Implementation of a Non-Opioid Protocol to Reduce Opioid Use in an Adult Outpatient Clinic

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Abstract

This project sought to curb the use of long-term opioids for the treatment of chronic pain through use of non-opioid topical analgesic (NOTA). The purpose of this project was to determine if implementation of a NOTA protocol for patients suffering from chronic pain will reduce the use of oral opioid agents and decrease reported pain levels in an outpatient primary care clinic over 6 weeks. The NOTA protocol included educating the providers at the clinical site and auditing the providers for compliance. This project included a pre-test to measure the provider's knowledge, skill and attitudes of opioids, an educational session, and a post-test. Data collection was done via retrospective chart audits of 25 patient charts to measure provider compliance with the protocol (including the use of screening tools), opioid prescribing practices, and reported pain levels. Improved test scores support the efficacy of the educational session. Provider compliance with NOTA was above 80%. Results further indicated a statistically significant decrease in opioid prescribing. A decrease in the dosage of opioid prescribed was not statistically significant although the mean dosage declined. There were only three instances of repeat pain scores, which showed decreased or no change in pain levels.

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Chronic noncancerous related pain affects over 50 million Americans and is one of the most prevalent reasons why individuals obtain medical care (National Pain Society, 2015). National Safety Council (NSC) reports that 74% of internal medicine or family care providers believe that opioid analgesics are the most effective way to treat pain (National Safety Council [NSC], 2016). Even more alarming is that 99% of primary care providers are prescribing opioids for longer than the three-days recommended by the Centers for Disease Control (CDC) 2016 Guidelines for the Treatment of Chronic Pain (CDC Guidelines) (NSC, 2016; Dowell, Haegerich, & Chou, 2016). These practices explain why in 2014 there were over 245 million prescriptions for opioid pain relievers in the United States (US) (Levy, Paulozi, Mack & Jones, 2015). Unfortunately, of these 245 million prescriptions, approximately nine to 11 million were prescriptions for long-term opioid therapy. Research supports that opioids can be effective for treating acute pain, but the efficacy of opioid treatment for chronic pain is questionable (Chou et al, 2014). Instead, non-opioid pharmacologic therapies such as acetaminophen, antidepressants, anticonvulsants, nonsteroidal anti-inflammatory drugs (NSAIDs), and nonpharmacologic treatments such as exercise therapy and cognitive behavioral therapy have been shown to be an effective and safer treatment (Dowell et al., 2016; Gudin et al, 2017).

What is not questionable, however, is that these prescribing practices have significantly contributed to a national epidemic of opioid-related overdoses and deaths, resulting in declaration of a nationwide public health emergency (The White House, 2017). Patients who take higher doses of opioid agents over extended periods of time are at greater risk of addiction

(NSC, 2016). Approximately 21 to 29 percent of patients prescribed opioids for chronic pain abuse their medication, resulting in approximately 2.5 million adults reporting addiction to opioids in 2014 (Vowles, 2015; Substance Abuse and Mental Health Administration, 2014). Even more alarming is that 91 people die daily from opioid overdoses in the US. (Center for Disease Control and Prevention [CDC], 2017). The cost of this epidemic is staggering. The CDC estimates that over $78.5 billion is attributed to opioid prescription misuse; this includes healthcare costs, addiction therapy, criminal justice expenses and lost productivity (Florence, Zhou, Lou & Xu, 2013).

Background

In the late 1990s, healthcare providers started increasing the number of opioid prescriptions after reassurance from pharmaceutical companies that patients would not become addicted (National Institute on Drug Abuse, 2017). Consequently, the number of opioid prescriptions sold to pharmacies, hospitals and provider's offices nearly quadrupled from 1999 to 2010, despite the fact that the overall reporting of pain had not increased (Chang, 2014; Daubrese, 2013). As such, the main source of opioid agents in the United States is from provider prescriptions (Shei, Rice & Kirson, 2015). Of huge concern is that primary care providers' express apprehensions about opioid pain abuse and find the management and treatment of chronic pain bothersome. They also report inadequate training on prescribing opioids, yet they still continue to prescribe long-term opioid therapy (Jamison et al., 2014). Healthcare providers from a range of specialties overall think that opioid pain medication is an effective treatment for controlling pain and that abuse is a consequence of long-term use, but also acknowledge that long-term opioid therapy is overprescribed for patients with chronic pain (Wilson et al, 2013). In response to the growing opioid abuse in the US., the CDC issued new practice guidelines to

address the over-prescribing of opioids by providers, recommending no more than a three-day supply of opioids (Dowell et al., 2016).

Given the rising concerns of long-term opioid use, healthcare providers have been developing new ways to manage pain and create a more customized treatment plan (Branvold & Carvalho, 2014). One such treatment plan includes compounded non-opioid topical analgesics (NOTA). NOTA medications offer a safer, yet effective way to treat chronic pain. Topical analgesics (TA) work through local application and consequently, have minimal systemic absorption (Gudin et al, 2017). The mechanics of TA result in decreased side/adverse-effects, minimal drug to drug interactions and extremely low risk of addiction (Branvold & Carvalho, 2014). Further, compounded TA offer the ability to target pain through different mechanisms and therefore, present an effective, more customized alternative to oral opioid therapy for the treatment of chronic pain (Cline & Turrentine, 2016).

This Doctor of Nursing Practice (DNP) scholarly project will partner with an outpatient primary care clinic, for the implementation of a NOTA protocol to treat patients suffering from chronic pain. This new protocol will offer a safer, yet effective standardized treatment plan for providers.

Problem Statement

The long-term use of opioids to treat chronic pain has limited efficacy and creates a significant risk of opioid abuse. Current practice at this outpatient clinic, patients suffering from chronic pain are currently being prescribed long-term opioid therapy. Furthermore, many of the patients have become dependent on their opioid therapy. The owner and primary provider at this outpatient clinic has expressed concern about a lack of a standardized and effective non-opioid pain management protocol for adult patients suffering from chronic pain. This is a concern

especially in light of recent research and guidelines highlighting the high risk of abuse and limited efficacy of long-term opioid use. Research supports that a pain management protocol using non-opioid topical analgesics for the treatment of chronic pain is a safe and effective alternative to long-term opioid medication use (Brennan et al., 2015).

A protocol advocating for the use of compounded NOTA will provide this outpatient clinic with a safer treatment option for patients suffering from chronic pain. In time, this protocol should reduce the patient's reliance on opioid therapy and decrease their reported pain levels (Gudin et al, 2017). This protocol will also provide the providers at this outpatient clinic with a standardized approach and the knowledge to properly educate their patients in the benefits of this treatment. Implementing this protocol should help the providers navigate the difficult practice of managing chronic pain (Manchikanti et al., 2017).

Purpose Statement

This project aims to determine if implementation of a pain management protocol, which includes the use of compounded, non-opioid topical analgesics in patients suffering from chronic pain will reduce the use of oral opioid agents and decrease patient pain severity ratings in an outpatient primary care clinic over 6 weeks.

Project Question and Objectives

In adult patients suffering from chronic pain, would implementing a NOTA protocol in a primary care outpatient clinic reduce patient's use of oral opioid agents and decrease reported pain levels within a 12-week period as compared to those receiving non-standardized care? In the time frame of this DNP scholarly project, the host site will implement an evidence-based protocol utilizing NOTA for the management of chronic pain. Implementation of this protocol includes:

- Develop a NOTA protocol for the providers that will deliver a standardized plan for the treatment of chronic pain. This protocol will include the use of screening tools including adapting the Brief Pain Inventory and the Opioid Risk Tool for the providers to administer to their patients.
- Educate the providers and staff in the use of the NOTA protocol.
- Perform chat audits on a weekly basis to ensure compliance with the protocol and monitor the opioid prescribing practices.

Review of Literature

This section will review the impact of the current opioid prescribing practices, examine current management of the problem, and review the evidence based practice for the non-opioid management of pain. A search of EBSCO Host, Academic Search Premiere, Google Scholar, CINAHLH Plus and government funded agencies was conducted. For the scholarly inquiries, the search terms topical analgesics and pain and opioid were used. A search was also conducted for compounded topical analgesics, alternative pain management, prescribing pain medications, risk factors for opioid addiction, and pain. Other inclusion criteria included articles published within the last seven years, qualitative and quantitative studies, and peer reviewed journal articles. From just the search of CINAHL Plus, EBSCO Host and Academic Search Premiere, using topical analgesics and pain from years 2010 to 2018, over 100 articles resulted. Results were further limited to include research and experimental studies and recent reviews of literature that examined TAs as a treatment for various noncancerous related pain in adults. They were then further narrowed by articles that were directly related and relevant to this DNP scholarly project. Further, emphasis was given to articles published within the last five years. A search of

Google Scholar yielded numerous results that were excluded, many of which were older, non-peer reviewed journal articles and/or duplicates of the articles found on the above databases.

Other searches were conducted on the above databases for prescriber perceptions of opioids, use of topical analgesics for pain and opioid crisis. Given the relevant nature of this project, government agencies were searched as well for healthcare statistics, prescribing practice statistics and current practice guidelines on the use of opioid agents.

Impact of the Problem

The widespread abuse of opioid agents in the US is caused in large part by healthcare providers who are over-prescribing opioids (Shei et al., 2015; Jamison et al., 2014). The ample supply of opioids in the market and the addictive nature of these drugs creates high risk of abuse and overdose. Educating healthcare providers in safer and effective alternative treatments to chronic pain, thus reducing the use of opioids to treat chronic pain, will help curb this nationwide problem (Dowell et al., 2016).

Review Synthesis

Educational Training

The lack of education and confidence in the treatment of chronic pain among providers is troublesome and contributing to poor patient outcomes and increased risk of opioid abuse (NSC, 2016; Wilson et al, 2013). Chronic pain is one of the most prevalent reasons why individuals obtain medical care (National Pain Society, 2015). Given the prevalence of this complaint, it is not surprising that primary care providers (PCPs) treat a significant number of patients for chronic pain as opposed to pain management specialists. In fact, evidence from one study indicated that patients who seek treatment for chronic pain from their PCP are not significantly different than those who present to pain management specialists in terms of pain severity and

complexity of treatment (Fink-Miller et al., 2014). However, PCPs often voice concern over whether their education and training has adequately prepared them to treat chronic pain; as many as half report dissatisfaction with their pain-management training (Fink-Miller et al., 2014). Patients reporting to their PCPs are often younger and report higher pain severity than those who report to pain management facilities. Given that youth is often an indicator of opioid abuse, research supports that these patients might present to their PCP simply to obtain opioids to misuse them (Fink-Miller, et al., 2014). Because of this high potential for opioid abuse among patients reporting to their PCP, provider training in recognizing opioid addiction and prescribing safer alternatives is essential.

Prescription Practices

Considering the voiced concerns over ineffective training in the treatment of chronic pain, it is not surprising that 99% of PCPs are prescribing opioids for longer than the three-days recommended by the CDC Guidelines (NSC, 2016; Dowell et al., 2016). According to the 2017 Surveillance Report of Drug-Related Risk and Outcomes, at least 20% of patients who present in an office-based clinical setting are being prescribed opioid agents and primary care providers are responsible for half of the opioid pain medications dispensed (CDC, 2017).

These prescribing practices are not supported by the evidence. Although research supports that opioids are effective for short-term treatment of pain, few studies have been conducted to assess the long-term benefits of opioids for chronic pain (Dowell, et al., 2016). However, the risks of long-term opioid use are clearly established including abuse, dependence, and overdose. In the past decade, the death rates associated with opioid pain medication have increased significantly (CDC, 2015). Lack of education and the resulting over prescribing of opioids for chronic pain has contributed to a national health emergency (CDC, 2016). Safer and

more effective treatment protocols are necessary to treat chronic pain in the primary care setting. The fact that PCP prescribing practices are contributing significantly to the number of opioids available to the public is a huge problem that needs to be addressed through education and the implementation of safer treatments for chronic pain.

Addressing the Problem with Current Evidence

With the newest practice guidelines and evidence supporting only the short-term use of opioids, alternative treatment options for chronic pain are necessary. In 2017, the CDC published guidelines for prescribing opioids for chronic pain with the goal of improving the ways that opioids are prescribed to ensure that patients have access to safer and more effective treatment for their chronic pain. The guidelines recommend using non-opioid therapies to treat pain when possible. One such alternative is the use of non-opioid topical analgesics to treat chronic pain (CDC, 2016). This section will address the best ways to prevent this problem, lack of awareness of topical analgesics as a treatment option, the current practices and the evidence supporting the use of a NOTA protocol in a primary care setting.

Prevention. One of the most effective ways to prevent the risk of opioid abuse in patients suffering from chronic pain is to improve opioid prescribing practices. The new CDC guidelines recommend that if opioids are prescribed for the treatment of chronic pain, the lowest dose possible for three days or less, but not to exceed seven days, should be utilized (Dowell, et al., 2016). Non-opioid therapies should be first-line treatment, and only in rare cases should opioid medications be prescribed for the treatment of chronic pain (CDC, 2016). Opioid prescribing practices can be improved through provider education and implementing safer, but effective treatment protocols (Dowell et al., 2016).

Another preventative method includes identifying and educating those patients at risk for opioid addiction. The longer a patient is on opioid therapy, the risk for abuse increases (Volkow & McLellan, 2016). Tools such as the Opioid Risk Tool is a screening tool designed specifically to help identify patients in the primary care setting who are at higher risk of abusive drug-related behavior (Webster & Webster, 2005). Education in safer practices and screening tools to identify high-risk patients will help prevent opioid misuse in primary care patients suffering from chronic pain.

Current management. Currently, healthcare providers are looking for alternatives to using long-term opioids for the treatment of chronic pain. The majority of providers are currently prescribing opioids for longer than the three days recommended by the CDC. In addition, there is a lack of education and awareness of safe alternative treatments. One major anticipated compliance issue with this new regiment is patient resistance. A recent study on provider and patient perspectives on pain embodies the issues present at outpatient primary care clinics. This study found that providers feel that alternative treatment options for chronic pain are limited and in return, many patients are unwilling to independently reduce their pain medication (Penney, Ritenbaugh, DeBar, Elder & Deyo, 2017).

Current recommendations. The recommendations to address this problem include (1) prescribing non-opioid topical analgesics for the treatment of chronic pain in lieu of opioid therapy and (2) increasing provider knowledge and awareness of the risks of long-term opioid use and the benefits of the safer topical analgesic protocol. This section will address the evidence that supports these recommendations.

Prescribing NOTA for the treatment of chronic pain. There is a growing and emerging body of research to support the use of compounded NOTA to treat chronic pain (Gudin

et al, 2017). Much of this research is in response to the cry from providers and other stakeholders to find a safer alternative to opioid therapy. Although topical application of medication reduces the risk of addiction, abuse of topical and/or transdermal opioid medications, such as fentanyl, is widespread (Schauer, Shand & Reynolds, 2015). This section examines the research to support the use of NOTA in the treatment of pain.

In 2014, Rehabilitation Research and Practice published an article that supports the use of topical menthol for the management of chronic and neuropathic pain. This study was a triple-blind, randomized placebo-controlled trial involving 10 participants. The results indicated that pain intensity decreased following the treatment of topical menthol compared to the placebo group, who just received a gel with a menthol scent (Sunstrup et al, 2014). The authors therefore concluded that topical menthol should be considered an effective nonsystemic alternative treatment for the management of chronic, localized musculoskeletal and neuropathic pain (Sunstrup et al, 2014).

In 2015, Pain Therapy conducted a review of various TA and their effectiveness in treating pain, examining research studies that have been conducted to determine their efficacy. Overall, the authors concluded that TAs are effective in interrupting the pain transmission signals within the body and can play a huge role in treating pain. Empirical research also supports that compounding two or more different topical analgesics can target pain through different mechanisms and therefore can be even more effective in the treatment of pain (Rehm, Binder & Baron, 2010; Peppin et al, 2015). The authors recommend developing a relationship with a pharmacy that can compound multiple TAs to provide a customized treatment (Peppin et al, 2015). Although there is research to support their effectiveness, the authors recognized that more research should be conducted to confirm these findings.

In 2015, a retrospective study was conducted evaluating the efficacy of two different compounded topical analgesics as compared to just a single agent (Voltaren gel). A total of 2177 patients were evaluated, 1141 received Cream one compound, 527 received Cream two compound and 509 received the single agent compound. Results indicated that the compounded creams reduced pain by 37% and 35%, whereas the single agent TA reduced pain by only 19% (Somberg & Molnar, 2015). This article supports the use of compounded TA are more effective than single agent TAs.

Recognizing the increase in popularity of compounded TAs for the treatment of chronic pain, the American Contact Dermatitis Society published a review of the efficacy of various types of TA and their side/adverse-effects. The authors reviewed seven common drugs used in topical application and their effectiveness as a compounded agent. They analyzed the results of at least 24 different studies that examined the effectiveness of pain reduction. The results of the studies ranged from finding that 81% of patients reported less pain to some that found no statistical difference. The majority of studies however found statistically significant reduction in reported pain. The authors, therefore, concluded that TAs provide an alternative treatment option with decreased side/adverse-effects and decreased drug-to-drug interaction. A rash seemed to be the most prevalent adverse reaction to these medications (Cline & Turrentine, 2016).

In 2016, a double blind, randomized controlled study was conducted in a human experimental model of pain. Sixty-nine healthy participants were divided into two groups. The first group received either a low-dose or a high-dose of compounded TA (clonidine and pentoxifylline) and two placebo treatments separated by 48 hours. The second group received single drug treatments. The visual analogue scale (VAS) rating was the primary measurement of

pain based on the effects of the central pain sensation (allodynia) after intraepidermal capsaicin injection and a post-capsaicin tourniquet-induced pain 50 minutes following capsaicin injection. Both the high and low compounded treatments significantly reduced the VAS pain intensity as compared to the placebo and the single drug treatment groups. Given the significant findings of pain interruptions with the use of compounded TA, the authors predict that high doses of compounded agents will be effective in treating patients with complex regional pain syndrome and neuropathic pain (Ragavendran et al, 2016).

The most recent and relevant research article specific to this DNP scholarly project was published in the *Journal of Pain Research* in October 2017. This article looked at changes in reported pain levels following the use of compounded TAs in the treatment of chronic pain at three and six-month follow-up. This was a prospective, observational study that compared changes from baseline pain levels, measuring overall severity and interference scores with the Brief Pain Inventory. It also measured the use of concurrent medication. A total of 631 patients enrolled; the patients treated with compounded topical analgesics were compared to the controlled groups at the three and six-month follow-up. A subset of the intervention group and the controlled group were matched based on sex, primary pain complaint and age, and data was collected and compared on these matched groups (Gudin, 2017).

Patients were prescribed various forms of topical analgesics that primarily included a compound of diclofenac, ketoprofen, flurbiprofen and/or other formulations not containing NSAIDs. Data was collected at baseline and at four-week intervals through the six-month period. The Brief Pain Inventory short form was used, which contained a numerical scale of 0-10; patients receiving the topical therapy were also asked to indicate any side/adverse-effects from the TA they observed. Information on other concurrent medications that were taken at

baseline and three days prior to the completion of the surveys was also collected. These concurrent medications included over the counter agents, NSAIDs, or prescriptions like opioids and/or anticonvulsant agents (Gudin, 2017).

The results of the study indicated that treatment with compounded TAs caused an overall reduction in pain severity and interference; these conclusions were the same of both the matched and unmatched intervention groups. Importantly, the majority of the patients in the controlled groups reported no side/adverse-effects associated with the topical therapy. The study is limited to its exploratory nature and the authors indicate that randomized, controlled trials should be conducted to confirm the results of this study. Other limitations include that the participants were volunteers and the pain complaints and changes in concurrent medication were reported by the patients, not based on a provider's assessment (Gudin, 2017).

The study also found that patients in the intervention groups reported a significant decrease in their use of concurrent pain medication as compared to patients in the controlled groups who reported increases in their concurrent medications. Specifically, after the use of TA, 49% of the patients in the three-month group and 56% of patients in the 6-month group reported that they were no longer using opioid medications. Other non-opioid medications decreased by 65% after 3-months and 74% after 6 months (Gudin, 2017).

Overall, there is a growing body of evidence to suggest that non-opioid topical analgesics are effective in the treatment of pain. Compounding two or more of these topical analgesics can increase the effectiveness of the treatment of pain.

Increasing awareness of TAs for the treatment of chronic pain. Awareness of compounded TAs as an alternative treatment for chronic pain has increased over the last several years. Older research suggests that only 27% of the 120 responding physicians reported that they

prescribed compounded TAs in their practice (Ness, Jones & Smith, 2002). More recently, however, a brief survey from 2014 capturing prescriber's beliefs concerning compounded TAs for pain indicate that 81% of respondents had prescribed TAs for the treatment of musculoskeletal pain and 63% have used it for the treatment of neuropathic pain. Although there was a 78% response rate to this survey, only eleven participant's responses were obtained (Warner & Tudor, 2014). Even though it appears there is some limited evidence that awareness and use of compounded TAs for the treatment of pain has increased among healthcare providers, additional efforts to educate on their effectiveness is necessary. Data suggests that topical analgesics are underutilized for the treatment of chronic pain (Peppin et al., 2015).

Benefits of Current Recommendations. There have been several recent journal articles that offer reviews of available evidence on the efficacy of compounded TAs and advocate for their continued use. In 2014, The Journal of General Practice published an article entitled, Pain Management Therapy: The Benefits of Compounded Transdermal Pain Medication (Branvold & Carvalho, 2014). This review was in response to the ever-growing concerns of the continued use of opioid medication and the increase in drug abuse, overdose and lack of efficacy. The study found the benefits of compounded analgesics include (1) customizable dosages, formulation and drug combinations, (2) lower systemic absorption, (3) minimal side/adverse-effects, (4) better adherence to treatment regimen, and (4) minimizing risk of abuse (Branvold & Carvalho, 2014).

Issues still under investigation. Many of the studies presented above focus on certain types of chronic pain. There is still a lack of general consensus if the results of these studies can be applied to all pain-related conditions. Additionally, many of the studies performed are for short duration and involve small participant groups (Cline & Turrentine, 2016). Long-term,

randomized controlled studies are needed to further validate the use of this treatment option (Gudin, 2017).

Controversies. In response to the call to curb opioid prescriptions, many organizations question if these new practices will increase suicide rates or cause patients to use heroin or other drugs illegally. The Pain News Network calls these possible negative consequences "the fallout from the CDC's guidelines." They conducted a survey of over 2,000 patients. The results of this survey are troubling and reflect lack of patient education and understanding of opioid pain medications. This survey revealed that 90% of patients thought that patients would suffer more as a result of the guidelines, 78% believed there would be more patient suicides, and 70% thought the use of heroin and other street drugs would increase. In addition, there is indication that street dealers are now targeting prescription pain patients and offering counterfeit pain medications. These counterfeit medications have been linked to nearly two dozen deaths (Anson, 2016).

Significance of Evidence to the Profession. Over prescribing of opioids is a huge problem in the healthcare, particularly in the primary care setting. A review of Medicare prescription drug claim data from 2013 indicates that the most opioids were prescribed by primary care providers (15.3 prescriptions) followed by internal medicine. Surprisingly, nurse practitioners (4.1 million prescriptions) and physician assistants (3.1 million prescriptions) were third and fourth on this list (Chen, Shah & Lembke, 2016). Given the popularity of the opioid crisis and the ongoing scrutiny of prescribing practice, it is even more imperative that nurse practitioners practice safe prescribing practices. Especially so when the American Medical Association and other organizational bodies are advocating to limit the autonomy of nurse practitioners (American Association of Nurse Practitioners [AANP], 2017). A review of the

literature supports TAs as alternative treatment for chronic pain. Because these alternative treatment options have the ability to reduce the patient's pain and lower the risk of abuse and prescriber liability with opioid prescribing and opioid disorders, it will play a significant role in the profession.

Theoretical Models

To provide a framework to guide this DNP project, a combination of Kurt Lewin's change theory and Malcolm Knowles' theory of adult learning will be used. Lewin's change theory will provide a framework for implementation of the NOTA protocol. Malcolm's adult learner theory will assist in the implementation of the education component of this project. It will be utilized by the project lead when educating the clinic providers in the new protocol as well as used by the providers themselves, when educating their patients.

Lewin's Change Theory

Lewin's change theory is a time-tested theory that can be applied to personal, group or organizational change. Lewin was a social psychologist, who has been coined the "father of social change theories" since many subsequent management models are based on his work (Kaminski, 2011). Lewin's change theory was developed in the 1940s and developed out of research into social action, group dynamics, and leadership styles. Today, Lewin's theory is used across nursing specialties for various quality improvement projects aiming at improving health outcomes (Wojciechowshi, Pearsall, Murphy & French, 2016).

Major tenets of Lewin's theory. Lewin's theory proposes that complex systems must adapt to ever-changing environments to maintain equilibrium and produce positive outcomes (See Appendix A). In response to this need to adapt, Lewin proposed a three-stage model for

change known as unfreezing-change-refreezing. This model requires former learning to be rejected and substituted with the new protocol (Petiprin, 2016).

Lewin defines behavior as "a dynamic balance of forces working in opposing directions" (Petriprin, 2016, para 2). Building on this definition, Lewin outlined three major concepts that impact change: driving forces, restraining forces and equilibrium. Driving forces are those that compel a change in a positive direction. Examples of driving forces include financial resources and management support. These forces create a shift in the equilibrium toward change. Pulling against this motivation to change are restraining forces. These forces impede change and can include staff resistance to change and lack of financial resources or management support. A state of equilibrium is where the driving forces and the restraining forces are equal, and no change occurs (Petiprin, 2016). Change requires the organization to execute specific activities to cause the change to occur.

Change comes about through the process of unfreezing, changing and then refreezing. Unfreezing is the process of making people aware of a problem and then need for change. This can occur through providing education, making individuals aware of the problem, and challenging the status quo. The next step, changing, requires finding alternatives to propose to the members of the organization. This includes outlining the benefits of the change and overcoming the restraining forces that oppose the change. This second step often includes brainstorming sessions, training and coaching on the new intervention. Finally, refreezing refers to the process of stabilizing a new equilibrium into the system, so it becomes the habit of the organization. It is necessary to celebrate the success of the intervention, re-train the participants and monitor their compliance in order to maintain the change (Wojciechowski et al., 2016). Without this final stage, it can be easy for the organization to revert back to the old practices.

Application of Lewin's theory to current practice. In today's rapidly advancing and changing healthcare environment, an organization's ability to evolve is essential. It is common to find healthcare staff being resistant to change because it can cause fear of failure or anxiety about a new process; this in turn produces the restraining forces discussed by Lewin. This resistance to change is particularly present in today's workforce due in large part to the rapidly developing technologies, new guidelines and the aging workforce (McNeil, Sharpe & Benbow, 2012).

Aging nurses and healthcare providers offer a wealth of experience but are often more resistant to technology and change. The outdated practice of long-term opioid treatment will be a difficult driving force to overcome, given that providers and patients have become comfortable with this treatment and many of patients are now dependent on opioid agents to function (Dowell, 2016). Effective change in this area will require involving the healthcare staff in the proposed changes. Research suggests that the most important management practices in retaining staff and enriching a workplace are recognition and respect, having a voice and receiving ongoing feedback on one's performance (McNeil et al., 2012). Application of Lewin's three-step change process can meet these identified factors by including the staff in the brainstorming process, providing education, celebrating successes and offering re-training, if needed.

Given the increasing awareness of the opioid crisis (part of Lewin's "unfreezing step") and the new CDC Guidelines for prescribing opioid agents, the driving forces for change as it relates to the management of pain and opioid prescribing practices are unmistakable. However, many organizations stop at or just before the "unfreezing" stage because the restraining forces of old practice habits and lack of education on alternative treatment options (Wilson et al, 2013). The educational component incorporated into Lewin's theory at all three stages of the process is

essential to successfully implementing change in this area. The status quo of prescribing long-term opioid therapy is no longer a safe standard of care (Dowell et al., 2016). Lewin's second phase of change can assist in the adoption and application of new guidelines and protocols in the treatment of chronic pain in primary care settings. Finally, without the refreezing stage, which involves sharing and recognizing the success and benefits of non-opioid treatments, it will be easy for the organization to slip back into old patterns of practice and cause an unstable and unsafe practice setting.

Malcom Knowles Adult Learning Theory

This DNP project includes an educational intervention for the providers. This intervention will utilize the learning concepts encompassed in Knowles' adult learner theory. This theory was developed after documenting the differences between adult and child learners. Examining these differences, the concept of andragogy, the art and science of adult learning, was developed (Pappas, 2013).

Major tenets of Knowles theory. Between 1980 and 1984, Knowles made five assumptions about the characteristics of adult learners. These assumptions include that adult learners are self-directed, they can draw from life experiences as a resource for learning, they must perceive a need to know, they are problem-centered, and genuinely interested in furthering their knowledge (Knowles, 1998). One of the basic underpinnings of this theory is that adult learners need to know the importance of learning something before they will take the time to apply themselves to learning it. In other words, if adult learners do not see the practical value in learning a subject, they will be less likely to apply themselves to the knowledge. They are independent learners and will not be open to situations where they feel others are imposing their

will upon them. Their motivation comes from the realization that learning this knowledge will help them perform tasks and deal with problems they encounter in life (Pappas, 2013).

Application of Knowles' theory to current practice. Education regarding appropriate screening along with safe and effective pharmacotherapy for patients presenting with chronic pain is imperative (Bhatt & Arespacochaga, 2017). The Food and Drug Administration (FDA) stresses that it is "critically important" to facilitate appropriate education to providers, including knowing when and for which patients opioids should be prescribed (FDA, 2013, para. 9). This intervention includes educating patients in the appropriate use of these scheduled II medications as well (FDA, 2013).

Knowles' model indicates that adult learners are more willing to engage in education if the knowledge will help them perform tasks and deal with problems they encounter in their practice. With the new guidelines and a clear indication that providers want further education, it is important to employ an educational model that will be effective for adult learners. Because the provider-patient relationship may be the most powerful tool to address the opioid crisis, it is imperative that providers receive appropriate education, so they can pass along their knowledge of the risk of opioids and the efficacy of other treatment options to the patient (CDC, 2016). Patient resistance is a resisting force that could impact the success of a new protocol.

Application of Lewin's and Knowles' Theories to DNP Project

Lewin's change theory will provide the guiding framework for the implementation of the NOTA protocol. The first step in this process is unfreezing the current prescribing practices of the outpatient clinic. This stage will include educating the providers in the new CDC guidelines, risk of opioid abuse and the how ineffective long-term opioid therapy is for the treatment of

chronic pain. Through this education, the driving forces of change should help to compel the necessary change.

Next, the changing stage involves proposing TAs as an alternative treatment to opioids. This will include another educational component outlining the benefits of TAs and brainstorming with the providers and stakeholders of possible issues that may arise with utilizing the new protocol. This stage will also include training sessions where the providers will be coached in how to introduce this new protocol to the patients who may likely be resistant at first. Finally, the refreezing stage will ensure the providers are adherent to the protocol through monitoring of the intervention and emphasizing the success of the NOTA protocol. This will be evaluated through the results of patient pain severity ratings and overall reported patient outcomes under the new treatment protocol.

This DNP project will enhance the providers' awareness of the new protocol, the dangers of long-term opioid use, and information regarding the efficacy of topical analgesics. The providers can then pass this information along to their patients when introducing the TA as an alternative treatment. Each step of Lewin's change process involves an educational component.

This educational component will be outlined as to the purpose and clearly identify the content, as well as the risks and benefits of each treatment option. Education, through application of Knowles Learning Theory, will be the primary and tertiary intervention that will be utilized in this DNP project. By providing appropriate pain management education to providers, they in turn can educate their patients more effectively about safer and more effective non-opioid treatments.

Effective education to the providers is of utmost importance because some patients will likely be unwilling to change their treatment plan or the stress of the new treatment will cause

resistance. When pain management treatment plans are changed, many times patients feel unheard, disempowered and cheated (Al Achkar et al., 2017). This is compounded by many patients feeling that chronic pain treatment is an unwinnable fight (Al Achkar et al., 2017). Providing effective education will help to overcome or lessen these possible stressors and should in time help strengthen the lines of communication.

Project Design

This project is a quality improvement initiative that will advocate for the implementation of the NOTA protocol (see Appendix B). The intended purpose of this protocol is to improve the quality of care and patient outcomes. This project will include an educational training for the providers on the use of the protocol. A pre-test will be administered prior to the educational session to assess the knowledge, skills and attitudes of the providers. After the educational session, a post-test will be administered to evaluate the effectiveness of the education and identify any areas that require further education.

The NOTA protocol is focused on the use of non-opioid topical analgesics as an alternative to long-term opioid therapy. Providers and clinic staff will be required to administer the Opioid Risk Tool to assess the patient's risk of abusing their opioid prescription. Data from the Opioid Risk Tool will not be measured, but whether this tool will be administered will be measured. This tool should be administered and reviewed by the providers for the purpose of identifying the patient's risk for addiction. The providers will also collect data using the Brief Pain Inventory to assess the patient's pain levels under the new treatment protocol to determine the efficacy of the new pain management regimen. This data will be collected and analyzed to determine if pain levels decrease during the course of this project. Data on prescribing practices will be collected to measure the dosage of any opioid prescription to see if the dosage or

frequency of prescribing opioids changes over time. This project will also monitor provider compliance with the protocol via retrospective chart audits over the period of the project. Data will be collected over the three-month period. Collected data will be organized and placed in a code-book. This data will then be analyzed through the use of SPSS Statistics software. McNemar's test and Wilcoxon Sign Rank test will be used to compare data at different time points.

Population of Interest

The population of interest are the providers and healthcare professionals working at the clinical site. Currently, there are two providers at the clinical site. The full-time provider is an advanced practice registered nurse (APRN) who manages the majority of the patients at the site. The second provider is an APRN that works per diem. Both providers will be included in the protocol training.

Setting

This protocol will be implemented at the clinical site, which is an outpatient primary care clinic. On average, the clinic sees 15- 20 patients per day. The patients range in age and ethnicity and present with various complains. At least 20% of the patients who regularly present to the clinic have some complaint of chronic pain. Currently, a large percentage of those patients presenting with chronic pain are receiving long-term opioid therapy.

Stakeholders

Immediate stakeholders include the project mentor, content expert and the staff at the clinical site. In addition, the patients will be referred to the content expert for their compounded TAs. Additional time needs to be spent with the per diem provider at the practice as she is a new hire. These stakeholders are instrumental to the project as they are the individuals who will

facilitate the project at the clinical site. The project mentor is the owner of the clinical site, if this project is successful, it will be a permanent protocol for the practice. The indirect stakeholders are the patients who will benefit from the a safer and effective treatment.

Recruitment Methods

Practitioners. The following project is a practice change initiative in the practice setting. Therefore, the two APRNs working at this facility will be participating. Inclusion criteria is: practitioners who are responsible for prescribing and caring for pain management patients. Exclusion criteria include: staff working at clinic, such as receptionists who are not directly responsible for prescribing and caring for pain management patients. Given the new laws and current guidelines concerning the prescribing of opioids participating in this protocol will provide the providers a safe alternative to long-term opioid therapy, which should provide an additional incentive for compliance.

Chart audits. Retrospective and post-implementation chart audits will be conducted to evaluate the effectiveness of the NOTA protocol. A total of 30 charts will be reviewed pre-implementation and those same 30 charts will be reviewed post implementation. Specific inclusion criteria include (1) age 18-64 years; (2) currently experience chronic pain attributed to any cause including neurological, musculoskeletal or other medical conditions; (3) both male and female. Patients are ineligible if they have a history of illicit drug use or misuse of prescription drugs or are currently being treated for cancer.

Tools/Instrumentation

Educational Tools

Prior to protocol training, the providers will be given a pre-test. This test will assess their knowledge, skills and attitudes towards opioids (See Appendix C). An educational session

relating to the new protocol will be presented at the clinical site. This training will include a PowerPoint presentation that will cover the NOTA protocol, common attitudes towards opioids, current guidelines concerning the prescribing of opioids, current laws concerning the prescribing of opioids and best practices (See Appendix D). Handouts will also be prepared for the providers to give/discuss with the patients concerning the risks of long-term opioid use and the benefits of using NOTA to treat their chronic pain (See Appendix E). After the presentation, a post-test will be conducted to assess the effectiveness of the presentation (See Appendix F). The content validity index for the pre and post test is included in appendix G.

NOTA Protocol

The protocol will be given in written format to the providers at the practice site. This will guide their use of the protocol (See Appendix B). The protocol contains inclusion criteria for patients who present with chronic pain, and screening and assessment tools to be used by the provider.

The Opioid Risk Assessment tool will be added to the NOTA protocol (See Appendix H). This assessment tool was developed in 2005, targeting adults who present to their primary care clinic. This tool assesses the risk of aberrant behaviors for patients who take opioids for chronic pain. Its limitations are the self-reporting nature of the information and possibly the patient's lack of knowledge of family history (Opioid Risk, n.d.). This assessment tool has been validated in both male and female patients suffering from pain and is effective for risk stratification. The omega hierarchy was .89, which indicates most of the variance is due to the general factors (Henrie-Barrus, Averill, Sudweeks, Averill & Mota, 2016). The stronger the explained common variance, the more confidence a researcher should have in applying this model (Reise, 2012). Permission to use this tool has been obtained from Dr. Webster (see Appendix I).

The Brief Pain Inventory will be used within the protocol to assess patient pain levels under the new treatment protocol (see Appendix J). Most of the patients that present for chronic pain have monthly appointments with their provider. Pain levels will be assessed prior to implementation and monthly thereafter. Improved pain levels will assist with justifying the sustainability of this protocol in the practice site. This tool was originally designed to assess pain in cancer patients but has since been used to assess pain in patients suffering from several different types of pain. This tool is one of the most commonly used tools to measure and assess pain in patients suffering from pain (Stanhope, 2016). This tool assesses the patient's level of pain and how that pain interferes with activities of daily living. Its Cronbach alpha reliability ranges from 0.77 to 0.91 (Brief Pain Inventory, n.d.). Permission to use this tool has been requested (See Appendix K).

NOTA Policy and Procedures

A clinic-wide policy concerning the NOTA protocol will be implemented at the practice site. (See Appendix L). If the project results are successful, this policy will be used to promote the sustainability of the protocol.

Chart Audits Tool

Retrospective chart audits will be used to assess provider compliance with the new protocol. These audits will be completed in two ways. First, data from the clinical site will be collected. Measurements include whether the NOTA protocol was initiated, the dosage and quantity of opioids that were prescribed to patients, and whether the Opioid Risk Assessment and the Brief Pain Inventory were utilized. Measurements also include pain levels of the patients taken from the Brief Pain Inventory too. This information will be inputted into an Excel spreadsheet that will then organized for use in SPSS (See Appendix M).

Audits will also be conducted from obtaining reports from WellCare Pharmacy, the pharmacy that mixes and dispenses the compounded TAs. This pharmacy keeps a record of patients by type of prescription and provider. This can be used to compare to the chart audits to ensure compliance. Additionally, the prescription monitoring program can provide additional information on the prescribing practices of the providers. This information can be used to verify the accuracy of the chart audits.

Data Collection Procedures

The educational component to this project will be measured by pre and post test scores and attendance at the initial training and follow-up trainings. Each provider will be given a number, this number will be used to identify their scores and chart audits. Assignment of a number will help insure that the data collected remains private. The results of these tests will be collected and inputted into an Excel spreadsheet for further analysis. If, during the chart audits it is clear that a provider or member of the staff is not complying with the protocol, additional education/training will be implemented with that employee.

Data collection of provider compliance with the protocol will be performed primarily through retrospective chart audits and reports from WellCare Pharmacy. Compliance with the protocol will be measured through pre and post-implementation of the number of patients prescribed opioids, notations in chart of opioid education provided to patients, completion of the Opioid Risk Assessment Tool and the Brief Pain Inventory. Pain scores from the Brief Pain Inventory will be collected and analyzed to justify the sustainability of the project at the clinical site. Patient charts will be assigned a letter to protect the anonymity of the patients.

Data from the tools and questionnaires discussed above will be collected via retrospective chart audits. Each provider in this project will be assigned an identification number. Data will

then be inputted into an Excel spreadsheet for organization into a codebook and later used with Statistical Package for Social Sciences (SPSS). Descriptive statistics will be run for all questions. Any statistically different statistics between the different audit times will be calculated using McNemar test for binomial data and Wilcoxon Sign Rank test for scale data. Alpha will be set at .05.

Project Timeline

This project will be implemented over a four to six-week period. The project is scheduled to start in July 2018. In preparation for a July 2018 start date, this proposal will be submitted to the academic and project mentors for review by June 12, 2018. By mid-June all the necessary tools will be completed for review. By June 22, 2018, approval will be obtained for implementation. The following is the projected timeline for this project by week.

Week 1: Obtain approval for implementation from the project mentor and recruit providers to participate. Because this is a QI initiative, all providers at the practice site are required to participate. Recruitment will include sending out emails, introducing the providers to the project and providing them with a general overview of this project. Attached to that email will be the questionnaire that they will be required to take. The first questionnaire will be collected and reviewed prior to the educational presentation. Data from questionnaire will be collected and input into a spreadsheet. The email will include a mandatory presentation time. The educational presentation will be offered to the providers who prescribe opioids and the NOTA protocol. A post presentation questionnaire will be given to providers. Data from the post presentation questionnaire collected and input into spreadsheet.

Week 2-6: Providers will begin implementation of the NOTA protocol. The project lead will monitor implementation via weekly visits to the clinical site and frequent communication

with the providers via phone and email. The project lead will reach out to the providers to see if they have any questions or concerns. The project lead will provide additional education if needed based on post education questionnaire scores. Chart audits will also be conducted during this time to ensure compliance and the protocol is being used effectively.

Week 2: At the end of week 2, a chart audit will be conducted.

Week 4: At the end of week 4, chart audits will be conducted. Data input into spreadsheet.

Week 6: At the end of week 6, chart audits will be conducted. Data will be obtained from partnering pharmacy regarding the amount prescribed NOTA treatments as well as concerning prescribing practices.

Week 8: Data will be entered into spreadsheet. Data will be analyzed via SPSS systems and the aforementioned statistical tests.

Week 12: Dissemination of project results will be presented to stakeholders

Week 14: Dissemination of project to instructors and colleagues will be completed.

Ethics & Human Subject Protection

In order to ensure ethical conduct and protect the human participants, the required coursework on research and protection of human subjects was completed. Since this is a practice change affecting the clinic, all providers are required to participate. Providers will be introduced to the protocol via initial discussions. Providers will not be given any incentive to participate. All information derived from this DNP scholarly project will be safeguarded and kept in a locked file cabinet. Results of this project will be disclosed in order to contribute to the body of nursing knowledge. Each provider will be assigned a number to ensure their anonymity in the process. The providers benefit from participation by practicing safer care for patients. The risks to

providers in this project are potential patient dissatisfaction with not being prescribed their opioid medications. The providers are not being compensated for their participation aside from their normal salaries from the practice site. Each patient chart will be assigned a number to ensure the confidentiality of the patient's information.

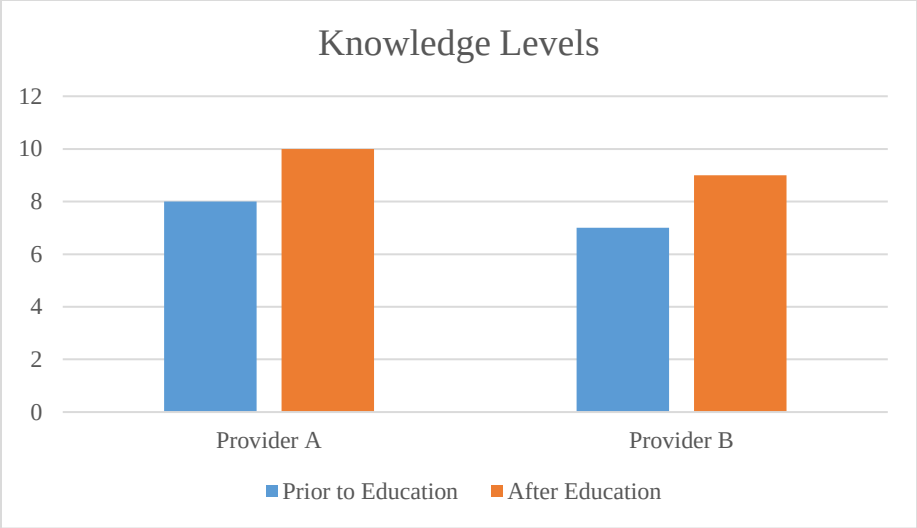
Since this DNP project has a quality improvement design it should be considered exempt for Institutional Review Board (IRB) review. The project site does not require IRB review for this project.

Analysis of Results

Over the course of this project, 25 patient charts were audited. Two providers participated in the project. One provider works at the clinic full time (Provider A) and the other worked a total of five days over the course of this study (Provider B). As such, the majority of patients were seen by provider A. Below is an analysis of the data based on outcome measurements.

Knowledge Questionnaire

Data from pre and posttests were collected and analyzed. Test scores were collected and the chart below indicates the results.



This chart indicates that the educational session was effective, with both providers increasing their scores after the educational session. There were 10 questions testing the provider's knowledge of prescribing laws, best practices, and treatment options. The chart above illustrates how the participants scored in knowledge and skills. Both providers increased their score on the post-test after the educational session.

A review of the answers concerning their attitudes/perceptions indicates the providers became more confident in their pain management and prescribing abilities. The answers to the four attitudes/perceptions questions either remained the same or increased (a Likert scale was used). For example, in response to the question "I am confident in my prescribing practices", the pre-test answer was "agree" (Provider A) and "somewhat agree" (Provider B). After the educational session and introduction of the NOTA protocol, the post-test revealed an answer of "strongly agree" (Provider A) and "agree" (Provider B). In addition, both providers gave higher scores to the question "I can identify patients at risk of misuse of pain medication" on the post-test than the pre-test.

Chart Audits

The audited charts consisted of 12 male patients and 13 female patients with an average age of 49. The sources of pain included low back, knee, shoulder, wrist, and ankle.

Prescribing practice. Prescribing practices were measured by two separate outcomes: (a) whether opioids were prescribed before the intervention and after and (b) whether the dosage of the opioids prescribed reduced as a result of the NOTA protocol.

In determining whether there was a statistical difference in opioid prescriptions before and after the intervention, a Wilcoxon Signed Rank Test was run. The Wilcoxon Signed Rank Test revealed a statistically significant reduction in occurrences of opioid prescribing following implementation of the NOTA protocol, $z = -3.00$, $p < .003$. with a medium effect size ($r = .42$) using Cohen's criteria.

In regards to the dosage of the opioid agent being prescribed, the Wilcoxon Signed Rank Test revealed that the average dosage of Norco at baseline was 5.7 and after the intervention it was 4.7. Despite this decrease, there was not a statistically significant decrease in opioid dosage ($z = -1.805$, $p = .071$). A review of the data however, shows that of the four patients that did not have an opioid prescription at baseline, none of those patients were prescribed an opioid at their subsequent visit.

Screening tools. Because the practice did not use the Brief Pain Inventory, the Opioid Risk Tool or the Patient Education Handout prior to this project, compliance with their use was measured by frequency of use after the intervention. The frequency calculations reveal that the BPI was obtained in 92% of chart audits. The Opioid Risk Tool was used 80% of the time and the Patient Education Handout provided to patients in 88% of patient encounters.

Pain scores. Changes in pain scores after being prescribed NOTA was a secondary measure of this project. Because of the short length of this project and the protocol recommending follow-up in four weeks, there were only three patient charts that included pain scores at two separate points in time. A review of these scores revealed that the patient's pain levels slightly reduced in two of the three patients and remained unchanged in the third.

Discussion of Findings

The results of this project demonstrate the effectiveness of the provider education that was provided as part of this project. The educational session not only increased the providers' knowledge of the management of chronic pain, but it increased their confidence in their prescribing practices. This is significant considering providers often report inadequate training in prescribing opioids (Jamison et al., 2014). These results support the importance of provider education in ensuring that best practices are being used in clinical settings.

The chart audits revealed promising results. The project question sought to determine if implementation of the NOTA protocol would reduce the use of oral opioid agents in patients with chronic pain. The chart audits reveal that the vast majority of patients treated with an opioid at this clinical site are prescribed Norco at varying dosages. The results demonstrate there was a significant reduction in the occurrence of prescribing opioids. Although there was not a statically significant reduction in the dosage of opioids prescribed, the average dosage of opioid agents did decrease. Further, the providers did not increase the dose of the opioids prescribed to the patients under the NOTA protocol. A retrospective review of the charts prior to the implementation of the protocol showed several patients were prescribed a steady increase in dosage of opioids over the course of their treatment.

What is even more significant is that in the four patients presenting for the first time with chronic pain, none of them were prescribed an opioid. Without the implementation of this protocol, it is likely those patients would have been prescribed an opioid medication, given prior clinical practices. Instead, these patients were offered a safer, yet effective treatment option. NOTA reduced the risk of possible opioid abuse/addiction by the patient and offered the provider a much safer treatment alternative.

The project results also show the success of implementation of screening tools. Screening tools concerning the risk of opioid abuse are recommended as a best practice when prescribing opioids. Prior to this protocol, the clinical site had no policy and one limited protocol requiring a screening tool that was not consistently used by the providers. After implementation of this protocol, the BPI was used in 92% of chart audits and the ORT was used in 80% of the patient encounters. The first chart audit revealed that the screening tools were still not being consistently utilized. Follow-up discussions with the providers seemed to address this lack of compliance. Further, the Opioid Risk Tool had the lowest compliance rate at 80%. A review of the data shows that on three instances, the tool was discussed with the patient, but an "N/A" was placed on the tool. The "N/A" notation was for patients who were not previously on an opioid medication and were prescribed NOTA rather than an opioid at that visit. Furthermore, the patient education was provided in 88% of charts that were audited. The increased use of the screening tools and patient education also support the effectiveness of the provider's educational session, which highlighted the importance of incorporating these tools and educational handouts into their practice.

The second part of the project question was to determine if implementation of the NOTA protocol would decrease patient pain levels. Given the timeframe of this project, there was not

sufficient data to provide a comprehensive answer to this question. The data collected however, does support that NOTA is effective in treating pain. There were only three repeat pain scores. Two patients reported decreased pain and one patient reported their pain levels unchanged. Also, of importance is that patient pain scores did not increase with the implementation of NOTA. The results of this project indicate that the answer to the question of whether NOTA will decrease reported pain levels will likely be yes, but without more data, no strong conclusions can be made.

Significance and Implications for Nursing

The results of this project have significant implications for nursing by providing a safe and effective non-opioid treatment for patients who present with chronic pain. Currently, there is national scrutiny related to opioid prescribing practices. Due to the escalating deaths associated with opioid overdoses, the CDC recently published new opioid prescribing guidelines (Dowell et al., 2016). The Food and Drug Administration (FDA) added a black box warning for prescribing opioids and benzodiazepines (FDA, 2016). U.S. Surgeon General, Vivek Murthy, addressed U.S. providers asking them for commitment to "Turn the Tide" on the opioid crisis, and the White House convened a summit of national leaders on this subject (The Surgeon General, 2016).

Locally, Nevada just passed the Prescription Drug Abuse Prevention Act, which became effective on January 1, 2018. This law requires strict prescribing practices for providers who prescribe controlled substances (Nevada.gov, 2017). This protocol can help answer the local and national call for providers to get better educated in opioid therapy practices and introduce a safer alternative to opioid therapy. The CDC Guidelines call for opioid prescribing practices to be improved through provider education and implementing safer, but effective treatment protocols,

which is the aim of this DNP scholarly project (Dowell et al., 2016). This project also has positive implications for the patients as it provides a safe and effective treatment for patients with chronic pain without unnecessary side/adverse-effects and the serious risk of causing dependence and/or addiction.

Limitations

This section will discuss the limitations to the project design, data recruitment and collection methods and the data analysis. The limitations in the project design included the fact that there was only one short, educational session and the scope of the pre and post-tests only tested the provider's skills, knowledge and perceptions on only some issues concerning pain management. Research suggests that providers a lack of training on a wide range of pain management treatment areas beyond simply opioids. A multi-session educational component with various pre and posttests would have provided more comprehensive training for the providers. Recruitment was limited by the size of the project site. Only two providers participated in this project, and one of those was only present in the clinic for approximately five days. This fact resulted in the majority of the compliance data being collected from one provider. Implementation of this project in a clinical site with more providers will allow a larger data set to be collected and analyzed. Further, limitation in data collected included the fact that data was reviewed via retrospective chart audits of only 25 patient charts. Increasing the number of chart audits would offer more complete data to analyze.

Gathering data over a longer period than six-weeks would have also allowed for more complete results, especially as it related to patient pain scores and measuring the effectiveness of NOTA's ability to reduce pain levels. The NOTA protocol in this case called for follow-up visits four-weeks after the initial visit. Given the six-week timeframe in this case and the limited

chart audits, data was collected from very few patients that returned for follow-up visits. Tracking the providers' compliance and patient outcomes for a longer period of time would have increased the data collected and many have resulted in more comprehensive results.

Despite these limitations, the results of this project are important for outpatient primary care clinics to consider in light of the high level of scrutiny of prescribing practices. The fact that there is some data indicating that patient pain levels did not increase further strengthens the appeal of implementing this project in other primary care settings. It is important that NOTA and similar protocols be presented as alternative treatment options for the treatment of chronic pain.

The fact that this project resulted in a reduction of prescribing opioids and increased use of screening tools supports its sustainability for the practice site. Locally, there is intense scrutiny on provider prescribing practices since the implementation of new, strict prescribing laws and regulations. A protocol that implements safeguards such as screening tools and offers an alternative pain management treatment to opioids is appealing in this current environment. Further, the cost of this project was minimal to the practice site and patients did not report increased pain levels when prescribed NOTA.

Dissemination

This project will be disseminated internally to my project mentor, content expert and student colleagues. I have met several times with my project mentor as the results from this project were being analyzed. Due to scheduling, in November 2018, I plan on officially disseminating my DNP project to my project mentor via a lunch presentation. Further, I am in communication with my content expert about scheduling a time to present the results to him in

the next several weeks. On October 23, 2018, I am scheduled to disseminate the results of this project to my student colleagues, academic mentor and other professors.

The project lead hopes to be able to present this project and its results to the American Association of Men in Nursing, Las Vegas local chapter. Communications concerning the presentation of this project are still in process concerning the date and venue. Further, on October 23, 2018, I am attending the local chapter meeting of the National Hispanic Nursing Association in Las Vegas, Nevada. I hope to be able to disseminate my results at this meeting. In April 2019, I plan on attending the 19th Stanford Symposium of Medicine. If I am unable to present at this conference officially, I plan on disseminating this project to the other participants through networking opportunities. Additionally, I work for a large medical group in Las Vegas. I am in communication with my supervisor to be able to present the results of this project at the winter provider meeting.

References

Ahmed, G. (2014). Kurt Lewin's Change Management Model – a three step change model. Retrieved from http://www.studylecturenotes.com/project-management/kurt-lewins-change-management-model-%E2%80%93-a-three-step-change-model

American Association of Nurse Practitioners (2017). American Association of Nurse Practitioners responds to American Medical Association amendment to resolution 214. Retrieved from https://www.aanp.org/press-room/press-releases/173-press-room/2017-press-releases/2156-aanp-responds-to-ama-amendment-to-resolution-214

Anson, P (2016). Are CDC opioid guidelines causing more suicides? *Pain News Network.* Retrieved from https://www.painnewsnetwork.org/stories/2016/5/27/are-cdcs-opioid-guidelines-causing-more-suicides

Branvold, A. & Carvalho, M. (2014). Pain management therapy: the benefits of compounded transdermal pain medication. *Journal of General Practice, 2*(6), 1-8.

Brennan, M., Gudin, F., Harris, E., Hurwitz, P., Dietze, D., & Viereck, C. (2015). Decreased pain following use of a topical analgesic: interim results from the optimizing patient experience and response to topical analgesics (OPERA) observational study. *Postgrad Med*icine, Early Online: 16.

Center for Disease Control and Prevention (2015), National Center for Health Statistics. Health, United States, 2014: with special feature on adults aged 55–64. U.S. Department of Health and Human Services.

Center for Disease Control and Prevention (2016). Nonopioid treatment for chronic pain. Retrieved from https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf

Center for Disease Control and Prevention (2017). Prescribing Data. Retrieved from https://www.cdc.gov/drugoverdose/data/prescribing.html

Chang, H., Daubresse, M., Kruszewski, S., et al. (2014). Prevalence and treatment of pain in emergency departments in the United States, 2000 – 2010. *American Journal of Emergency Medicine, 32*(5), 421-31.

Chen, J. H., Humphreys, K., Shah, N.H., Lembke, A. (2016). Distribution of opioids by different types of Medicare prescribers. *JAMA Internal Medicine, 176*(2), 259-261. doi:10.1001/jamainternmed.2015.6662

Chou, R., Deyo, R., Devine, B., Hansen, R., Sullivan, S. & Jarvik, J. (2014) The effectiveness and risks of long-term opioid treatment of chronic pain: Evidence Report/Technology Assessment. *Agency for Healthcare Research and Quality*, No. 218.

Cline, A. E., Turrentine, J. E. (2016). Compounded Topical Analgesics for Chronic Pain. American Contact Dermatitis Society. DOI: 10.1097/DER.0000000000000216

Daubresse, M., Chang, H., Yu, Y., & Viswanathan S, et al. (2013). Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000 – 2010. *Medical Care, 51*(10), 870-878.

Dowell, D., Haegerich, T. M., & Chou, R. (2016). CDC guideline for prescribing opioids for chronic pain — United States. *Centers for Disease Control and Prevention*. Retrieved from http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm#suggestedcitation

FDA (2017). FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning. Retrieved from:www.fda.gov/Drugs/DrugSafety/ucm518473.htm

Fink-Miller, E.L., Long, D. L. & Gross, R.T. (2014). Comparing chronic pain treatment seekers in primary care versus tertiary care settings. *Journal of American Board of Family Medicine, 27*(5), 594-301.

Florence, C.S., Zhou, C., Luo, F., & Xu L. (2013). The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States. *Medical Care, 54*(10), 901-906. doi:10.1097/MLR.0000000000000625.

Gudin, J. A., Brennan, M. J., Harris, E. D., Hurwitz, P. L., Dietze, D. T. & Strader, J. D. (2017). Changes in pain and concurrent pain medication use following compounded topical analgesic treatment for chronic pain: 3- and 6-month follow-up results from the prospective observational optimizing patient experience and response to topical analgesics study. *Journal of Pain Research, 10,* 2341-2354.

Henrie-Barrus, P., Averill, L. A., Sudweeks, R. R., Averill, C. L., & Mota, N. (2016). Development and preliminary validation of the Opioid Abuse Risk Screener. *Health Psychology Open, 3*(1), 2055102916648995. http://doi.org/10.1177/2055102916648995

Institute of Medicine (2011). Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. *The National Academies Press*. Retrieved from https://www.nap.edu/read/13172/chapter/2.

Jamison, R.N., Sheehan, K.A., Scanlan, E., Matthews, M., Ross, E.L. (2014). Beliefs and attitudes about opioid prescribing and chronic pain management: survey of primary care providers. *Journal of Opioid Management, 10*, 375–82.

Kaminski, J. (2011). Theory applied to informatics – Lewin's Change Theory. *CJNI: Canadian Journal of Nursing Informatics, 6* (1), Editorial. http://cjni.net/journal/?p=1210

Levy, B., Paulozzi, L., Mack, K.A. & Jones, C.M. (2015). Trends in opioid analgesic-prescribing rates by specialty, U.S., 2007-2012. *American Journal Preventive Medicine, 49,* 409-413.

Manchikanti, L., Kaye, A. M., Knezevic, N. M., McAnally, H., Slavin, K., et al . . . Hirsch, J. A. (2017). Responsible, safe, and effective prescription of opioids for chronic non-cancer pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines. *Pain Physician, 20*(2S), S3-S93.

McNeil, J., Sharpe, D., & Benbow, D. (2012). *Aging workforce: Retaining valuable nurses. Nursing Management, 43*(3), 50-54.

National Institute on Drug Abuse (2017). Opioid overdose crisis. Retrieved from https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#three

National Pain Society (2015). NIH study shows prevalence of chronic or sever pain in U.S. adults. Retrieved from http://americanpainsociety.org/about-us/press-room/nih-study-shows-prevalence-of-chronic-or-severe-pain-in-u-s-adults

National Safety Council (2016). NCS Poll: 99% of doctors prescribe highly-addictive opioids longer than CDC recommends. Retrieved from http://www.nsc.org/Connect/NSCNewsReleases/Lists/Posts/Post.aspx?ID=108

Ness, T. J., Jones, L., & Smith, H. (2002). Use of compounded topical analgesics – results of an internet survey. *Regional Anesthesia and Pain Medicine, 27*(3), 309-312.

Penney, L. S., Ritenbaugh, C., DeBar, L. L., Elder, C., & Deyo, R. A. (2017). Provider and patient perspectives on opioids and alternative treatments for managing chronic pain: a qualitative study. *BMC Family Practice, 17*(164), https://doi.org/10.1186/s12875-016-0566-0

Peppin, J. F., Albrecht, P. J., Argoff, C., Gustorff, B., Pappagallo, M., Rice, F. L., & Wallace, M. S. (2015). Skin Matters: A Review of Topical Treatments for Chronic Pain. Part Two: Treatments and Applications. *Pain and Therapy, 4*(1), 33–50. http://doi.org/10.1007/s40122-015-0032-z

Petiprin, A. (2016). Lewin's Change Theory. *Nursing Theory*. Retrieved from http://www.nursing-theory.org/theories-and-models/Lewin-Change-Theory.php

Ragavendran, J. V., Lerrière, A., Bennett, G. J., Ware, M. A., Gandhi, W., Bley, K., & ... Laferrière, A. (2016). Effects of topical combinations of clonidine and pentoxifylline on capsaicin-induced allodynia and postcapsaicin tourniquet-induced pain in healthy volunteers: a double-blind, randomized, controlled study. Pain (03043959), 157(10), 2366-2374. doi:10.1097/j.pain.0000000000000659

Rehm, S., Binder, A., & Baron, R. (2010). Post-herpetic neuralgia: 5% lidocaine medicated plaster, pregabalin or a combination of both? A randomized, open clinical effectiveness study. *Current Medical Research and Opinion, 26,* 1607–19.

Reise, S.P. (2012) The rediscovery of bifactor measurement models. Multivariate behavioral research, 667–696.

Schauer, C. K., Shand, J. A., & Reynolds, T. M. (2015). The Fentanyl patch boil-up – a novel method of opioid abuse. *Basic & Clinical Pharmacology & Toxicology, 117*(5), 358-359.

Shei, A., Rice, J.B., Kirson, N.Y., et al. (2015). Sources of prescription opioids among diagnosed opioid abusers. *Current Medical Research Opinion, 31*, 779-784.

Somberg, J. C., & Molnar, J. (2015). Retrospective evaluation on the analgesic activities of 2 compounded topical creams and Voltaren gel in chronic noncancer pain. *American Journal of Therapeutics, 22*(5), 342-349. doi:10.1097/MJT.0000000000000275

Stanhope, J (2016). Brief Pain Inventory review. *Occupational Medicine*, 66(6-1), 496–497. https://doi.org/10.1093/occmed/kqw041

Substance Abuse and Mental Health Services Administration (2014). Results from the 2013 National Survey on Drug Use and Health: summary of national findings. NSDUH series H-48: HHS publication no. (SMA) 14-4863.

The White House (2017). President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis. *Office of Secretary of Press*. Retrieved from https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis

Turn the tide Rx (2016). The Surgeon General's call to end the opioid crisis. Washington, DC: Surgeon General of the United States. Retrieved from: http://turnthetiderx.org/

Volkow, N. D. & McLellan, A. T. (2016). Opioid abuse in chronic pain – misconceptions and mitigation strategies. *The New England Journal of Medicine, 374*, 1253-1263.

Vowles, K.E., McEntee, M.L., Julnes, P.S., Frohe, T., Ney, J.P., & Van der Goes, D.N. (2015). Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. *Pain, 156*(4), 569-576. doi:10.1097/01.j.pain.0000460357.01998.f1.

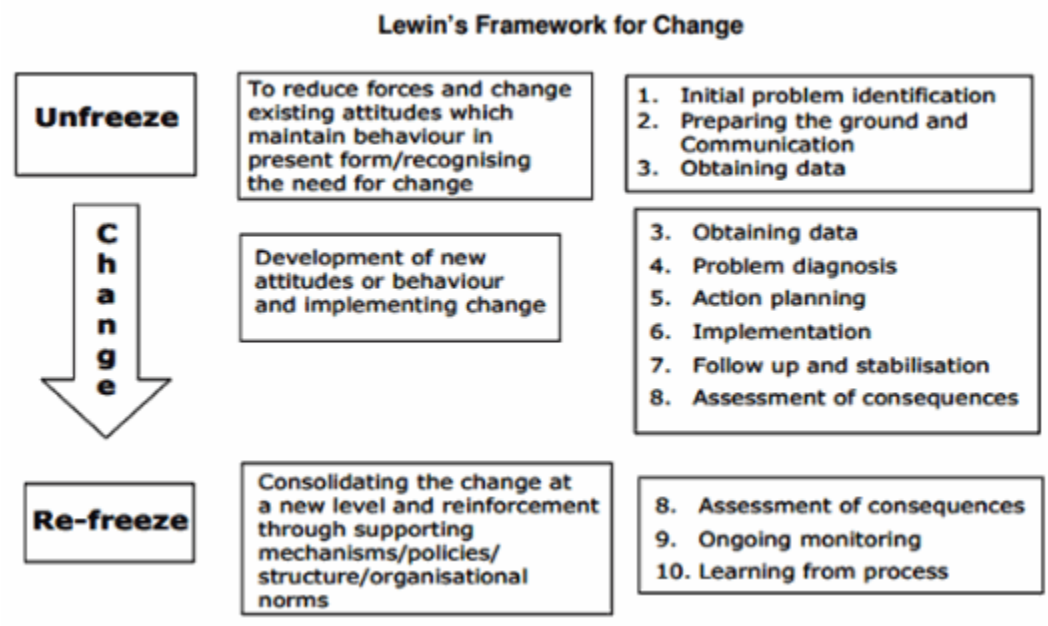
Warner, M. & Tuder, D. (2014). A brief survey on prescriber beliefs regarding compounded topical pain medications. *International Journal of Pharmacy Compound, 18*, 182-188.

Webster, L.R., & Webster, R. (2005). Predicting aberrant behaviors in Opioid-treated patients: preliminary validation of the Opioid risk tool. *Pain Med, 6*(6), 432.

Wilson, H.D., Dansie, E.J., Kim, M.S., Moskovitz, B.L., Chow, W. & Turk, D.C. (2013). Clinicians' attitudes and beliefs about opioids survey (CAOS): instrument development and results of a national physician survey. *Journal of Pain, 14*, 613–27.

Wojciechowski, E., Murphy, P., Pearsall, T., French, E. (2016). A Case Review: Integrating Lewin's Theory with Lean's System Approach for Change. *OJIN: The Online Journal of Issues in* Nursing, *21*(2), Manuscript 4.

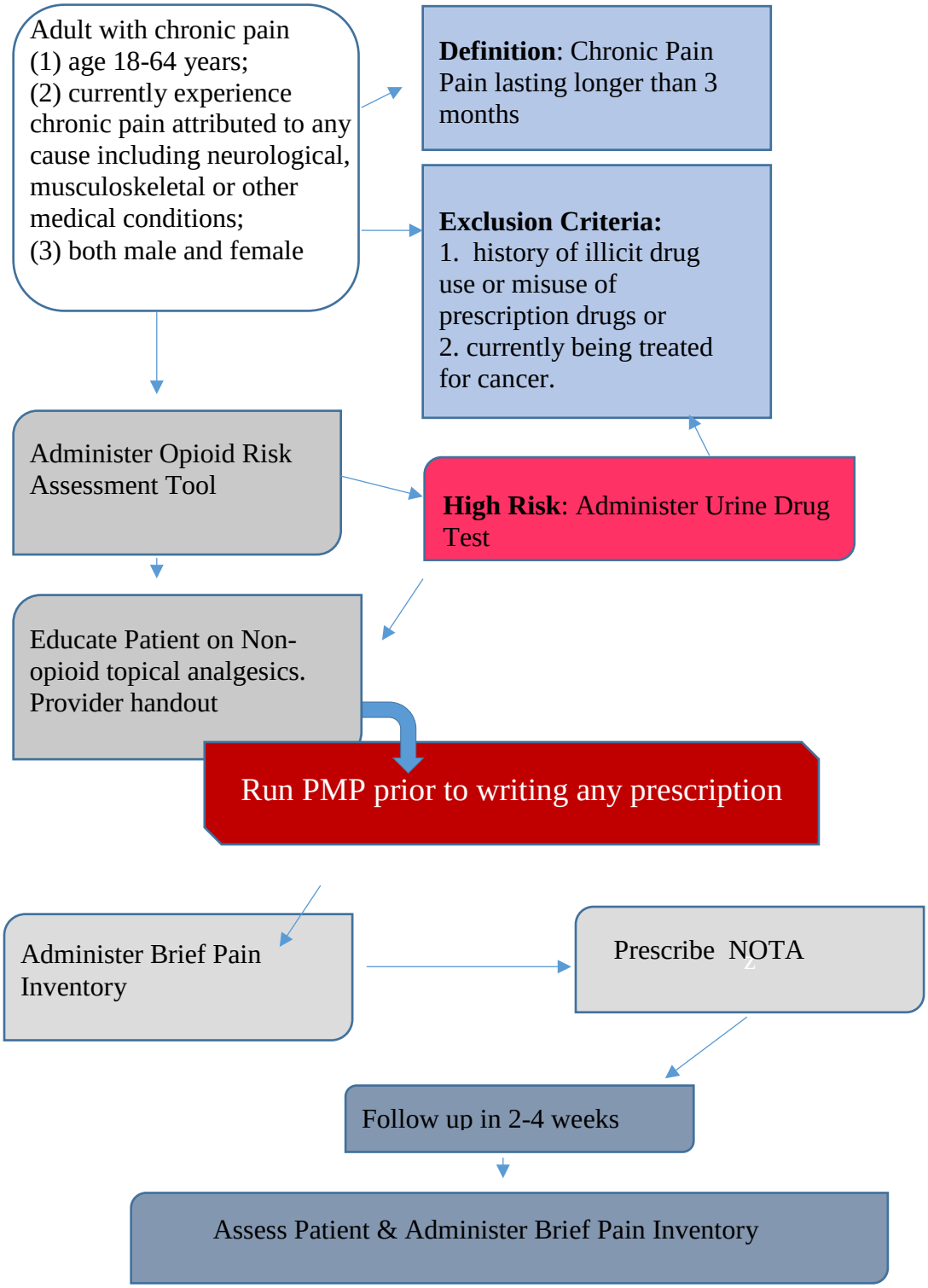
Appendix A



(Ahmed, 2014).

Appendix B

NOTA Treatment Protocol (Gudin, et al, 2017).



Appendix C

Pre-Test

Title:
Years of Practice:
Practice Specialty:

1. I can identify patients at risk of misuse of pain medication. -

1	2	3	4	5
Strongly Agree	Agree	Somewhat agree	Disagree	Strongly Disagree

2. I fear my patients will become addicted to opioids. -

1	2	3	4	5
Strongly Agree	Agree	Somewhat agree	Disagree	Strongly Disagree

3. I am confident in my prescribing practices of patients with chronic pain. -

1	2	3	4	5
Strongly Agree	Agree	Somewhat agree	Disagree	Strongly Disagree

4. Changes in vital signs are an indicator of pain severity. -

1	2	3	4	5
Strongly Agree	Agree	Somewhat agree	Disagree	Strongly Disagree

5. Federal regulations limit the number of - opioid dosages I can prescribe.

True False

6. I should run an urine analysis if a patient is suspected of opioid misuse. -

True False

7. Pain patients with long term use of opioid therapy have a higher chance of abuse/addiction of opioids. -

True False

8. Pain patients can not be effectively tapered off of opioids. -

True False

9. Compounded analgesics can be effective in treating pain.

True False

10. The Center for Disease Control recommends prescribing opioids for 30 days.

True False

11. AB 474 requires a bonefide relationship before prescribing opioids.

True False

12. In the state of Nevada, running a Prescription Monitoring Program report is mandatory before writing any prescription for a controlled substance.

True False

13. If a 40-year-old comes into the clinic with a family history of substance abuse and has been on opioid therapy for over a year, but has known marijuana use, and is seeing you for the first time and would like a refill for her controlled substance, what is the first thing you should do for the treatment plan for this patient.

a. Refill the opioid medication and advise the patient not to smoke marijuana while on it
b. Perform a drug screen analysis before considering to refill opioid medication.
c. Advise the patient you will not be able to refill the medication but offer a non-controlled medication.

14. Mr. Smith, a 68-year-old Caucasian male, an established patient, but has been seeing a colleague of yours, but the colleague is on vacation and the patient is there to see you for a refill on their controlled substance,

a. Since the patient is established refill medication
b. Its unlawful to refill this patient's medication according to AB 474
c. Change the controlled substance to something else after a full assessment

Appendix D

Educational Presentation (see attached PPT).

Appendix E

CMC's New Pain Treatment Protocol

Did you know?

- Research does not support that long-term opioid therapy is effective in treating chronic pain
- The longer you are on opioid therapy, the higher the risk of abuse and addiction
- 91 people die daily from opioid overdoses

What are Topical Analgesics?

Its just a medical way of saying creams that are rubbed on the skin to relieve pain. Because they are not ingested, your entire system does not absorb the medication, which reduces side effects and interactions with other drugs. Instead, the area of your body in pain, gets the direct application of pain killing medicine. We are working with a local pharmacy to provide compounded topical analgesics.

What does compounding mean?

It means that the pharmacist combines several different pain killing agents to create a cream that is tailored to your pain.

Is it effective?

Yes, studies show that topical analgesics are not only effective, but they are safe for you and your body. They have minimal side effects and rarely do they interact with other medication. Recent studies support that patients report significantly reduced pain when using topical analgesics.

Will insurance cover it?

Yes, in most cases, insurance will cover this treatment. Most of the time, insurance requires prior approval. CMC will work with your insurance to get the prior approval to cover the cost of this treatment.

Reference: Gudin, J. A., Brennan, M. J., Harris, E. D., Hurwitz, P. L., Distan, D. T. & Sessler, J. D. (2017). Changes in pain and concurrent pain medication use following compounded topical analgesic treatment for chronic pain: 3- and 6-month follow-up results from the prospective observational optimizing patient experience and response to topical analgesics study. *Journal of Pain Research, 10*, 2341-2354.

Appendix F

Post-Test

Title:
Years of Practice:
Practice Specialty:

1. I can identify patients at risk of misuse of pain medication. -

1	2	3	4	5
Strongly Agree	Agree	Somewhat agree	Disagree	Strongly Disagree

2. I fear my patients will become addicted to opioids. -

1	2	3	4	5
Strongly Agree	Agree	Somewhat agree	Disagree	Strongly Disagree

3. I am confident in my prescribing practices of patients with chronic pain. -

1	2	3	4	5
Strongly Agree	Agree	Somewhat agree	Disagree	Strongly Disagree

4. Changes in vital signs are an indicator of pain severity. -

1	2	3	4	5
Strongly Agree	Agree	Somewhat agree	Disagree	Strongly Disagree

5. Federal regulations limit the number of - opioid dosages I can prescribe.

True False

6. I should run an urine analysis if a patient is suspected of opioid misuse. -

True False

7. Pain patients with long term use of opioid therapy have a higher chance of abuse/addiction of opioids. -

True False

8. Pain patients can not be effectively tapered off of opioids. -

True False

9. Compounded analgesics can be effective in treating pain.

True False

10. The Center for Disease Control recommends prescribing opioids for 30 days.

True False

11. AB 474 requires a bonefide relationship before prescribing opioids.

True False

12. In the state of Nevada, running a Prescription Monitoring Program report is mandatory before writing any prescription for a controlled substance.

True False

13. If a 40-year-old comes into the clinic with a family history of substance abuse and has been on opioid therapy for over a year, but has known marijuana use, and is seeing you for the first time and would like a refill for her controlled substance, what is the first thing you should do for the treatment plan for this patient.

d. Refill the opioid medication and advise the patient not to smoke marijuana while on it
e. Perform a drug screen analysis before considering to refill opioid medication.
f. Advise the patient you will not be able to refill the medication, but offer a non-controlled medication.

14. Mr. Smith, a 68-year-old Caucasian male, an established patient, but has been seeing a colleague of yours, but the colleague is on vacation and the patient is there to see you for a refill on their controlled substance,

d. Since the patient is established refill medication
e. Its unlawful to refill this patient's medication according to AB 474
f. Change the controlled substance to something else after a full assessment

Appendix G

Content Validity Index Table for Pre and Post Test

Item	Expert 1	Expert 2	Expert 3	Mean
1	4	4	4	4
2	3	4	4	3.66
3	3	4	4	3.66
4	4	4	4	4
5	4	4	4	4
6	4	4	3	3.66
7	4	4	4	4
8	4	4	4	4
9	4	4	3	3.66
10	4	4	3	3.66
11	4	4	2	3.33
12	4	4	3	3.66
13	4	4	3	3.66
14	4	4	3	3.66

Average Mean for all question is 3.76 indicating all the questions are moderately/highly relevant.

Q1: CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q2 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q3 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q4 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q5 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q6 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q7 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q8 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q9 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q10 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q11 CVR = [(2-(3/2)) / (3/2)] → [(2-1.5) /1.5] = .5/1.5
Q 12 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q13 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5
Q14 CVR = [(3-(3/2)) / (3/2)] → [(3-1.5) /1.5] = 1.5/1.5

Appendix H

Opioid Risk Assessment Tool

Opioid Risk Tool

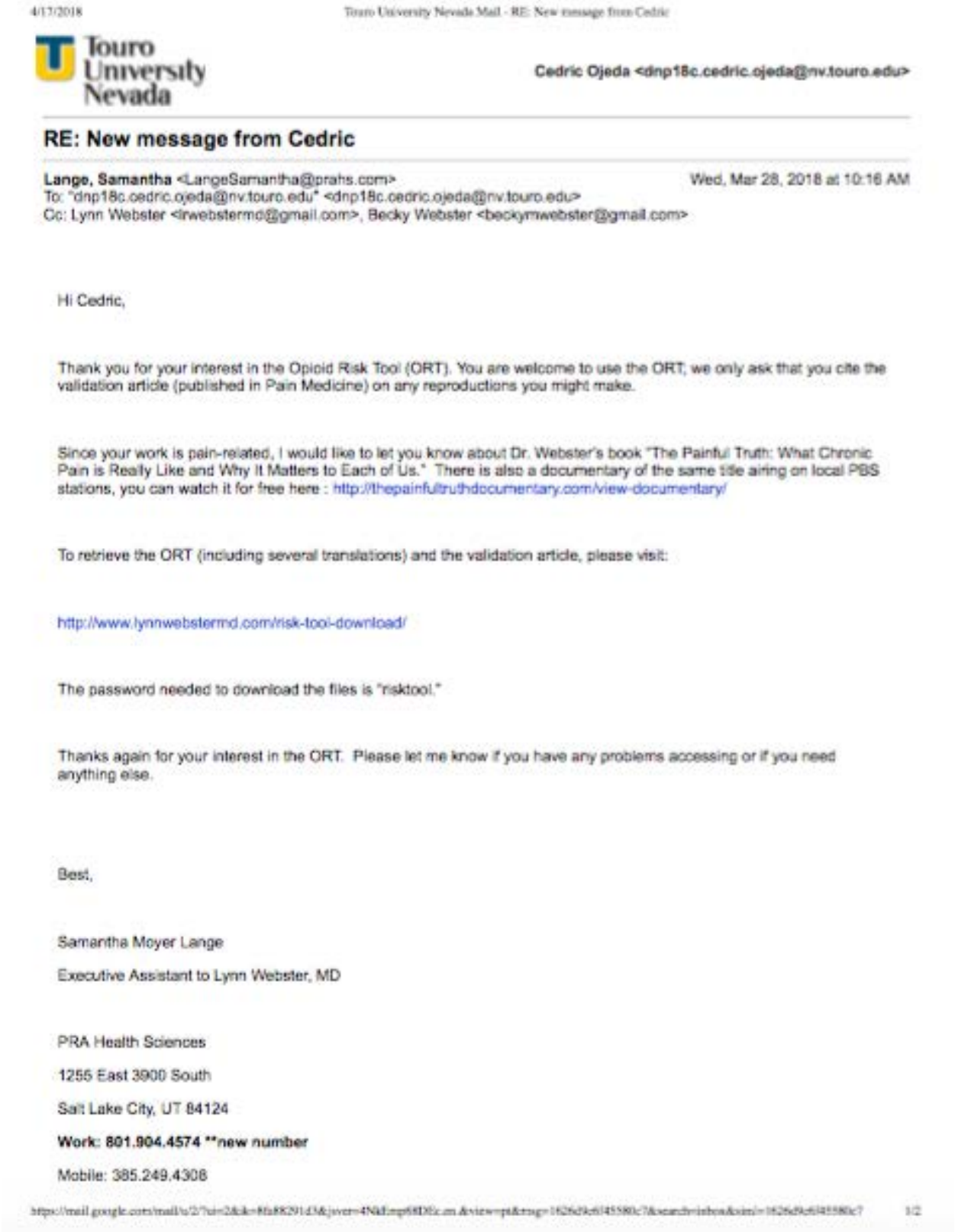
This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

Questionnaire developed by Lynn R. Webster, MD to asses risk of opioid addiction.

Webster LR, Webster R. Predicting aberrant behaviors in Opioid-treated patients: preliminary validation of the Opioid risk too. Pain Med. 2005; 6 (6) : 432

Appendix I



4/17/2018 Touro University Nevada Mail - RE: New message from Cedric

Touro University Nevada

Cedric Ojeda <dnp18c.cedric.ojeda@nv.touro.edu>

RE: New message from Cedric

Lange, Samantha <LangeSamantha@prahs.com> Wed, Mar 28, 2018 at 10:16 AM
To: "dnp18c.cedric.ojeda@nv.touro.edu" <dnp18c.cedric.ojeda@nv.touro.edu>
Cc: Lynn Webster <lrwebstermd@gmail.com>, Becky Webster <beckymwebster@gmail.com>

Hi Cedric,

Thank you for your interest in the Opioid Risk Tool (ORT). You are welcome to use the ORT; we only ask that you cite the validation article (published in Pain Medicine) on any reproductions you might make.

Since your work is pain-related, I would like to let you know about Dr. Webster's book "The Painful Truth: What Chronic Pain is Really Like and Why It Matters to Each of Us." There is also a documentary of the same title airing on local PBS stations, you can watch it for free here : http://thepainfultruthdocumentary.com/view-documentary/

To retrieve the ORT (including several translations) and the validation article, please visit:

http://www.lynnwebstermd.com/risk-tool-download/

The password needed to download the files is "risktool."

Thanks again for your interest in the ORT. Please let me know if you have any problems accessing or if you need anything else.

Best,

Samantha Moyer Lange

Executive Assistant to Lynn Webster, MD

PRA Health Sciences

1255 East 3900 South

Salt Lake City, UT 84124

Work: 801.904.4574 **new number

Mobile: 385.249.4308

https://mail.google.com/mail/u/2/?ui=2&ik=8fa88291d3&jver=4Ndl.mp68D0.en.&view=pt&msg=1626d9e6145580c7&search=inbox&siml=1626d9e6145580c7 1/2

Appendix J

Brief Pain Inventory

1903

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials : _____

Study Subject #: ☐☐☐☐

Study Name: _____

Protocol #: _____

Pt: _____

Revision: 07/01/05

PLEASE USE BLACK INK PEN

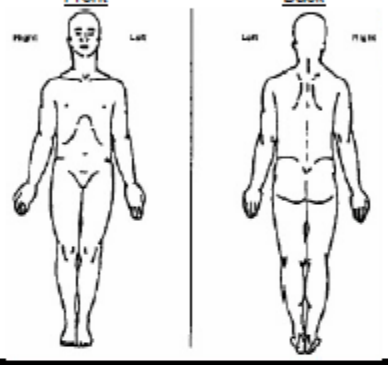
Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

Front Back



3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10

No Pain — Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10

No Pain — Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10

No Pain — Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10

No Pain — Pain As Bad As You Can Imagine

Page 1 of 2

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1903

Date: (month) / (day) / (year)

Subject's Initials: _____

Study Subject #:

PLEASE USE BLACK INK PEN

Study Name: _____

Protocol #: _____

PI: _____

Revision: 07/01/05

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐ No Relief	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐ Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

B. Mood

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

C. Walking ability

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

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

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

E. Relations with other people

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

F. Sleep

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

G. Enjoyment of life

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

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Pain Research Group
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Appendix K

Touro University Nevada

Cedric Ojeda <dnp18c.cedric.ojeda@nv.touro.edu>

Signed License Agreement

Cedric Ojeda <dnp18c.cedric.ojeda@nv.touro.edu> Mon, Jun 11, 2018 at 9:36 PM
To: symptomresearch <symptomresearch@mdanderson.org>

Good Evening,

Please see attached signed agreement.

Thanks,

Cedric

On Wed, Jun 6, 2018 at 12:54 PM, symptomresearch <symptomresearch@mdanderson.org> wrote:

> Hello,
>
> Cedric, this is for your Student Research / Dissertation, however we will need to have an authorized person sign the agreement.
>
> Unfortunately, we cannot proceed with a license to an individual in this case. MD Anderson requires that an appropriate organization be the Licensee for the use you specify.
>
> If the form is acceptable, please have it signed by an appropriate representative of the University at the bottom of page 2 and return to me.
>
> Regards,
>
> Sharlet Gordon
>
> **From:** Cedric Ojeda [mailto:dnp18c.cedric.ojeda@nv.touro.edu]
> **Sent:** Tuesday, June 05, 2018 1:45 PM
> **To:** symptomresearch <symptomresearch@mdanderson.org>
> **Subject:** Re: Signed License Agreement
>
> Here is the revised document.
>
> On Tue, Jun 5, 2018 at 9:37 AM, symptomresearch <symptomresearch@mdanderson.org> wrote:
>
>> Hello,
>>
>> Cedric appears to have entered his credentials in the "Title" line. The title line should read as his position within the Licensee, not his credentials.

Appendix L

Non-Opioid Topical Analgesic Policy for Patients that Present to Clinical Site

This protocol will address the long-term prescribing of opioid medication to adult patients who present to CMC with chronic pain. Long-term use of opioids is not recommended and imposes a risk of opioid abuse.

The goal of this protocol is to limit the number of patients receiving long-term opioids to treat their chronic pain. Further, use of compounded topical analgesics, in partnership with Wellcare Pharmacy, will improve patient pain scores

This protocol includes three separate components:

1) **Education of providers and medical staff**

   The providers and members of the staff will attend an initial training on opioid risk, using the opioid risk screening tools and identifying patients at risk for opioid abuse. This training will also provide the benefits of using NOTA as an alternative to opioids. The goal is for the providers and healthcare staff to understand the protocol and be able to explain its benefits to possible participants.

2) **Provider compliance with protocol**

   Charts of patients who meet the inclusion criteria will be monitored to ensure compliance with the protocol.

3) **Improved patient outcomes**

The brief pain inventory will be used to monitor patient outcomes who meet inclusion criteria. Concurrent use of other medications will also be noted.

Procedures:

1. Staff training will be scheduled and is mandatory.
2. All patients who are scheduled for a visit who suffer from chronic pain and otherwise meet the inclusion criteria need to be considered for NOTA as an alternative treatment to opioid therapy. This protocol should be used in patients who present to the clinical site with chronic pain. Specific inclusion criteria include (1) age 18-64 years; (2) currently experience chronic pain attributed to any cause including neurological, musculoskeletal or other medical conditions; (3) both male and female. Patients are ineligible if they have a history of illicit drug use or misuse of prescription drugs or are currently being treated for cancer.
3. All patients who meet the inclusion criteria should be administered an opioid risk assessment tool.
4. The provider should then explain the new protocol to the patient, the benefits of non-opioid topical analgesics, risk of long-term opioid abuse, etc. If the patient choses to participate in the protocol, a brief pain inventory and other questionnaire should be obtained. This chart should be flagged as a project participant.
5. The results of the screening tools and questionnaires should be preserved in the records for the chart audits **(**Gudin, et al, 2017; Cline & Turrentine, 2016, Dowell et al., 2016)

Appendix M

Chart Audit Tool (attached in as Excel spreadsheet)