Ballantyne, 2017; Chou et al., 2015; CDC, 2016). Reuben et al. (2015) and Zhou & Warycha (2012) also cited a lack of evidence in long-term opioid use; however, they point out that due to inadequate research for alternatives, opioids therapy is the most effective option for patients suffering from chronic pain.

Combine Use of Benzodiazepines and Opioids

From 2004 to 2011, benzodiazepine use reported in cases of opioid overdose deaths increased from 18% to 31% (Hirschtritt, Delucchi, & Olfson, 2018). Jones, Mogali, & Comer (2012) published a review on polydrug use and the combination of these two medication classes. They discovered that combined use of these medications is more prominent in people using them recreationally, patients using them at "less than therapeutic" doses to supplement undermanaged pain, and patients being treated for chronic pain (Jones, Mogali, & Comer, 2012). Pierce et al. (2019) found that combined use is also attributed to those with a history of physical abuse and its effect on chronic pain and anxiety. The most-reported type of pain in patients

prescribed both opioids and benzodiazepines are chronic back and hip pain (Hirschtritt, Delucchi, & Olfson, 2018). Anxiety disorders are increasingly prevalent in patients that suffer chronic pain; thus, the combined use of these medications (Cheatle & Shmuts, 2015). The continued dependence on both benzodiazepine and opioids, alone or in combination, is a suspected consequence of the dismantling of multidisciplinary pain clinics (Cheatle & Shmuts, 2015; Gatchel et al., 2014; Schatman, 2012). No study was found that discussed dose correlations between benzodiazepines and opioids.

Framework

This QI project was completed using the Plan-Do-Study-Act (PDSA) framework. The PDSA cycle was developed for the use in quality improvement initiatives using a systematic, rapid-cycle approach (Polancich, Roussel, & Miller., 2017). The PDSA cycle is used to help determine a need, implement a change, analyze the information collected, then dissemination of the data (Polancich, Roussel, & Miller., 2017).

Methodology

Setting

This QI project took place in a nurse practitioner run chronic pain management clinics in the southeast region of the United States. The clinics are located in six cities throughout Middle Tennessee. They include one central office with five satellite clinics. The distance between the satellite clinics range from 40 to 70 miles from the central office. There are two physicians and seven NP's who staff the six clinics. Each NP sees an average of 20 to 25 patients per day.

Participants

Six of the seven NP's participated in the QI project. Participation was not voluntary. Additionally, participants were asked to take part in a post-intervention evaluation to assess their opinions on the ease of use of the protocol (Appendix A).

Tapering Tool

The RxFiles Opioid Tapering Template was used for this QI project (Appendix B). The Associate Director of RxFiles granted permission for the use of the RxFiles Opioid Tapering Template (Appendix C). The protocol provides practitioners with considerations when tapering opioids (RxFiles Academic Detailing, 2018). It provides guidance in the patient discussion, goal setting, time frames for fast or slow tapers as well as beginning taper increments suggestions of five to ten percent (RxFiles Academic Detailing, 2018). The protocol discussed the use of long-acting opioids as well as short-acting opioids and daily dosing if required. Methods to combat opioid-related side effects, the anticipation of increased pain and withdrawal were provided to include medication and dosages (RxFiles Academic Detailing, 2018). The protocol recommends an interdisciplinary approach for complex patients and tips for holding or secession of taper (RxFiles Academic Detailing, 2018). Finally, the protocol contains easy to use taper scheduling handouts that can be given to the patient so that both patient and provider can track progress together (RxFiles Academic Detailing, 2018).

Intervention and Data Collection

The “plan” phase was accomplished during a staff meeting where participants were given information regarding the opioid crisis, the lack of evidence supporting long-term opioid use and high dose opioids, and why tapering opioids is essential. The selected opioid tapering protocol was disseminated to each NP. The participants were allowed to ask questions at any time during

the meeting. Inclusion criteria included adult patients with chronic pain and patients treated with opioids for greater than six months. Exclusion criteria included patients being treated for cancer or substance abuse, patients with implanted pain pumps, surgery within the last three months, and previous suicide attempts.

The "do" phase was implementing the protocol into practice. Participants flagged charts of patients; they determined appropriate for opioid tapering by initiation an "action" in the electronic medical records (EMR) system. Nurse Practitioners completed patient teaching explaining the need and method of tapering opioids. Care plan adjustments were made based on the patient's individual needs. Opioid tapering was accomplished following the provided protocol over three months. Patient charts were reviewed each visit to monitor pain scores, Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) scores, Current Opioid Misuse Measures (COMM) scores, their CSMD, and urine drug screens. Based on compliance, the physical exam, and patient interview, the NP determined if the opioid medication was tapered farther, the taper was held, or in some cases, stopped. Data was collected each month and entered into a spreadsheet.

The "study" phase included the collection of the initial and final MEDD, benzodiazepine use as well as a post-intervention evaluation. Data collected were analyzed using SPSS statistical software. The analysis included descriptive statistics of the patients' initial MEDD, MEDD at each visit over the three months, the percentage of each reduction, and the total percentage of reduction after the three months. A paired t-test was done to compare the patients' initial and final MEDD's to determine the effectiveness of the opioid tapering protocol. This test was determined to be appropriate to evaluate the difference between the two variables while having a limited sample size (Kim, 2015). An ANOVA was conducted comparing the co-use of

benzodiazepines and opioids, those that solely use opioids, and the effect on the total percent decrease in MEDD.

At the end of the project the six participating NP's were emailed an eight-question evaluation regarding the effectiveness of the protocol (Appendix A). Seven questions used a five-point Likert scale ranging from "strongly disagree" to "strongly agree" and one open-ended question for protocol improvement suggestions. Participants were given seven days to complete the survey with one reminder email sent on the fourth day. No demographic questions were asked; however, the small group of participants answering the survey questions were well known to each other, decreasing the likelihood of anonymity.

The "act" phase included assessing the protocol for effectiveness and how it could be used in the improvement of clinical practice and company policy. Limitations and recommendations were assessed and disseminated to all providers within the practice.

Ethical Considerations

Institutional review board (IRB) approval was granted for this project by the University of Alabama in Huntsville (Appendix D). This was a quality improvement project designed to determine the efficacy of an opioid tapering protocol. There was a risk of withdrawal to patients; however, treatment for this is built into the protocol. Tapering was done at a slow pace to avoid withdrawal symptoms.

Informed consent was obtained from NP's willing to participate (Appendix C). The participating NP's were not compensated, and no regular patient care was modified. There was no cost to the providers or the clinic involved in this project.

Patient consent to participate in this project was not requested. All patients attending the clinic sign a Notice of Privacy Policies & Practice allowing the use of their personal health

information (PHI) for research purposes and the advancement of medical education (Appendix F). No personal data was collected, and CNCP patients are often unwilling to taper; taking this into consideration an IRB exemption form was submitted. Recommendations made by Sullivan et al. (2017) after patient willingness to taper yielded poor participation rates in their study supports this.

No identifying participant or patient information was recorded. Data was collected and input directly into SPSS. Data was stored on an encrypted file on a password-protected laptop stored in a locked cabinet in the DNP student's office.

Results

Seventy-two patients were initially identified that were deemed appropriate to have opioids tapered. Tapering was due to inappropriate dosing, aberrant behavior, lack of adequate pain control despite high doses, or side effects. Thirty-three patients were lost to attrition (figure 1). Three patients moved out of the area, five were identified but not tapered, one developed a new disease process, one did not return to the office after their initial visit, five carried Blue Cross Blue Shield of Tennessee insurance and were required to be placed on a long-acting opioid temporarily increasing their MEDD, five due to surgery or acute injury, three lost referral or insurance was no longer in-network, three were tapered appropriately but outside of study limitations, four were increased by a different provider, two were discharged due to aberrant use, and one was allowed to return to original MEDD. It should be noted that the two patients removed for aberrant behavior were tapered following the protocol using a rapid taper of 10% every two weeks for three weeks. Both prescribed MEDD's below 60, so were deemed safe for a rapid taper.

Data from 42 patients were used for analysis. Patients were required to come to their usually scheduled monthly visits and were monitored over three months. All appointments were conducted at 26 to 30-day intervals. No demographics or identifying data were collected to include the patient diagnosis for which they are receiving opioid pain medications. Patients were withdrawn if they missed a visit during the three months or for deviation of the protocol. Patients monitored in the project share similarities with the majority of patients being treated with opioid therapy for CNCP. Patients care plans included single opioid therapy, combination therapy with a long-acting and short-acting opioid, or combinations of opioids and benzodiazepines. All project variables were entered into SPSS, so to assess descriptive statistics (Table 1).

Comparison Between Initial and Final Morphine Equivalent Daily Dose

A paired t-test was conducted to assess the NP's effective use of the protocol by comparing the MEDD at the patient's initial taper, and their MEDD after the third visit. We recorded each patients MEDD at month one ($\mu = 191.67$, [SD = 198.03]) and their MEDD after month three ($\mu = 116.35$, [SD = 122.29]), $t(41) = 5.662$. The reduction of 75.31mg was found to be statistically significant ($p = .000$, $\alpha = .05$). The total percent decrease in MEDD exceeded the 20% goal, with an average of 39.62%. Only two patients fell below the goal tapering 12.2% and 16.67

Relationship Between Concomitant Benzodiazepine and Opioid Use, Sole Opioid Use, and the Total Percentage Decreased

The 42 patients in this project were assessed for benzodiazepine use. A one-way ANOVA was conducted to evaluate the efficacy of the tapering protocol on patients prescribed both benzodiazepines and opioids, compared to patients only prescribed opioids. Patients prescribed both benzodiazepines and opioids had an average MEDD decrease of $\mu 38.84\%$ (SD = 16.21%),

=15.10%). A t-test reveals that a 1.12mg difference is not statistically significant ($p = .830$, $\alpha = .05$), suggesting that neither the co-use of benzodiazepines nor sole use of opioids affected patients opioid tapering. It should be noted that none of these patients had any known history of substance abuse or non-compliance with medication regimens.

Post Intervention Questionnaire

The six NP's completed the questionnaire at the end of the three months (Table 2). The questions included their thought on the protocol's ease of use, effectiveness, patient tolerance and compliance, use of other modalities, and future use. All of the NP's answered "agree" or "strongly agree" to the use, effectiveness, and future use of the protocol. Two NP's were neutral on patient compliance, and half of the group were neutral as to whether other modalities were helpful during tapering.

Discussion

Multiple aspects of patient care were assessed while implementing an opioid tapering protocol in a chronic pain clinic. The participating NP's successfully exceeded the goal of tapering MEDD's greater than 20%. It was also determined that benzodiazepine use in the group of patients did not affect their ability to taper.

Some doses were decreased greater than 10% due to the MEDD of different opioids or simple quantity adjustments. For example, oxycodone-acetaminophen 10-325mg four times a day has a MEDD of 60, a decrease to three times a day is a MEDD of 45 equaling a 25% decrease. Even if this medication were decreased to three and a half tablets a day, this would be a MEDD of 52.5mg and a 12.5% decrease. Methadone has an extended half-life and can have significant shifts in MEDD with a 5mg decrease. All MEDD's were calculated using the

Washington State Agency Medical Directors' Group's Opioid Dose Calculator to maintain consistency (Agency Medical Directors' Group, 2015).

The attrition rate was significant and could not be avoided in some cases. Several patients are no longer being treated at the facility, and new medical complications could have falsely skewed data. Attrition due to provider oversight could have been avoided with improved communication and including all medical personal at the initial presentation. Finally, five patients carried Blue Cross Blue Shield of Tennessee and were required to be placed on an approved long-acting opioid causing an increase in their MEDD. This prescribing mandate by the insurance company was made in response to the opioid crisis and the latest chronic pain guidelines (Anson & Farmer, 2018). Mandates like this can be considered extreme and limit medication that patients have otherwise been stable taking. While the insurance company reports a significant decline in prescribed opioid claims over that last three years, overdose rates in 2018 were at a record high with more than half related to illegal opioids (Anson & Farmer, 2018; NIH, 2018).

Several tools are used in chronic pain clinics to assess patients' risk when prescribed opioids and pain levels. The clinic in which this project was conducted collects an Opioid Risk Tool (ORT) at the new patient visit and SOAPP-R and COMM scores in three-month rotations throughout the year. During the development of this project, we intended to assess the SOAPP-R and COMM scores of each patient to discern any correlation between those scores and the patient's MEDD. Incidentally, during a routine chart audit by the company attorney, it was discovered that the SOAPP-R was being delivered incorrectly. The purpose of the SOAPP-R is to aid prescribers in predicting the risk of abuse and aberrant behavior before beginning chronic opioid therapy (Butler, Fernandez, Benoit, Budman, & Jamison, 2008). Due to the ORT

conducted at the new patient visit, it was decided to remove the SOAPP-R from the assessment rotation. The removal date of the SOAPP-R caused a fluctuation in the rotation of the COMM. At the end of the project, 15 patients had SOAPP-R scores, and only seven had COMM scores. It was determined that the incorrect use of the SOAPP-R and the small number of COMM scores would not have yielded any significant data useful to this project, so it was removed.

When determining if a patient is appropriate to taper their pain level is an obvious concern; however, pain is subjective. Elevated pain scores can make it difficult for providers when making care decisions. The 42 patients' pain scores were assessed at each visit via the patient tablet. They were asked to rate their "current," "least," "usual," and "worst" pain on a scale of 0-10. These self-reported scores were often missing or thought to be exaggerated when held against physical assessment and patient interviews. During the chart review, 15 of the 42 patients were found to have not rated all of their pain. For these 15 patients, 25% of their pain scores were not captured.

Three recent studies were available that discussed self-reported pain levels that are pertinent when considering tapering. Chronic pain patients commonly report high pain levels, often 10 out of 10 (Ballantyne, 2017). The increased self-reported pain scores are thought to be caused by tolerance, dependence, and fear of opioid tapering if adequate pain control is reported (Ballantyne, 2017; Elman & Borsook, 2016). They are also attributed to changes in the reward pathway after long term opioid use; the patient becomes overly sensitized to pain and is in a state of hyperalgesia (Ballantyne, 2017; Elman & Borsook, 2016).

Chen et al. (2013) completed a retrospective analysis on 109 chronic pain patients on long-term opioid therapy treated for an average of one year and 11 months. They assessed self-reported pain scores against age, gender, nociceptive, neuropathic, mixed pain, as well as; dose

increase, decrease, and continuation (Chen et al., 2013). Their results show no statistical difference in self-reported pain scores were seen in any of the groups (Chen et al., 2013). Thorough patient interviews can help NP's navigate pain levels.

Recommendations

The findings of this project support the need for a more extensive study, with more patients, over a more extended period. If implemented on a large scale, decreasing inappropriately high opioid use in CNCP patients will improve patient outcomes. Decreasing high-dose opioids can reduce the risk of accidental overdose as well as help combat one aspect of the current opioid crisis.

A charting macro or dot phrase documented in a specific location in the patient chart is helpful for consistency amongst providers. Specific reasons for tapering should be documented along with the patients' progress at each visit. While this project focused on the NP's ability to use the protocol, all providers seeing patients in the clinic should be educated on its use to prevent variations in patient care.

Active participation in the patient's pain management should be strongly encouraged. Patients prescribed opioids often need a significant amount of support and patient teaching. An up to date list of support groups, mental health facilities, and primary care providers should be kept available for patients that require or request assistance.

Limitations

Several limitations were discovered during this project. The most notable is the lack of participation by NP's. One NP chose not to participate, two provided one patient each, and a third identified six patients; however, only tapered three.

Second, was the patient's inability to taper. The inability to taper was only seen in one patient who was removed after the initial attempt to decrease at seven percent significantly affected his quality of life. After a discussion with the overseeing physician, the decision was made to revert to the original dose.

Third, as Ballantyne (2017) noted, CNCP patients often self-report a 10/10 on a pain scale. This potentially causes the NP to question if tapering is appropriate regardless of their physical assessment and patient interview. It was also noted during data collections that 9% of patients did not report pain scores on the patient check-in tablet.

Fourth was provider oversight. Four patients were removed for significant dose increases after seeing a different provider. It is suspected that not only was the provider unaware that the patients were being tapered, but that the patients requested to switch clinics due to the opioid taper. One patient tapered for two months, changed clinics, receiving an increase back to the original dose, and documentation for that visit states that the patient would need to begin tapering.

Finally, self-reported answers may be positively biased. To avoid interprofessional conflict, the NP's responses to the post-intervention evaluations are potentially munificent. All NP's answered positively to ease of use, overall effectiveness, and continued use of the protocol despite the lack of participation.

Application to Practice

This project supports the use of a tapering protocol within a chronic pain management clinic by achieving an average reduction of MEDD's by 39.6% over three months. When applied to practice, tapering protocols assist NP's in safely and effectively decreasing patient's MEDD's while addressing fears and avoiding adverse effects. With proper use, the protocol provides

consistency when patients see multiple providers within a clinic. The protocol used in this project allows for individualization depending on the patient's needs and promotes provider-patient communication.

Summary

Addressing prescription opioid overuse is only a small aspect of the current national crisis. Along with the lack of evidence of their efficacy, long term, high-dose opioid usage puts patients at increased risk of overdose, addiction, and hyperalgesia. When tapering opioids is necessary, the risks as well as the patient's disease process, comorbidities, history of opioid use, and socioeconomic status must be considered. Tapering inappropriate doses of opioids increases patient safety and compliance with chronic pain guidelines. Alternatively, at this time, there are few other options available for the management of chronic pain.

It must be understood by the medical community and the general public that legally, safely prescribed opioids, even at high doses, are not the crux of the opioid crisis. When used as intended, protocols and guidelines provide considerations for improving patient outcomes. The guidelines should not be used as strict rules, as this could potentially perpetuate the opioid crisis.

Implementing a protocol to decrease the MEDD's of appropriate patients helps NP's better care for their patients while addressing overprescribing. Listening to patient concerns allows the patient to be part of their care plan while giving them a sense of control. This project suggests that tapering opioids can be done safely and effectively for both clinicians and patients while providing meaningful patient care.

Professional Journal Selection

The completed manuscript will be submitted to The Journal of the American Association of Nurse Practitioners (JAANP). Established in 1989, this journal provides up-to-date information to advanced practice nurses regarding evidence-based research, career advancement, professional development, and clinical practice. The journal seeks a broad range of peer-reviewed topics to include; continuing education, advanced practice nursing outcome research, economic research, systematic reviews and meta-analyses of health care interventions, health policy analysis, and quality improvement projects. Submissions for quality improvement projects must follow SQUIRE guidelines, contain a structured abstract, and allow for a max text count of 4,500 words excluding the allowed 30 references and up to five tables and figures. The Journal of the American Association of Nurse Practitioners is a closed access journal published monthly for registered members of the American Association of Nurse Practitioners. The Journal of the American Association of Nurse Practitioners is an appropriate journal for this manuscript submission. Manuscript submission can be seen in Appendix G.

Decreasing Morphine Equivalent Daily Doses of Chronic Noncancer Pain Patients

Abstract

Background and Local Problem: Rising opioid related deaths have prompted the development of chronic pain guidelines. These guidelines suggest opioid tapering when necessary however they offer no formal guidance. Unfortunately, no evidence of a tapering protocol was found, nor is there a way to assess the nurse practitioners use of a protocol for pain management.

Method and Intervention: This quality improvement project was completed using the Plan-Do-Study-Act framework. Nurse practitioners implemented an opioid tapering protocol into practice over three months to taper opioids in chronic noncancer pain patients by 20% or more.

Results: Six nurse practitioners successfully tapered opioid use in chronic noncancer pain patients (n=42) by 39%. MEDD at month one ($\mu = 191.67$, [SD = 198.03]) and their MEDD after month three ($\mu = 116.35$, [SD = 122.29]). The reduction of 75.31mg was found to be statistically significant ($p = .000$, $\alpha = .05$).

Conclusion: Tapering opioids increases patient safety and compliance with chronic pain guidelines. Alternatively, at this time, there are few other options available for the management of chronic pain.

Application to Practice: Implementing a protocol to decrease the MEDD's of appropriate patients helps NP's better care for their patients while addressing overprescribing. This QI project suggests that tapering opioids can be done safely and effectively while providing meaningful patient care.

Keywords: opioid reduction, tapering protocol, opioid crisis, chronic non-cancer pain, guidelines

Decreasing Morphine Equivalent Daily Doses in Chronic noncancer Pain Patients

Introduction

Background knowledge

The increased use of prescription opioids for chronic pain has contributed to the opioid crisis in the United States. The opioid crisis was first recognized in the early 1990s with the rise of prescription opioids and opioid-related deaths (Center for Disease Control and Prevention [CDC], 2019; Liu, Pei, D., & Soto, 2019). The increase in prescription opioids was blamed on well-meaning physicians trying to reduce patient suffering (Ballantyne, 2017; Tolba, Meselhy & Guerra, 2018). It has since been attributed to influence by pharmaceutical companies, inadequate prescribing education, illicit drug use, and potentially the dismantling of multidisciplinary clinics (CDC, 2019; Gatchel, McGeary, McGeary, & Lippe, 2014; Liu, Pei, & Soto, 2019).

From 1999 to 2017, there has been a six-fold increase in drug-related deaths (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019). In 2017, 70,000 people died from drug overdoses; 47,000 caused by opioids (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019; Singer, Sullum, & Schatman, 2019; Tennessee Department of Health, 2018). An estimated 36% involving prescription opioids while 75% involved fentanyl and heroin (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019; Singer, Sullum, & Schatman, 2019; Tennessee Department of Health, 2018).

As opioid-related death rates remain above the national average in Tennessee, the most restrictive chronic pain guidelines have been published (National Institute on Drug Abuse [NIH], 2018; Tennessee Department of Health, 2019). These chronic pain guidelines have specific suggestions including regulating morphine equivalent daily doses (MEDD); the measurement used to compare all opioids to an equivalent dose of morphine. The guidelines suggest; single opioid prescriber, starting morphine equivalent daily doses (MEDD) below 40mg, MEDD's

greater than 120mg should be referred to a pain specialist, compliance monitoring such as urine drug screens and review of the Controlled Substance Monitoring Database (CSMD) (Tennessee Department of Health, 2019). They also suggest opioid tapering due to side effects, aberrant behavior, poor efficacy, or financial hardship (Tennessee Department of Health, 2019). The guidelines state that multiple opioid tapering protocols exist; however, none are referenced or suggested (Tennessee Department of Health, 2019).

A literature review was conducted using the Cumulative Index to Nursing and Allied Health Index (CINAHL), Education Resources Information Center (ERIC), PubMed, ProQuest, and Science Direct databases using the University of Alabama, in Huntsville's library with keywords; opioid reduction, weaning, weaning protocol, taper, nursing protocols, opioid crisis, chronic pain, chronic non-cancer pain, Morphine Equivalent Daily Dose, guidelines, and benzodiazepines. Additional parameters included articles published between 2013 and 2019, peer-reviewed, available online, and full-text articles. A total of 50,206 articles were identified. After careful review of articles for relativity to the project, 57 were chosen for further review. Abstracts were read to determine significant. Articles were discarded based on the age of the patient population, practice setting, and disease process. Twenty articles were found to be relevant to the topic. Three common themes were; insufficient evidence of tapering protocols, patients fear of tapering and insufficient evidence of the benefits of long-term opioid use in CNCP (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Sullivan et al., 2016; Sundhu et al., 2018). Opioid tapering is often done due to over prescribing, aberrant behavior, or ineffective treatment regardless of elevated doses. Tapering too rapidly or without consideration to the patients' needs can be harmful. Patients can experience withdrawal, unnecessary increases in

pain, or feel forced to seek medication illegally. Using an opioid tapering protocol could prevent these unnecessary outcomes.

Insufficient Evidence of Tapering Protocols

The CDC, Tennessee, and Washington State guidelines advise tapering by ten percent of the MEDD but provide no recommendations for a protocol or formal guidance MEDD (Agency Medical Directors Group, 2015; Dowell, Haegerich, & Chou, 2016. Tennessee Department of Health, 2019). Noted in the CDC Guidelines for Prescribing Opioids for Chronic Pain, high-quality studies have been found to compare tapering protocols (Dowell, Haegerich, & Chou, 2016). The lack of guidance has left tapering to the providers and is inconsistent (Berna, Kulich & Rathmell, 2015). Providers are strictly implementing the CDC guidelines into daily practice (Dowell, Haegerich & Chou, 2019; Kroenke et al., 2019). The improper use of the guidelines has causing harsh dosage limitations, abrupt tapering, and prescription regulations that limit or mandate coverage (Dowell, Haegerich & Chou, 2019; Kroenke et al., 2019; Kertesz & Gordon, 2019).

Only one study was found in an outpatient pain clinic that evaluated an opioid tapering protocol. Sullivan et al. (2016) assessed an opioid tapering support protocol used to reduce patient's MEDD by 50% (Sullivan et al., 2016). Over three years, 35 patients were randomized into two tapering groups. The "usual care" group continued their usual care with no change, whereas the "support" group received weekly visits, motivational interviewing, self-management training, and cognitive-behavioral therapy (Sullivan et al., 2016). They were successful in tapering but yielded no statistical difference between groups (Sullivan et al., 2016). The small sample size is attributed to their recruiting method of patient willingness to taper. Of 144 patients referred, 76 declined because they did not want, or were afraid to tapering (Sullivan et al., 2016).

Patients Fear of Opioid Tapering

Multiple studies found fears including; increased pain, withdrawal, ineffective treatment with non-opioid modalities, decrease function, and effect on relationships to hinder tapering opioids (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019; Sullivan et al., 2017; Sandhu et al., 2018). Berna, Kulich & Rathmell (2015), Frank et al. (2016), and Sullivan et al. (2017) found that patients fear an increase in pain during tapering more than the side effects caused by long-term opioid use. Opioid withdrawal was a concern due to previous experience or the accompanying symptoms (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019; Sandhu et al., 2018). The ineffectiveness of surgery, injections, and non-opioid medications led patients to believe their pain could not be controlled without opioids (Frank et al., 2016). Finally, patients were afraid that tapering would cause decreased function and effect relationships by hindering their ability to work or fulfill family roles (Henry et al., 2019). The risk of addiction and overdose were not considered relevant to these patients (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019)

Insufficient Evidence of Long-Term Opioid Use

Due to the lack of evidence of long-term opioid use, tapering is suggested to reduce these risks of overdose and death (Agency Medical Directors Group [AMDG], 2015; Dowell, Haegerich, & Chou, 2016; Tennessee Department of Health, 2019). To better determine the efficacy of long-term and high-dose opioid use, the CDC commissioned two studies, a systematic review of current data and a contextual analysis of population data (Ballantyne, 2017; Chou et al., 2015; Tolba, Meselhy & Guerra, 2018). Both reported strong evidence of increased risks with long-term opioid use, but neither found evidence to support the efficacy (Ballantyne, 2017; Chou et al., 2015; CDC, 2016). Despite the lack of evidence of efficacy, research for

alternatives is inadequate, leaving opioids as the most effective option for patients with chronic pain (Reuben et al., 2015; Zhou & Warycha, 2012).

Combine Use of Benzodiazepines and Opioids

From 2004 to 2011, benzodiazepine use reported in opioid overdose deaths increased from 18% to 31% (Hirschtritt, Delucchi, & Olfson, 2018). Jones, Mogali, and Comer (2012) published a review on the combination of these two medication classes. They discovered combined use is more prominent in; recreational use, use at "less than therapeutic" doses to supplement undermanaged pain, and use in patients being treated for chronic pain (Jones, Mogali, & Comer, 2012). Pierce et al. (2012) also report combined use in patients with a history of physical abuse. Anxiety disorders are prevalent in CNCP patients; thus, the combined use of these medications (Cheatle & Shmuts, 2015). No study was found that discussed dose correlations between benzodiazepines and opioids.

Local problem, rational, and framework

Patients are being referred to pain management clinics where treatment is often provided by nurse practitioners (NP). Nurse practitioners must use the appropriate tools and understand their patient's perceptions of pain when prescribing opioids pain (Berna, Kulich & Rathmell, 2015; Frank et al., 2016; Henry et al., 2019). Protocols are used to maintain standardization of care. Multiple opioid tapering protocols have been published. Unfortunately, no evidence of use in a chronic pain management setting, nor is there a way to assess the NP's use of a protocol for pain management.

This QI project was completed using the Plan-Do-Study-Act (PDSA) framework. The PDSA cycle was developed for quality improvement initiatives using a systematic, rapid-cycle approach (Polancich, Roussel, & Miller., 2017). The PDSA cycle is used to help determine a

need, implement a change, analyze the information collected, then dissemination of the data (Polancich, Roussel, & Miller., 2017).

Clinical question

The purpose of this quality improvement (QI) project is to improve the use of a protocol in a chronic pain management setting that will help NP's decrease MEDD's while maintaining pain control and reducing the risk of withdrawal or aberrant behavior. The aim of the project was to prove that a tapering protocol would help nurse practitioners lower the MEDD by 20% or more over three months in chronic non-cancer pain patients.

A common factor in opioid overdose is the combined use of benzodiazepines and opioids (Peirce et al. 2019). Studies show that the risk of overdose increases 10-fold in patients using both opioids and benzodiazepines (Dasgupta et al., 2016; Hirschtritt, Delucchi, & Olfson, 2018). With this in mind, a secondary outcome was developed to determine if there was a difference in the percentage of MEDD decrease in patients who were prescribed benzodiazepines and opioids compared to patients only prescribed opioids.

Methods

Setting, participants, and tool

This project was implemented in six pain management clinics located in the Southern United States. They include one central office and five satellite clinics. There are two physicians and seven NP's. Each NP sees an average of 20 to 25 patients per day. The patient population assessed at all clinical sites share similarities with the majority of patients being treated with opioid therapy for CNCP Participants included six of the seven NPs. Participation was voluntary. Additionally, participants were asked to take part in a post-intervention evaluation to assess their opinion on the ease of use of the protocol.

The RxFiles Opioid Tapering Template was used for this project (Table 1). The Associate Director of RxFiles granted permission for its use (Appendix D). The protocol provides considerations when tapering opioids (RxFiles Academic Detailing, 2018). It guides the patient discussion, goal setting, time frames for tapering as well as beginning taper increments suggestions of five to ten percent (RxFiles Academic Detailing, 2018). The protocol discussed the use of long-acting opioids as well as short-acting opioids and daily dosing if required (RxFiles Academic Detailing, 2018). Methods to combat opioid-related side effects, the anticipation of increased pain and withdrawal were provided to include medication and dosages (RxFiles Academic Detailing, 2018). The protocol recommends an interdisciplinary approach for complex patients and tips for holding or stopping taper (RxFiles Academic Detailing, 2018). Finally, the protocol contains easy to use dosing schedules that can be given to the patient so that both patient and provider can track progress together (RxFiles Academic Detailing, 2018).

Intervention and data collection

Participants were given information regarding the opioid crisis and the lack of evidence supporting long-term, high dose opioids, why tapering is essential, and the RxFiles protocol during a staff meeting. Tapering was done due to inappropriate dosing, aberrant behavior, lack of pain control despite high doses, or side effects. Inclusion criteria included adult CNCP patients and patients treated with opioids for greater than six months. Exclusion criteria included patients with cancer, a history of substance abuse, implanted pain pumps, surgery within the last three months, or previous suicide attempts.

Participants flagged charts of patients they determined appropriate for tapering by initiation an "action" in the electronic medical records (EMR) system. Patient teaching on the need and method of tapering opioids was completed at monthly appointments. Care plans were

adjusted based on individual needs. Tapering was accomplished over three months. Charts were reviewed monthly to monitor pain scores, Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), and Current Opioid Misuse Measures (COMM) scores, CSMD's, and urine drug screens. Based on compliance, the physical exam, and patient interview, the NP determined if the opioid medication was tapered farther, held, or stopped.

Data was collected and analyzed using SPSS statistical software. The analysis included descriptive statistics of the initial MEDD, MEDD at each visit over the three months, the percentage of each reduction, and the total percentage of reduction after the three months. A paired t-test was done to compare the initial and final MEDD's. An ANOVA was conducted comparing the co-use of benzodiazepines and opioids and those that solely use opioids and the effect on the total percent decrease in MEDD.

At the end of the project a post-intervention evaluation with seven, five-point Likert scale questions ranging from "strongly disagree" to "strongly agree" and one open-ended question for improvement suggestions was emailed to participants. Participants were given seven days to complete the survey with one reminder email sent on the fourth day. No demographics were asked; however, the group of participants were well known to each other, decreasing the likelihood of anonymity. The protocol was assessed for potential adjustments to better fit the practice and how it could be used in the improvement of patient outcomes and company policy. Final data, limitations, and recommendations were assessed and disseminated to the participants.

Ethical Considerations

Institutional review board (IRB) approval was granted for this project by the University of Alabama in Huntsville (Appendix F). Informed consent was obtained from NP's willing to participate. There was no risk to participants. The NP's were not compensated, and no regular

patient care was modified. There was no cost to the providers or the clinic involved in this project.

Patient consent was not requested. Patients attending the clinic have signed a Notice of Privacy Policies & Practice allowing the use of their personal health information for research purposes and the advancement of medical education. CNCP patients are often unwilling to taper; recommendations made by Sullivan et al. (2016) support this after patient willingness to taper yielded poor participation rates. An IRB exemption form was submitted and approved.

Data was collected and input directly into SPSS. It was kept on an encrypted file on a password-protected laptop stored in a locked cabinet in the principal investigator's office.

Results

Seventy-two patients were initially identified. Thirty-three patients were lost to attrition (Figure 1.) Patients were withdrawn if they missed a monthly appointment or for deviation from the protocol. Data from 42 patients were used for analysis.

Patients were required to come to their usually scheduled monthly visits and were monitored over three months. No demographics or identifying data were collected to include the patient diagnosis for which they are receiving opioid pain medications. Patients were withdrawn if they missed a visit during the three months or for deviation of the protocol. Patients monitored in the project share similarities with the majority of patients being treated with opioid therapy for CNCP. Patients care plans included single opioid therapy, combination therapy with a long-acting and short-acting opioid, or combinations of opioids and benzodiazepines. All project variables were entered into SPSS, so to assess descriptive statistics (Table 2).

Comparison Between Initial and Final Morphine Equivalent Daily Dose

A paired t-test was conducted for comparing the initial and final MEDD. We recorded patients MEDD at month one ($\mu = 191.67$, [SD = 198.03]) and after month three ($\mu = 116.35$, [SD = 122.29]), $t(41) = 5.662$. The reduction of 75.31mg was found to be statistically significant ($p = .000$, $\alpha = .05$). The total percent decrease in MEDD exceeded the 20% goal, with an average of 39.62%. Only two patients fell below the goal tapering 12.2% and 16.67%.

Relationship Between Concomitant Benzodiazepine and Opioid Use, Sole Opioid Use, and the Total Percentage Decreased

A one-way ANOVA was conducted to evaluate the difference in MEDD's of patients prescribed both benzodiazepines and opioids, compared to patients only prescribed opioids. Patients prescribed both benzodiazepines and opioids had an average MEDD decrease of $\mu 38.84\%$ (SD = 16.21%), whereas those not prescribed benzodiazepines had an average MEDD decrease of $\mu 39.96\%$ (SD = 15.10%). A t-test reveals that a 1.12mg difference is not statistically significant ($p = .830$, $\alpha = .05$). It should be noted that none of these patients had any known history of substance abuse, physical abuse, or non-compliance with medication regimens.

Post Intervention Questionnaire

Nurse practitioners completed a post-intervention evaluation after three months (Table 3). The questions included their thought on the protocols' ease of use, effectiveness, patient tolerance and compliance, use of other modalities, and future use. All of the NP's/NP's answered "agree" or "strongly agree" to the use, effectiveness, and future use of the protocol. Two NP's/NP's were neutral on patient compliance, and half of the group were neutral as to whether other modalities were helpful during tapering.

Discussion

The participating NP's exceeded the goal of tapering by achieving an average reduction of MEDD's by 39.6% over three months. It was also determined that benzodiazepine use did not affect the patient's ability to taper; however, both groups had small sample sizes, so data is not conclusive. Some decreases were greater than 10% by merely decreasing one pill a day. All MEDD's were calculated using the *Washington State Agency Medical Directors' Group's Opioid Dose Calculator* to maintain consistency (Agency Medical Directors' Group, 2015).

The attrition rate was significant. Attrition due to provider oversight could have been avoided with improved communication and including all medical personal at the initial presentation. Five patients carried Blue Cross Blue Shield of Tennessee and were required to be placed on long-acting opioids, increasing their MEDD. This prescribing mandate was made in response to the opioid crisis and chronic pain guidelines limiting the number of short-acting opioids covered by insurance (Anson & Farmer, 2018). While the insurance company reports a significant decline in prescribed opioid claims over that last three years, overdose rates in 2018 were at a record high with more than half related to illegal opioids (Anson & Farmer, 2018; NIH, 2018).

The clinic collects an Opioid Risk Tool (ORT) at new patient visits and SOAPP-R and COMM scores throughout the year. We intended to assess SOAPP-R and COMM scores for any correlation of those scores and the MEDD's. During a chart audit by the company attorney, it was discovered that the SOAPP-R was delivered incorrectly. It was decided to remove the SOAPP-R from the rotation as the patient risk was determined using the ORT. The removal of the SOAPP-R caused a fluctuation in the rotation of questionnaires; only 15 patients had

SOAPP-R scores, and seven had COMM scores. It was decided that the incorrect use and lack of data would not yield meaningful information, so it was not used.

Elevated pain scores make it difficult for providers when making care decisions. Patients were asked to rate their "current," "least," "usual," and "worst" pain on a scale of 0-10 at each visit. Self-reported scores were missing or exaggerated compared to physical assessments. Fifteen of the 42 patients did not rate 25% of their pain scores.

Chronic pain patients commonly report 10 out of 10 pain simultaneously, reporting adequate pain control (Ballantyne, 2017). Elevated pain scores can be caused by tolerance, dependence, or fear of opioid tapering if pain control is reported, and hyperalgesia (Ballantyne, 2017). Chen et al. (2013) completed a retrospective analysis of 109 CNCP patients on long-term opioid therapy. They assessed self-reported pain scores against age, gender, nociceptive, neuropathic, mixed pain, dose increase, decrease, and continuation (Chen et al., 2013). No statistical difference in self-reported pain scores in any group (Chen et al., 2013).

Recommendations

The findings of this project support the need for a more extensive study with more patients. A charting macro or dot phrase documented in a specific location would be helpful for consistency. Reasons for tapering and monthly progress should be documented at each visit. While this project focused on the NP's, all providers in the clinic should be educated on its use to prevent variations in care. Active participation in the patient's pain management should be strongly encouraged. Patients prescribed opioids need support and education. A list of support groups, mental health facilities, and primary care providers should be kept available for patients.

Limitations

The most notable limitation was the lack of participation by NP's. One NP chose not to participate, two provided one patient each, and a third identified six patients; however, only tapered three.

Second was provider oversight. Four patients were removed for significant dose increases after seeing a different provider. It is suspected that the provider was unaware that the patients were being tapered and did not review the previous month's note.

Third, was elevated pain scores. Elevated pain scores potentially caused NP's to question if tapering was appropriate regardless of their assessment.

Finally, self-reported answers may be positively biased. To avoid interprofessional conflict, responses to the post-intervention evaluations are potentially over-generous. All NP's answered positively to ease of use, overall effectiveness, and continued use of the protocol despite the lack of participation.

Application to Practice

The findings support the use of a tapering protocol within a chronic pain management clinic by achieving an average reduction of MEDD's by 39.6% over three months. When applied to practice, tapering protocols assist NP's in safely and effectively decreased patient's MEDD's while addressing fears and avoiding adverse effects. With proper use, the protocol provides consistency among providers. The protocol used in this project allows for individualization depending on the patient's needs and promotes provider-patient communication. Additionally, the use of a tapering protocol aids in adherence to chronic pain guidelines.

Conclusion

Addressing prescription opioid overuse is only a small aspect of the current national crisis. Along with the lack of evidence of efficacy, long term, high-dose opioid usage puts patients at increased risk of overdose, addiction, and hyperalgesia. When tapering opioids is necessary, the risks as well as the patient's disease process, comorbidities, history of opioid use, and socioeconomic status must be considered. Tapering inappropriate doses of opioids increases patient safety and compliance with chronic pain guidelines. Alternatively, at this time, there are few other options available for the management of chronic pain.

It must be understood by the medical community and the general public that legally, safely prescribed opioids, even at high doses, are not the crux of the opioid crisis. When used as intended, protocols and guidelines provide considerations for improving patient outcomes. The guidelines should not be used as strict rules, as this could potentially perpetuate the opioid crisis.

Implementing a protocol to decrease the MEDD's of appropriate patients helps NP's better care for their patients while addressing overprescribing. Listening to patient concerns allows the patient to be part of their care plan while giving them a sense of control. This QI project suggests that tapering opioids can be done safely and effectively for both clinicians and patients while providing meaningful patient care.

Disclosures

There are no financial conflicts of interest to disclose.

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Table 1. Rx Files Opioid Tapering Template Example


OPIOID TAPERING & WITHDRAWAL MANAGEMENT		L Regier BSP © www.RxFiles.ca	Jun 2018
<p>A) General Considerations  See RxFiles Opioid Tapering Template- version of this document http://www.rxfiles.ca/rxfiles/uploads/documents/Opioid-Taper-Template.pdf</p>			
<p>1) Determine if the goal of dose reduction is reasonable (e.g. opioids have demonstrated some benefit) or if complete discontinuation is more suitable (e.g. trial has been highly problematic/ineffective, opioid induced hyperalgesia is a concern, or patient is addicted &/or at very high risk).</p> <p>2) If goal is to reduce dose, option to taper further & more gradually may be considered at a later point. Tapering plan may be paused/reassessed at any point if pain/function worsens or withdrawal symptoms persist for 1 mos or more. However, the "hold off on further taper & plan to restart taper" conversation should usually have a designated endpoint and be one conversation, not two!</p> <p>3) Gradual tapers can often be completed in 1-6 months; some may benefit from a longer time frame of 12-24 mos. Literature varies. Some may benefit from opioid agonist therapy.</p>	<p>4) Set a start date! Initial daily dose reductions in the range of 5-10% every 2-4 weeks may be reasonable.¹ Once 1/3 of the original dose is reached, smaller dose reductions (e.g. 5% every 4-8 weeks) may be more optimal for a successful taper.¹ (May require formulation change).</p> <p>5) Long-acting formulations that offer small dose increments are useful for more gradual tapers once in the lower end of the dosage range. (Examples: morphine long-acting: M-ESLON 10mg cap q12h, KADIAN 10mg or 20mg cap q24h)</p> <p>6) More rapid tapers are possible & sometimes desired. In such cases, use of an opioid withdrawal scale & corresponding protocols may be recommended, allowing for successful withdrawal within 1-2 weeks. (See links)^{2,3}</p> <p>7) Given the complexities in some cases, discussion with experienced colleagues and an interdisciplinary approach</p>	<p>will help optimize management. Continue to use "best practice" tools (e.g. functional assessment, <i>Opioid Manager</i> from Canadian guidelines, urine drug screens, etc).</p> <p>PATIENT MANAGEMENT</p> <p>1) Anticipate withdrawal & have a plan to manage (see Rx).</p> <p>2) Optimize other pain management (e.g. non-drug e.g. CBT, interdisciplinary team); add co-analgesics for neuropathic pain e.g. nortriptyline, duloxetine, gabapentin or pregabalin).</p> <p>3) Encourage functional goal setting.</p> <p>4) Optimize non-drug tx for insomnia, anxiety & depression.⁹</p> <p>5) Strongly caution patients that a) they have lost their tolerance to opioids after as little as 1-2 weeks of taper, and b) they are at high risk for overdose if they relapse/ resume their pre-taper dose. Rx Naloxone Kit OTC X ▼ !</p>	
<p>B) Timeline & Tips for Stopping or Tapering</p> <ul style="list-style-type: none"> Allow for gradual dose reductions: e.g. q3 day, weekly, bi-weekly or monthly. Reassess as necessary. In general, the higher the dose & longer the duration of previous opioid therapy, the more time should be allotted for tapering. Consider switching to 50-75% of the MED of an alternate opioid +/- further taper May consider cross-over switch/rotation taper: e.g. switch to alternate opioid at 50-75% equivalent dose (lower dose accounts for incomplete cross tolerance). Slowly (over ~4 weeks) up-titrate new opioid to ~50% MED/d while tapering off previous opioid. Tapering the last 20-60mg/day morphine equivalent (MED), may require more time. 	<p>EARLY symptoms may include:</p> <ul style="list-style-type: none"> - anxiety / restlessness - sweating - rapid short respirations - runny nose, tearing eyes - dilated reactive pupils - other: sympathetic/stimulation - brief ↑ in pain (usually few days but up to 2-4wks) <p>Early = hours to days Late = days to weeks Prolonged = wks to ~6mos</p>	<p>LATE symptoms may include:</p> <ul style="list-style-type: none"> - runny nose, tearing eyes - rapid breathing, yawning - tremor, diffuse muscle spasms, bone/joint aches - pilo-erection (gooseflesh skin) - nausea and vomiting; diarrhea; abdom. pain - dysphoria; - fever, chills - ↑ white blood cells (if sudden withdrawal) 	<p>PROLONGED symptoms may include:</p> <ul style="list-style-type: none"> - irritability, fatigue, malaise, psychological/wellbeing (dysphoria, coping, craving) - bradycardia - decreased body temperature <p>Some people with chronic pain will find that fatigue, function & general well-being improve over time with opioid tapering.^{4,5} In such cases, gradual, incremental gains in function will be possible & should be explored.</p>
<p>C) Opioid Withdrawal Symptoms (See table to the right.)</p> <ul style="list-style-type: none"> Many of these symptoms may not be seen with a gradual taper! Physical withdrawal symptoms generally resolve over 5-10 days. Psychological withdrawal symptoms (dysphoria, insomnia) may take longer. 			

Table 2. SPSS Descriptive Statistics of Monthly MEDD and Percentage Data

		Statistics							
		Initial MEDD	month 1%	Month 1 MEDD	Month 2%	Month 2 MEDD	Month 3%	Month 3 MEDD	Total % decreased
N	Valid	42	42	42	42	42	42	42	42
	Missing	0	0	0	0	0	0	0	0
Mean		191.6679	17.2883%	162.2762	15.9152%	135.9238	12.2229%	116.3555	39.6152%
Median		127.5000	16.6700%	93.7500	14.5850%	72.5000	5.7800%	61.2750	33.3300%
Mode		90.00 ^a	0.00%	120.00	0.00%	15.00	0.00%	15.00	33.33%
Std. Deviation		198.02721	12.57108%	173.00414	13.99228%	140.60537	15.25842%	122.29074	15.26487%
Minimum		22.50	0.00%	15.00	0.00%	15.00	0.00%	13.13	12.20%
Maximum		990.00	60.00%	870.00	48.98%	630.00	60.00%	530.00	73.33%

a. Multiple modes exist. The smallest value is shown

Table 3. Post-Intervention Evaluation Questions and answers

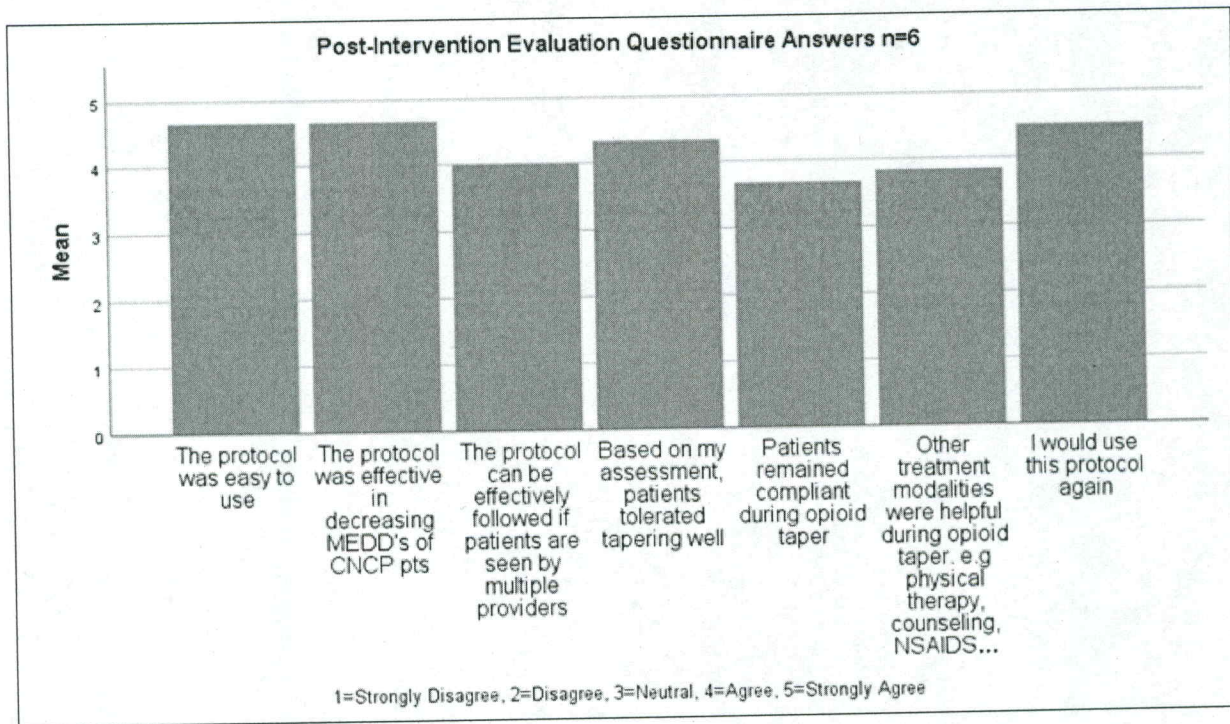
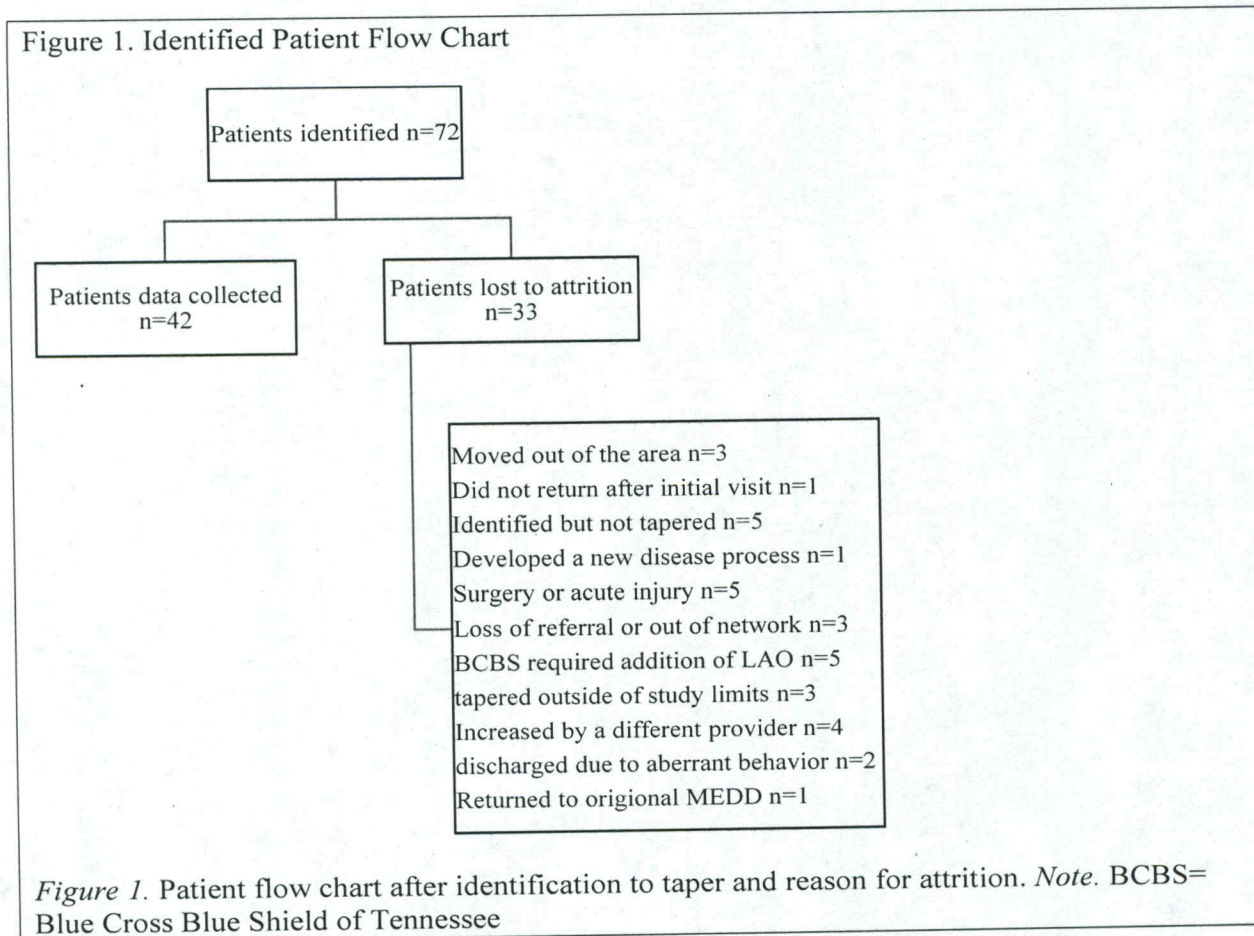


Figure 1. Patient Flow Chart



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a. Multiple modes exist. The smallest value is shown

Table 2. Post-Intervention Evaluation Questionnaire Answers

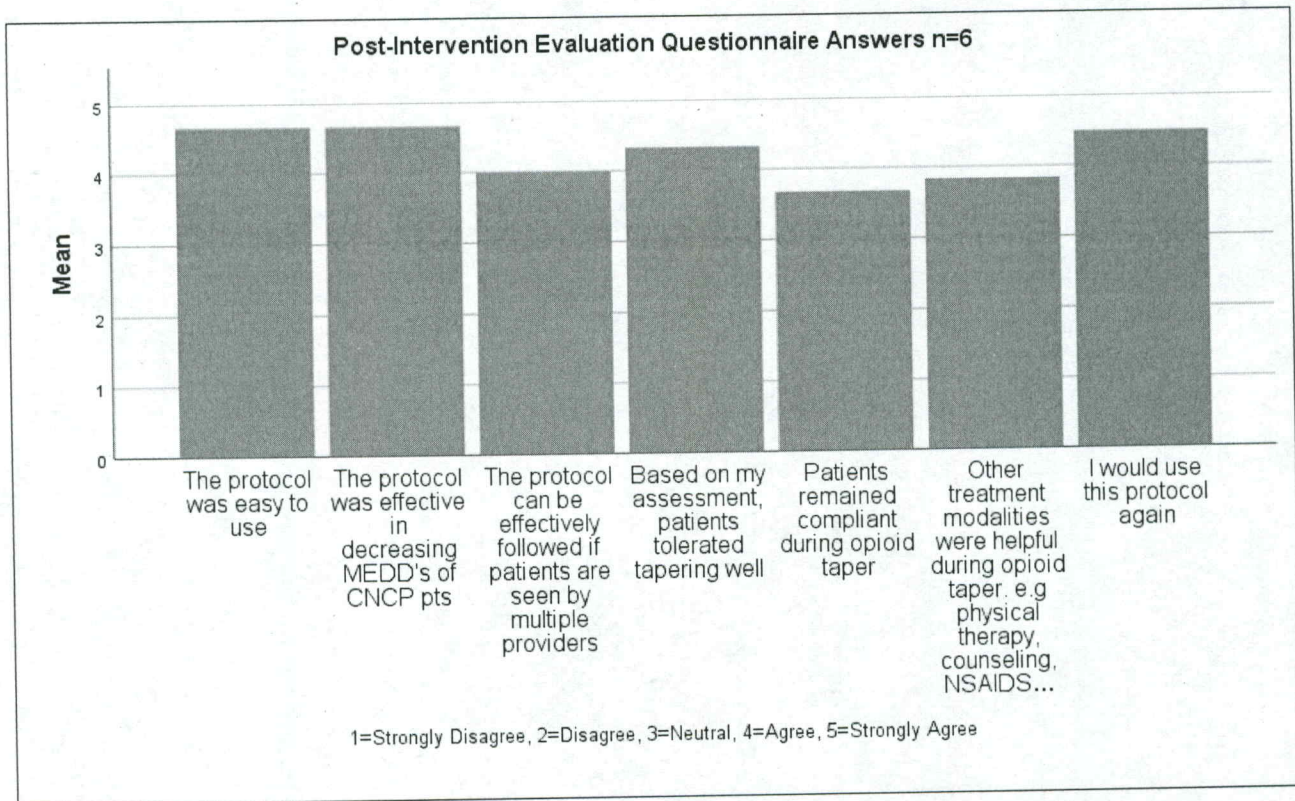
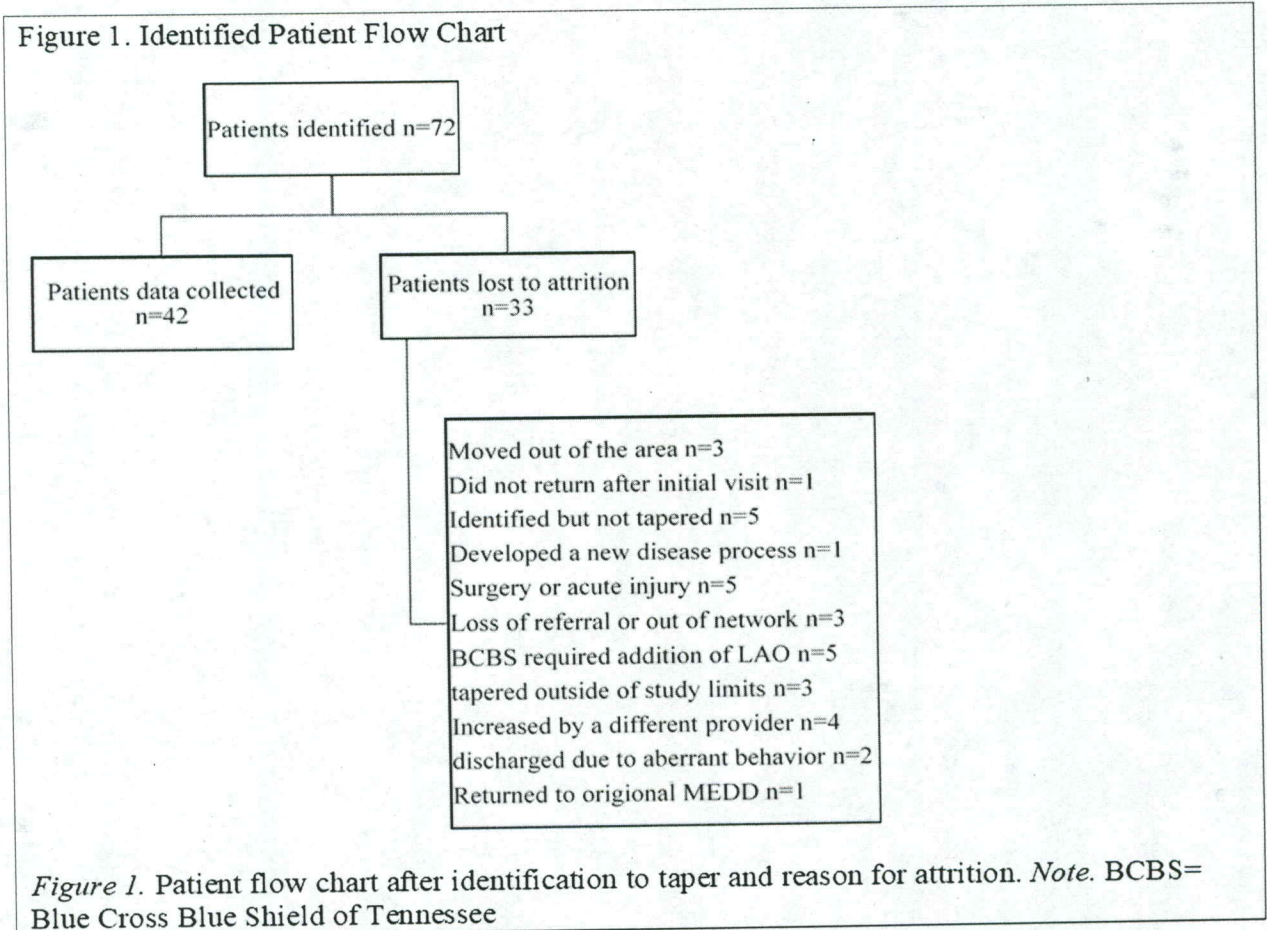


Figure 1. Patients Flow Chart



APPENDIX A

Opioid Tapering Protocol Post-Intervention Evaluation

	Strongly disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly agree 5
1. The protocol was easy to use					
2. The protocol was effective in decreasing MEDD's of chronic pain patients					
3. The protocol can be effectively followed if patients are seen by multiple providers					
4. Based on my assessment, patients tolerated tapering well					
5. Patients remained compliant during opioid taper					
6. Other treatment modalities were helpful during opioid taper. e.g. physical therapy, counseling, NSAIDS...					
7. I would use this protocol again in the future					
8. Are there any improvements that you feel we could make to the protocol?					



Opioid Tapering Template

For use when a decision is made to reduce or discontinue an opioid in chronic non-cancer pain (CNCP).

General approach considerations:

1. In discussion with the patient, set a reasonable start date for the taper.
2. Gradual tapers can often be completed in the range of **1 to 6 months**. However, some may benefit from a longer time frame of 18-24 months. Initial daily dose reductions in the range of 5-10% every 2-4 weeks are reasonable.¹ Once a dose of approximately 1/3 of the original dose is reached, smaller dose reductions (e.g. 5% every 4-8 weeks) may be more suitable for some & more likely to result in a successful taper.¹ More rapid tapers are possible and sometimes desired. In such cases, use of an opioid withdrawal scale (e.g. COWS) & corresponding withdrawal protocols may be recommended, allowing for successful withdrawal within 1-2 weeks. (See links ²⁻⁴)
3. Long-acting formulations that offer smaller dose increments are useful for more gradual tapers once in the lower end of the dosage range. (Examples: morphine long-acting: M-ESLON 10mg cap q12h, KADIAN 10mg cap q24h.)
4. Consider daily dispensing of opioids or blister packs for those at high risk of overdose or aberrancy use.
5. Determine if the goal of dose reduction is reasonable (e.g. opioids have offered some benefit) or if complete discontinuation is more suitable (e.g. opioid trial has been highly problematic/non-helpful or there is a concern regarding opioid induced hyperalgesia).
6. If goal is to reduce dose, option to taper further & more gradually may be entertained at a later point. Tapering plan may be held/reassessed at any point if pain/function deteriorate or withdrawal symptoms persist for 1 month or more. However, the "hold off on further taper & plan to reassess/restart taper" conversation should have a designated endpoint & be one conversation, not two!
7. Encourage functional goal setting & efforts to enhance non-drug approaches in management plan.
8. Optimize other pain management (e.g. Is something needed for neuropathic pain such as nortriptyline, gabapentin or pregabalin).
9. Anticipate likely and possible withdrawal effects & have a management plan in place. (See Pg 2 & Withdrawal Rx)
10. Given the complexities in some cases, discussion with experienced colleagues and an **interdisciplinary approach** will help optimize management. Continue to use "best practice" tools (e.g. Opioid Manager, UDS).
11. Strongly caution patients that a) they have lost their tolerance to opioids after as little as a week or two of abstinence, & b) they are at risk for overdose if they relapse/resume their original dose. Consider a Take Home Naloxone Kit OTC **X** ▼ !

Timeline for discontinuation or reaching a taper "target dose"

Current dose _____

Proposed target dose _____

Timeline (in weeks or months) _____ weeks months

⇒ Allow for gradual q3 day, weekly, bi-weekly or monthly dose reductions. Reassess as necessary.

⇒ In general, the longer the duration of previous opioid therapy, the more time should be allotted for tapering. Rate of tapering should often be even more gradual as total daily dose reaches lower end of range (e.g. ≤120 mg Morphine/day)

See page 2 for customizable Tapering Template, or go online for customizable Opioid Withdrawal Prescription.

Name: _____

Date: _____

Address: _____

(May switch/rotate to 50-75% equivalent morphine dose of an alternate opioid.)

Reduced dose accounts for incomplete cross tolerance. See Opioid Manager Switching Tool.

A) Tapering Schedule*: Drug

	Dates	(# wks)	AM Dose**	PM Dose	Total Dose/Day	Quantities Needed
0.	<i>Start Date!</i>		mg	mg	mg	
1.		x wk	mg	mg	mg	
2.		x wk	mg	mg	mg	
3.		x wk	mg	mg	mg	
4.		x wk	mg	mg	mg	
5.		x wk	mg	mg	mg	
6.		x wk	mg	mg	mg	
7.		x wk	mg	mg	mg	
8.		x wk	mg	mg	mg	
9.		x wk	mg	mg	mg	
10.		x wk	mg	mg	mg	
11.		x wk	mg	mg	mg	
12.		x wk	mg	mg	mg	

*template may be adjusted based on patient's progress; decisions on further tapering, etc. Last 20-30 mg may require more time.
**if once daily formulation (i.e. KADIAN or JURNISTA) record dose in respective AM or PM column.

B) Opioid withdrawal symptoms:

- Many of these symptoms may not be seen with a gradual taper!
- Physical withdrawal symptoms generally resolve by 5-10 days following opioid dose reduction/cessation.
- Psychological withdrawal symptoms (dysphoria, insomnia), if seen, may take longer (months) to resolve.

Early symptoms may include:	Late symptoms may include:	Prolonged symptoms may include:
<ul style="list-style-type: none"> - anxiety and restlessness - sweating - rapid short respirations - runny nose, tearing eyes (minor) - dilated reactive pupils - brief ↑ in pain (usually few days) 	<ul style="list-style-type: none"> - runny nose, tearing eyes - rapid breathing, yawning - tremor, diffuse muscle spasms/aches - pilo-erection (goose bumps) - nausea and vomiting; diarrhea - abdominal pain - fever, chills - ↑ white blood cells (if sudden withdrawal) 	<ul style="list-style-type: none"> - irritability, fatigue; hormonal related Δ - bradycardia (slower heart rate) - decreased body temperature <p>♦ Some people with chronic pain will find that symptoms such as fatigue & general well-being are improved over time with tapering of the opioid. In such cases, <u>gradual gains in function</u> will be possible & should be explored.</p>
<p>Early = hours to days Late = days to weeks Prolonged = weeks to ~6 months</p>		

C) NSAID (e.g. naproxen 250-375mg twice daily or ibuprofen 400-600mg four times daily): useful for pain & withdrawal aches/pains.

D) Laxative: continue initially; with time, or if diarrhea emerges, reduce, hold & eventually stop laxative (see Q&A)⁵

E) Management of other side effects:

1. Clonidine 0.1mg twice daily PRN (up to 4 times daily) may be prescribed for *general relief/prevention of physical withdrawal sx's*. (Caution if SBP <100, orthostasis, or HR <60); Some patients may not require if gradual taper. May use SOWS (patient administered scale) for monitoring (e.g. score 10-20 take clonidine) see Pg 9. [Cochrane review documented use for 7-14 days up to 30 days,⁶ but some may need longer]. If used regularly, taper, over ~7-10d, to stop.
2. Acetaminophen (650-1000mg every 6 hours as needed) may be used for *aches, pains, flu-like symptoms*.
3. Loperamide may be used as necessary for *diarrhea*; however, may not need with gradual taper.
4. Non-drug & "sleep hygiene" measures should be employed (e.g. U of R pain course www.onlinetherapyuser.ca/pain; regular bedtime/wake-time; sleep restriction).⁷⁻⁹ If additional tx required, short-term trazodone 25-50-100mg HS is an option.
5. Dimenhydrinate 50-100mg every 6 hours as needed for *nausea/vomiting* [Alternatives: prochlorperazine 5-10mg q6h, haloperidol 0.5-1mg q12h]
6. Other
7. Remember tolerance to previous dose of opioid is lost after 1-2 weeks!
Consider *Naloxone Kit* OTC X ▼ for risk of overdose!

Physician: _____

A) Sample Slow Tapering Schedule*: Drug Morphine long acting_ (MS CONTIN)

	Dates	(# wks)	AM Dose**	PM Dose	Total Dose/Day	Quantities Needed
0.	Current	-	245mg	245mg	490 mg	
1.		X2 wk	230 mg	230 mg	460 mg	(4x100mg) + (2x30mg) x14d
2.		X2 wk	215 mg	215 mg	430 mg	
3.		X2 wk	200 mg	200 mg	400 mg	
4.		X2 wk	190 mg	190 mg	380 mg	
5.		X4 wk	175 mg	175 mg	350 mg	
6.		X4 wk	160 mg	160 mg	320 mg	
7.		X4 wk	145 mg	145 mg	290 mg	
8.		X4 wk	130 mg	130 mg	260 mg	
9.		X4 wk	115 mg	115 mg	230 mg	
10.		X8 wk	100 mg	100 mg	200 mg	
11.		X8 wk	90 mg	90 mg	180 mg	
12.		X8 wk	80 mg	80 mg	160 mg	Switch to M-ESLON, or once daily KADIAN for smaller titrations
13.		X8 wk	140 mg	0 mg	140 mg	
14.		X12 wk	120 mg	0 mg	120 mg	
15.						
16.						

*this template may be adjusted based on patient's progress; decisions on further tapering, etc.

**if once daily formulation (i.e. KADIAN or JURNISTA) record dose in respective AM or PM column and "0" in other.

Additional information:

¹2017 Canadian Guideline for Opioids for Chronic Pain (May 2017) - Links

- **Link to Guideline Site:** <http://nationalpaincentre.mcmaster.ca/guidelines.html>
- **Opioid Tapering- Information for Patients – English:**
[http://nationalpaincentre.mcmaster.ca/documents/Opioid%20Tapering%20Patient%20Information%20\(english\).pdf](http://nationalpaincentre.mcmaster.ca/documents/Opioid%20Tapering%20Patient%20Information%20(english).pdf)
- **Opioid Tapering- Information for Patients – French:**
Sevrage des opioïdes : informations à l'intention des patients.
<http://nationalpaincentre.mcmaster.ca/documents/Opioid%20Tapering%20Patient%20information%20FRENCH.pdf>

Other

- **CAMH: Video discussion of issues around how to taper.**
http://knowledgex.camh.net/videos/Pages/tapering_presopioids_selby2013.aspx
- **RxFiles: Opioid Taper Template & related materials at:** www.RxFiles.ca
 - Pain/Opioid Resource Links: <http://www.rxfiles.ca/rxfiles/uploads/documents/RxFiles-Pain-and-Opioid-Resource-Links.pdf>
 - RxFiles Pain/Opioid Newsletter Part 1 – Fall 2017: <http://www.rxfiles.ca/rxfiles/uploads/documents/Opioids-Pain-2017-Newsletter.pdf>
- **TheWell (Centre for Effective Practice):**
 - **Opioid Tapering Template (2018) at:** <https://thewellhealth.ca/opioidtaperingtool>
 - **Opioid Manager tool to support the Canadian Opioids in CNCP guideline:** <https://thewellhealth.ca/pain>
- **CDC - POCKET GUIDE: Tapering Opioids For Chronic Pain:**
https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf

² Clinical Opiate Withdrawal Scale (COWS).

<https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf>

³ Subjective Opiate Withdrawal Scale (SOWS).

<http://www.bccsu.ca/wp-content/uploads/2017/08/SOWS.pdf>

⁴ Butt P, McLeod M. Opioid withdrawal protocol, Saskatchewan.

⁵ Opioid Induced Constipation Q&A: <http://www.rxfiles.ca/rxfiles/uploads/documents/members/Opioid-Induced-Constipation-QandA.pdf>

⁶ Gowling L, Farrell MF, Ali R, White JM. Alpha2-adrenergic agonists for the management of opioid withdrawal. Cochrane Database Syst Rev. 2014 Mar 31;3:CD002024.

⁷ Merrigan JM, Buysse DJ, Bird JC, Livingston EH. JAMA patient page. Insomnia. JAMA. 2013 Feb 20;309(7):733. Accessed online 21 Oct, 2013 at <http://jama.jamanetwork.com/article.aspx?articleid=1653524>.

⁸ Sedative Patient Information Sheet (RxFiles) <http://www.rxfiles.ca/rxfiles/uploads/documents/PSYC-Sedative-PtHdout.pdf>

⁹ Chronic Insomnia in Older Adults (RxFiles Q&A) <http://www.rxfiles.ca/rxfiles/uploads/documents/Insomnia-Older-Adults-QandA.pdf>

OPIOID TAPERING & WITHDRAWAL MANAGEMENT

A) General Considerations See RxFiles Opioid Tapering Template-version of this document <http://www.rxfiles.ca/rxfiles/uploads/documents/Opioid-Taper-Template.pdf>

- 1) Determine if the goal of dose reduction is reasonable (e.g. opioids have demonstrated some benefit) or if complete discontinuation is more suitable (e.g. trial has been highly problematic/ineffective, opioid induced hyperalgesia is a concern, or patient is addicted &/or at very high risk).
- 2) If goal is to reduce dose, option to taper further & more gradually may be considered at a later point. Tapering plan may be paused/reassessed at any point if pain/function worsens or withdrawal symptoms persist for 1 mos or more. However, the "hold off on further taper & plan to restart taper" conversation should usually have a designated endpoint and be one conversation, not two!
- 3) Gradual tapers can often be completed in 1-6 months; some may benefit from a longer time frame of 12-24 mos. Literature varies. Some may benefit from **opioid agonist therapy**.

- 4) **Set a start date!** Initial daily dose reductions in the range of 5-10% every 2-4 weeks may be reasonable.¹ Once 1/3 of the original dose is reached, smaller dose reductions (e.g. 5% every 4-8 weeks) may be more optimal for a successful taper.¹ (May require formulation change).
- 5) Long-acting formulations that offer small dose increments are useful for more gradual tapers once in the lower end of the dosage range. (Examples: morphine long-acting: M-ESLON 10mg cap q12h, KADIAN 10mg or 20mg cap q24h)
- 6) More rapid tapers are possible & sometimes desired. In such cases, use of an opioid withdrawal scale & corresponding protocols may be recommended, allowing for successful withdrawal within 1-2 weeks. (See links)^{2,3}
- 7) Given the complexities in some cases, discussion with experienced colleagues and an interdisciplinary approach

will help optimize management. Continue to use "best practice" tools (e.g. functional assessment, *Opioid Manager* from Canadian guidelines, urine drug screens, etc).

PATIENT MANAGEMENT

- 1) Anticipate withdrawal & have a plan to manage (see Rx).
- 2) Optimize other pain management (e.g. non-drug e.g. CBT, interdisciplinary team; add co-analgesics for neuropathic pain e.g. nortriptyline, duloxetine, gabapentin or pregabalin).
- 3) Encourage functional goal setting.
- 4) Optimize non-drug tx for insomnia, anxiety & depression.⁹
- 5) Strongly caution patients that a) they have lost their tolerance to opioids after as little as 1-2 weeks of taper, and b) they are at high risk for overdose if they relapse/ resume their pre-taper dose. Rx Naloxone Kit OTC X ✓ !

B) Timeline & Tips for Stopping or Tapering

- Allow for gradual dose reductions: e.g. q3 day, weekly, bi-weekly or monthly. Reassess as necessary. In general, the higher the dose & longer the duration of previous opioid therapy, the more time should be allotted for tapering.
- Consider **switching to 50-75%** of the MED of an alternate opioid +/- further taper
- May consider **cross-over switch/rotation taper**: e.g. switch to alternate opioid at 50-75% equivalent dose (lower dose accounts for **incomplete cross tolerance**). Slowly (over ~4 weeks) up-titrate new opioid to ~50% MED/d while tapering off previous opioid.
- Tapering the last 20-60mg/day morphine equivalent (MEQ), may require more time.

C) Opioid Withdrawal Symptoms (See table to the right.)

- Many of these symptoms may not be seen with a gradual taper!
- Physical withdrawal symptoms generally resolve over 5-10 days.
- Psychological withdrawal symptoms (dysphoria, insomnia) may take longer.

EARLY symptoms may include:	LATE symptoms may include:	PROLONGED symptoms may include:
<ul style="list-style-type: none"> - anxiety / restlessness - sweating - rapid short respirations - runny nose, tearing eyes - dilated reactive pupils - other: sympathetic/stimulation - brief ↑ in pain (usually few days but up to 2-4wks) 	<ul style="list-style-type: none"> - runny nose, tearing eyes - rapid breathing, yawning - tremor, diffuse muscle spasms, bone/joint aches - pilo-erection (gooseflesh skin) - nausea and vomiting; - diarrhea; abdom. pain - dysphoria; - fever, chills - ↑ white blood cells (if sudden withdrawal) 	<ul style="list-style-type: none"> - irritability, fatigue, malaise, psychological/wellbeing (dysphoria, coping, craving) - bradycardia - decreased body temperature • Some people with chronic pain will find that fatigue, function & general well-being improve over time with opioid tapering.^{4,5} In such cases, gradual, incremental gains in function will be possible & should be explored.
<ul style="list-style-type: none"> Early = hours to days Late = days to weeks Prolonged = wks to ~6mos 		

D) Management of Other Withdrawal Related Side Effects See RxFiles Withdrawal Prescription

Aches/Pains/Myalgia:

- ⇒ NSAID (e.g. naproxen 375-500mg twice daily or ibuprofen 400-600mg four times daily): useful for pain & withdrawal. **(Give regularly initially.)**
- ⇒ Acetaminophen (650-1000mg q6h as needed) for aches, pains, flu-like symptoms

Bowel Function (Constipation / Diarrhea): ensure adequate hydration

- ⇒ Laxative - continue initially to prevent constipation; with time, reduce, hold & eventually stop laxative (See RxFiles Opioid Induced Constipation, page 61)
- ⇒ Loperamide - used if necessary for diarrhea; may not need with gradual taper.

Nausea/Vomiting: ensure adequate hydration

- ⇒ Dimenhydrinate 50-100mg q6h PRN [others: haloperidol 0.5-1mg po q8-12h; prochlorperazine 5-10mg po q6-8h; nabilone 0.25-0.5mg HS up to 0.5-1mg TID].

Sweating: ⇒ Oxybutynin 2.5-5mg po BID PRN (short-term); ensure adequate hydration!

Anxiety, Itchiness, Lacrimation, Cramps, Rhinorrhea, Diaphoresis, Insomnia:

- ⇒ hydroxyzine 25-50mg po TID PRN, or sometimes just needed at HS (short-term)

Insomnia: encourage sleep hygiene (e.g. limit stimulation near bedtime: caffeine, alcohol, TV)

- ⇒ Employ non-drug & sleep hygiene measures (e.g. CBT, regular bedtime & wake-time; sleep restriction).^{5,7,8} If short-term pharmacologic tx necessary, options: **trazodone** 25mg po HS ^{5,12} up to 100mg; **amitriptyline** 10mg po HS ^{2,3}; **doxepine SILENOR** 3-6mg po HS ^{5,30-32}

Pain/Insomnia/Anxiety: (nabilone ⇨ tx of N/anorexia AIDS; ⇨ N/V cancer, palliative)

- ⇒ gabapentin 300mg HS, pregabalin? 75mg HS; nabilone 0.25⁴-0.5mg HS up to 0.5-1mg TID³³; ⇨

Physical Withdrawal Sxs (e.g. agitation) – by ↓ sympathetic activity (α₂-adrenergic agonist):

- ⇒ Clonidine 0.1mg BID PRN (some patients may need up to 4 doses/day). Some patients may not require if gradual taper. May use SOWS (patient administered scale) for monitoring (e.g. score 10-20 take clonidine) see Pg 9. **Caution:** if SBP <100, orthostasis, HR <60. Duration (Cochrane): typical use for 7-14 days up to 30 days;⁹ however, some may need longer tx (e.g. high dose, ≥ 5 yrs of use, fentanyl). If used regularly, taper, over ~7-10 days, to stop. Some evidence that it may ↑ duration of abstinence decoupling stress from craving.¹⁰ (Lofexidine LUCEMYRA (not available in Canada): 0.18 mg tabs, 0.54 mg po QID; similar & alternative to clonidine, less hypotension but ↑ cost.)
- {Tizanidine ZANAFLEX ⇨ ⇨: 2mg po HS, may ↑ by 2-4mg/d to max ~ 8mg q8h. Taper gradually!}

Appendix C

Informed Consent Document

Purpose of study

You are being asked to take part in a research study. Before deciding to do it, you should understand why the study is being done and what it will involve. Please read the following information carefully. Please ask me if there are any questions or if you need more information.

The purpose of this study is to use an opioid lowering protocol to decrease “morphine equivalent daily doses” (MEDD) in chronic, non-cancer pain patients.

Chronic pain lasts longer than 12 weeks. It is often treated with opioid medication. Decreasing the dose of opioids is needed when the following occurs:

- Pain is no longer controlled with opioids.
- Higher doses are needed.
- Poor behavior is displayed.
- The patient is feeling ill effects of the medication.

Study Procedures

You will be asked to select patients you feel have MEDD's that need to be lowered. You will be given instructions for a weaning protocol. You will be asked to evaluate the protocol's ease of use. Participation in this study is voluntary. Patients will be assessed over three months. After the evaluation you will be asked to complete a final evaluation of the protocol.

Risks

There are no risks for taking part in this study. The patients may experience increased pain or withdrawal from lower doses of opioids. A mild increase in pain is expected when lowering opioid pain medication. The possibility for withdrawal is addressed in the protocol. However, it is not expected due to the small monthly lowering doses.

Benefits/Compensation

There is no compensation for taking part in the study. The goal of the study is to:

- Determine if an opioid lowering protocol will improve personal safety.
- Improve their quality of life.
- Improve safe prescribing practice.

Privacy

No identifying information will be collected. All information collected will be kept on a password protected computer in an encrypted file in the DNP students locked office. Your responses will be private. Only select personnel will have access to them.

Voluntary Participation

Participation is voluntary. You may choose not to participate in this study without effecting your relationship with Comprehensive Pain and Neurology Center. There is no punishment for:

- Not participating.
- Skipping questions.
- Stopping your participation.

Contact Information

If you have any questions or concerns about this project, please contact me. A copy of this form will be given to you to keep for your records.

If you have questions about your rights or have a research-related injury, please contact the chair of the UAH Institutional Review board by calling (256) 824-6992 or emailing irb@uah.edu.

Thank you for your consideration.

Sincerely,

Kelly A. Jackson
Phone: 615-631-7156

Email: kaj0025@uah.edu

Casey L. Norris
Phone: 865-310-2301

Email: cln0004@uah.edu

John R. Schneider
Phone: 615-490-4110

Email: jrschneider@tnpainexperts.com

Consent

I _____ (print name) attest that I am at least 18 years of age and agree to take part in this research study.

Signature: _____ Date: _____

Appendix D

RxFiles request for permission to use Opioid Tapering Template and approval

Good afternoon,

I am a Doctorate of Nursing Practice (DNP) student at the University of Alabama in Huntsville and a nurse practitioner at Comprehensive Pain and Neurology Center in Murfreesboro, TN. I am requesting permission to use your Opioid Tapering Template. I am at the point in my courses that I have begun my final project. Our practice cares for chronic pain patients. As we are presented with the current opioid crisis I feel that it is important to implement a tapering protocol for patients with high MEDD's. We do not currently have a protocol at our facility; it is left to provider discretion. We do have a company policy to try to maintain MEDD's below 120. We have absorbed several patients from other pain clinics in the area with much higher, and often inappropriate MEDD's. I would like to use your opioid tapering template and implement it into our practice for my DNP project. The end goal of this project is to determine if implementing a protocol will help nurse practitioners more successfully and safely decrease chronic pain patients MEDDs while maintaining adequate pain control.

The practice I work at has 4 locations and 6 nurse practitioners. My overseeing physician Dr John Schneider supports my project thus far. If given permission to use your template I will continue to gather evidence for the need for reduced opioid use and the importance of the consistency of using protocols. I have to meet with an IRB board and obtain formal permission for my project then I will introduce it to the other providers. They will flag patients that are appropriate for MEDD reduction and using your template begin to decrease medications. I will monitor their progress through chart review. We use several scales that we monitor at each monthly visit; 1-10, Screener and Opioid Assessment for Patients with Pain (SOAPP) and Current Opioid Misuse Measure (COMM) as well as monitoring drug screens and the Controlled Substance Monitoring Database for compliance.

I would very much appreciate your permission and will be more than happy to provide any information you may need.

Respectfully,

Kelly A. Jackson, MSN, AGACNP-BC

Hi there Kelly,

My name is Alex and I'm the Associate Director of the RxFiles.

We received your request below with great interest. We would be happy to allow you to use our template for your project, and ask just one thing - please share the results with us after your project is completed!

I'll also direct you to the following link which you may find additionally helpful:
<https://www.rxfiles.ca/RxFiles/uploads/documents/members/Opioid-Withdrawal-Rx.doc>

Good luck and we hope it all goes well.

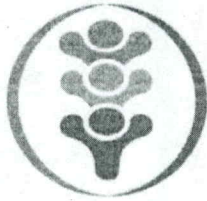
Yours sincerely,

Alex Crawley
RxFiles Associate Director
alex@rxfiles.ca

Alex Crawley
RxFiles Associate Director

Appendix E

Comprehensive Pain and Neurology Center Letter of Support



COMPREHENSIVE PAIN
& NEUROLOGY CENTER PLLC
RELIEVE PAIN & RECLAIM LIFE

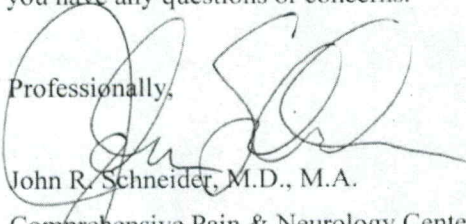
Phone (615) 410-4990 Fax (615) 410-4250

June 1, 2019

To whom it concerns,

I support and approve the research project to assess an opioid tapering protocol planned by the University of Alabama, Huntsville DNP student Kelly A. Jackson, NP. I have been in contact with her project chair, Dr. Casey L. Norris, and understand the scope of the project that is to be carried out at all Comprehensive Pain and Neurology Center clinics. Please contact me if you have any questions or concerns.

Professionally,


John R. Schneider, M.D., M.A.

Comprehensive Pain & Neurology Center, PLLC-

Medical Director and President

ABMS Board Certified- Neurology and Pain Medicine

Tennessee Pain Society- President

Tennessee Society of Interventional Pain Physicians- Treasurer

Drug Utilization Review Board, Tennessee Dept. of Health- Board Member

Amerigroup TN Scientific Advisory Board for Pain Medicine- Board Member

Contact information:

(615) 410-4990 (work)

(615) 410-4250 (fax)

(608) 217-0469 (cell)

e-mail: jrschneider@tnpainexperts.com

Appendix F

The University of Alabama in Huntsville IRB Approval Letter



Date: 17 June 2019

PI: Kelly Jackson
PI Department: College of Nursing
The University of Alabama in Huntsville

<input type="checkbox"/> Expedited (see pg 2)
<input type="checkbox"/> Exempted (see pg 3)
<input type="checkbox"/> Full Review
<input type="checkbox"/> Extension of Approval

Dear Kelly,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal titled: *Decreasing Morphine Equivalent Daily Doses of Chronic Pain Patients; a Protocol Driven Weaning Process* and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with these institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

Ann L. Bianchi
IRB Chair
Associate Professor, College of Nursing

Appendix G

Submission of Manuscript

