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An Evidenced-Based Pain Management Module to Improve Clinicians' Knowledge

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This is to certify that the doctoral study by

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Abstract

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by

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Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Chronic pain syndrome continues to be a national health concern among all medical specialties. It has an impact on the entire health care system and if current trends continue, the economic impact alone will exceed 100 billion dollars. In 2014, 254 million prescription opioids were written in the United States. During this time, an increase in prescription opioid related deaths was seen, with approximately 20,101 deaths occurring in 2015. Properly trained clinicians across the health care system are needed to achieve successful patient outcomes, while reducing cost, morbidity, and mortality. The purpose of the scholarly project was to develop a comprehensive, opioid-specific, expert reviewed and evidenced-based educational module for health care clinicians of all specialties. Using the guidelines offered by the Center for Disease Control in 2016, the content of the project was developed with a primary focus on the clinical processes, pharmacological properties, and appropriateness of opioids in the treatment of chronic pain. The educational module was disseminated to 10 experts in the field of pain management and family practice. Each of them was asked to evaluate the educational module and evaluate it from an expert standpoint via Likert-scale evaluation form. The data revealed a median score of 4.5 out of 5 for most all categories, demonstrating the project's ease of use, evidenced-based content, and its ability to further expand the knowledge of clinicians. The project will be presented to stakeholders and state representatives for wide spread distribution. Educating health care professional over the continuum will ensure effective social change and shift the current trends in prescription opioid related mortality and morbidity.

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Dedication

To my wife and children, Maria, Kendrick and Brenna. Without your love and support this would not be possible. Your support and encouragement throughout this process is inspiring. I love you all. Always shoot for the stars and don't ever think it's not possible to achieve great things

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Section 1: Overview of the Evidenced-Based Project

Introduction

In the United States, chronic pain syndrome (CPS) is a common medical problem and it is growing in prevalence (Chou, Ballantyne, Fanciullo, Fine, & Miaskowski, 2009). Currently, there are 100 million sufferers and the cost to the health care systems has reached over $100 billion (Chou et al., 2009). An estimated $5–10,000 is spent per patient annually for medication management with opioid analgesics (Whitfill et al., 2010). CPS is the leading cause of disability and loss of function in the United States (Chou et al., 2009). Of the 100 million with CPS, about 7 million adults suffer moderate to severe limitations in daily function, leading to a significant reduction in quality of life (Chou et al, 2009). Disability compensation for CPS accounts for approximately $43 billion annually (Gatchel & Okifuji, 2009). According to Hart (2010), an estimated 149 million workdays are lost each year due to symptoms of chronic pain (Hart, 2010) and accounts for an estimated $61.2 billion in lost productivity.

This reduction in quality of life and function, according to Neugebauer and Heusser (2010), also leads to significant changes in the psychological status of this population. It is common to see maladaptive psychological coping, often leading to fear, avoidance, and anxiety toward treatment. These behaviors can produce ineffective treatment and alter the patient's perspective regarding care. The ability to provide adequate pain relief has a direct impact on overall psychological health. The prevention of psychological dysfunction can occur only when adequate treatment is implemented.

Clinicians can often exacerbate this process by developing treatment plans with opioids without proper training.

The treatment of CPS requires a comprehensive multimodality approach that includes pharmacological, behavioral, interventional, and holistic management (Von Korff, 2013). The use of the pharmacological approach has become more prevalent over the last 20 years. It is estimated that 5.4–6.2 million chronic pain patients require daily opioid treatments (Gudin, 2013). Clinicians along with federal and state regulators recognize the need to balance adequate, legitimate medical treatment of chronic pain against the misuse and diversion of opioids. The APS and the AAPM have developed a multidisciplinary panel to provide evidenced-based guidelines for the use of pharmacological approaches to chronic pain (Chou et al., 2009). These guidelines recognize the use of two analgesic agents: short-acting and long-acting (Chou et al., 2009). These guidelines support the use of the long-acting analgesics in the patient population suffering from CPS (Compton & Volkow, 2006). This analgesic agent has several clinical advantages over the shorter-acting version, including increased therapeutic drug plasma levels, decreased peak–trough fluctuations, and prolonged analgesic properties (Compton & Volkow, 2006). Additionally, most long-acting agents allow for less frequent dosing and reduced end-of-dose failure (Compton & Volkow, 2006). Despite the recommendations by APS and AAPM, clinicians continue to prescribe the alternative short-acting version of these medications (Rauck, 2009). The continued use of this version often leads to a decreased therapeutic response, a higher addiction probability, a higher tolerance rate, and a higher end-of-dose-failure (Compton &

Volkow, 2006). The pharmacokinetic properties of these medications are important to clinical outcomes in this patient population (Rauck, 2009). A primary reason for the lack of compliance with the clinical guidelines has been identified as the education of the health care provider (Von Korff, 2013). The goal of this project was to advance the knowledge base of clinicians across the health care sector, which would allow them to translate the guidelines into practice, with the intent of improving practice.

Problem Statement

Despite the advancements and practice guidelines that were established regarding the use of long-acting pain medications, clinicians continue to treat chronic pain with short-acting agents (Chou et al., 2009). According to Von Korff (2013), the use of short-acting medications in this patient population has proven to be ineffective and inconsistent over the long term. Nurse practitioners are becoming more involved in the care of these patients, and are often responsible for prescribing and maintaining pharmacological treatments. Clinicians must be able to determine the most appropriate treatment in the clinical setting, which often includes the use of one or more of these agents. Establishing the most appropriate agent is paramount to producing effective, safe, and cost-effective care. Until the knowledge of health care providers improves, short-acting agents will continue to be used, leading to inconsistent and ineffective pain management (CDC, 2011).

Purpose

The purpose of the capstone project was to design and evaluate a clinician-focused education module on the use of opioids to improve the knowledge base of health

care providers in any setting, including medical doctors (MD), doctors of osteopathic medicine (DO), nurse practitioners (NP) and physician assistants (PA). In this project, I used the most up-to-date clinical guidelines developed by the Center for Disease Control (CDC), APS, and the AAPM to support the project's content. Clinical experts in the field of chronic pain management and family practice were selected to review the educational module and determine its appropriateness for clinician training. The end result of this project was to create a continuing medical education (CME) module that would be used by CME organizations to expand the knowledge of nurse practitioners and other clinicians who are interested in the treatment of chronic pain. The anticipated result would be improved patient safety, clinical outcomes, and overall management of patients suffering from chronic pain. A complete measure of these variables will be conducted at a later date following the academic setting.

Objectives

The main objective of this capstone project was to produce an expert-reviewed, clinician-focused education module to help improve the way pain management is provided to patients in the health-care settings when opioid analgesics are needed (Rauck, 2009). Experts in the field of chronic pain management and family practice were used to provide an unbiased opinion on the usability, content, and expansion of knowledge of the educational module by completing a post-educational survey, the expert-rating tool, which was used to determine the module's appropriateness for clinical use. This data were collected and analyzed to determine if the module met the educational objectives required of a CME. A standard five-rating Likert scale was used (see Appendix I).

Practice Significance and Relevance

Regardless of a clinician's specialty, the use of opioid analgesics in the practice setting can create several practice concerns. (Gatchel & Okifuji, 2006). Clinicians who use these treatment modalities inappropriately can suffer criminal and civil penalties (Allen, Asbridge, MacDougall, Furlan & Tugalev, 2013). Clinicians need to be aware of all regulatory guidelines and understand their responsibilities under these laws (Rauck, 2009). This is becoming extremely important to the practice of nursing, given the expansion of scope of practice laws regarding nurse practitioners. Treatment decisions need to be based on evidenced-based research; they need to be made with a thorough knowledge of the standards of each of the federal and state regulatory agencies (Gatchel & Okifuji, 2006). The failure to recognize and account for each of these practice concerns can lead to significant licensure and criminal penalties in the practice setting (Gatchel & Okifuji, 2006).

The development of an evidenced-based education module can provide clinicians with the guidance to foster appropriate treatment modalities, while at the same time, reducing the risk of inappropriate treatment for patients suffering chronic pain (Peiris et al., 2014).

Tolerance and addiction needs to be addressed in the clinical practice setting (Gudin, 2013). The use of long-acting opioids does not negate the risk of tolerance or addiction; but they do provide the clinician with a means of reducing the oral intake of these medications and peak-trough fluctuations that are commonly seen in the use of short-acting opioids (Rauck, 2009). Reducing the number of orally consumed opioids can

reduce a patient's risk of developing tolerance over a short period of time (Gudin, 2013). Opioid analgesics attach to the neurotransmitters and receptors in the brain and become less responsive when multiple doses are taken over a short period (Gudin, 2013). Receptor availability is directly related to the development of tolerance (Gudin, 2013). The use of short-acting analgesics requires multiple doses throughout the day, which inherently decreases the availability of these receptors and increases the risk of tolerance (Rauck, 2009). The development of tolerance often leads to treatment failure in the chronic pain population (Gudin, 2013). In contrast, the use of long-acting analgesics decreases the development of tolerance by reducing the daily consumption of oral analgesics (Gudin, 2013). The pharmacokinetic makeup of long-acting analgesics allow for daily or twice a day dosing, while producing maximum therapeutic response (Gudin, 2013). This reduces the patient's receptor utilization and reduces tolerance over the long term (Gudin, 2013).

Addiction is seen in the chronic pain population and can produce practice and patient safety issues (Compton & Volkow, 2006). Reducing a patient's risk of addiction is imperative when using narcotic analgesics in treatment (Compton & Volkow, 2006). The use of short-acting analgesics produces several peaks and troughs during the course of treatment (Rauck, 2009). These fluctuations can produce a physical need for this medication in just a short period of time. In comparison, the use of long-acting agents produces less of a peak and maintains stable plasma blood levels during the course of the treatment (Rauck, 2009). These pharmacological properties can help reduce the development of addiction over a short period, and can help produce a stable treatment

environment (Compton & Volkow, 2006). The use of long-acting analgesics does not negate the risk of addiction in this population, but they can slow the development of this untoward effect (Rauck, 2009).

Finally, the risk of misuse and abuse of narcotic analgesics is a nationally recognized concern in clinical practice (Compton & Volkow, 2006). The development of long-acting analgesics has incorporated the use of abuse-deterrent formulations and tamper-resistant tablets (Fine, Mahajan & McPherson, 2009). Extended release formulations contain properties that inactivate the active ingredient when tampering occurs (Fine et al., 2009). These formulations reduce abuse liability for the clinician and protect the patient from toxicity that may occur from crushing, snorting, and injecting long-acting opioid analgesic (Fine et al., 2009). This does not negate all the risk for the clinician or patient. It is, though, a step toward reducing the misuse and diversion of opioid analgesics.

Project Question

CMEs remain a primary tool, used by clinicians of all specialties to increase their knowledge. Members of the pain management community and members of the family practice setting often lack the training needed to implement evidenced-based guidelines (Von Korff, 2013). The development of a comprehensive education module that could be used by all specialties would likely further empower nursing professionals and clinicians who are interested in the treatment of chronic pain. The following project question applies to the current project: Does the evidenced-based education module meet

the content requirements to further the knowledge of health care clinicians according to the expert review?

Implications for Social Change in Practice

Clinicians across the country struggle to balance the need to manage the chronic pain population against the numerous barriers in clinical practice (Compton & Volkow, 2006). These barriers are identified in the report issued by the Institute of Medicine, titled "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research," and include regulatory, legal, institutional, financial, and cultural barriers (IOM, 2011). As nurse practitioners continue to gain autonomy in the prescribing of opioid analgesics, they need further knowledge to develop appropriate treatment plans for the treatment of their patient population. Clinicians, regardless of setting, must understand the complex biological and psychological aspects of chronic pain, while evaluating the available treatment options.

As with any chronic disease, management is an essential part of maintaining function while reducing the risk of mortality and morbidity (Chou et al., 2009). According to Institute of Medicine (2011) "Approximately 100 million U.S adults--more than the number affected by heart disease, diabetes, and cancer combined--suffer from common chronic pain" (p. 19). A substantial number of these patients classify their pain treatment as inadequate. The IOM report also identifies inadequate treatment as the result of barriers and providers' misconceptions of patients suffering chronic pain. Providers often presume that chronic pain patients misuse, abuse, and divert narcotic analgesics.

These views present barriers that can lead to ineffective or inadequate treatment over the over time. According to the IOM report (2011), "The majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others" (p. 145). Significant attention needs to be directed toward the prescribing and management of chronic narcotic analgesics in this population while removing the perceived judgment.

In addition to the clinician's perception, another reason for the reluctance to prescribe narcotic analgesics is the regulatory and legal implications (Compton & Volkow, 2006). Federal and state drug prevention laws and enforcement practices continue to make clinicians apprehensive to prescribe narcotic analgesics, even when it's clinically appropriate to do so (Compton & Volkow, 2006). This further complicates access to care and contributes to the ineffective treatment of patients in this population. The apprehension involved with the treatment of chronic pain often translates into an attitude of denial and avoidance (IOM, 2011). The need to change the cultural and social views on the treatment of chronic pain will be essential to providing effective treatments in this unique population (IOM, 2011).

Nurse practitioners have an opportunity to improve the way chronic pain is treated and viewed across the healthcare spectrum. Changing the social fabric will not be easy and will require an expansion of knowledge over time. The development of an evidenced-based educational module will assist with the additional knowledge needed in the practice setting (Peiris et al., 2014). While the development of such a module may not remove all of the regulatory, legal, institutional, financial, and cultural barriers, it will certainly

facilitate a greater level of confidence within the clinical practice. This capstone project is expected to provide a useful educational tool for clinicians regardless of specialty (Peiris et al., 2014).

Using opioid analgesics without proper knowledge can result in significant issues for society as a whole (Compton & Volkow, 2006). In the United States, prescription opioids are the fastest growing cause of drug misuse, which is leading to accidental overdose and mortality, accounting for over 20,101 deaths in 2015. Studies tie this directly to the increased rates of heroin use in the United States (IOM, 2011). Evaluating the risk and benefits of long-acting analgesics is imperative when initiating a management modality. The use of long-acting analgesics is often reserved for patient populations that have explored and tried multiple other non-pharmacological treatment modalities. This capstone will expand the knowledge of clinicians using these medications; thus they will better understand how they should be used, and for whom.

Assumptions

1. It is assumed that the experts chosen for the purpose of this evaluation will be unbiased.
2. It is assumed that the information provided in the education will be accurate and represent the most current and up-to-date evidence.
3. It is assumed that the experts will be similar in education and knowledge in both clinical and academic settings.
4. It is assumed that the patients requiring opioid analgesics can gain access to the medications that the continuing education module addresses. It is assumed

that the clinicians will be up-to-date on the resources needed to improve their patient's access to these medications.

Limitations

1. The number of experts reviewing the proposed educational module will be small and only represent a portion of the experts available in the health care community.
2. This education must be generalized, in order to be adequate for all specialties. This may limit its usefulness for the pain expert.

Definition of Terms

The following definitions will help in understanding the nature of the project.

Chronic pain syndrome (CPS): Ongoing unpleasant sensations that last beyond the standard healing period. Usually lasting greater than 3-6 months and affects quality of life and function (IOM, 2011).

Opioid analgesics: Opioid (narcotic) analgesics are derived from the by-product of Opium. They bind to opioid receptors in the brain, which are present in the brain and nervous system. These receptors are responsible for the transduction of pain perception (Gudin, 2013).

Long-acting opioid: Pharmacological compounds that attach to the opioid receptors of the brain that have the ability to produce an extended period of pain relief, typically greater than 8 hours (Gudin, 2013).

Short-acting opioid: Pharmacological compounds that attach to the opioid receptors of the brain that have the ability to produce duration of action typically shorter than 4 hours (Gudin, 2013).

Pharmacokinetics: The process by which a formulation (drug) is processed throughout the human body (Von Korff, 2013). It is a complete understanding of absorption, distribution, metabolism and excretion of the selected drug. This process occurs over a continuum and concurrently when a prescription drug is administered via the oral, intravenous and intrathecal routes.

Pharmodynamics: The process or study of the chemical and physiological effects of drugs on the human body (Von Korff, 2013). This includes the interaction between opioid's and mu-receptors in the body during administration.

Addiction: The presence of compulsive drug use and the continuous craving for opioids for the use of the effects without concern for actual pain relief.

Tolerance: An uncontrollable neuroadaptation process that occurs overtime with the use of analgesics agents that is characterized by a minimizing of effects of the drug (Chou et al., 2009).

Neurotransmitters/Receptors: A chemical substance that releases when a nerve impulse is stimulated. This transmitter causes a response within the nerve fiber and distribution occurs throughout the selected fibers. The receptor is the location in which the process occurs and the area where the transmitters attach themselves to produce the desired effect.

Therapeutic drug plasma levels: Therapeutic drug plasma levels refer to the measurable amount of drug particulate in the blood that produces a therapeutic response. This measure is performed often in toxicology testing or urine screenings. Threshold can be over or under a predetermined value, representing toxicity or sub-therapeutic ranges.

End-of-dose failure: This process occurs when the selected opioid analgesic does not produce the expected duration of relief, often leading to failure in treatment goals and expectations (Compton & Volkow, 2006). This process can occur in both the short-acting and long-acting versions of medications, however a higher prevalence is seen in the short-acting version.

Clinicians: Health care providers involved in patient care including registered nurses, advanced practice nurses, physician's assistants, medical doctors and osteopathic doctors of medicine. These professionals are responsible for direct patient contact and care consistent with chronic pain management.

Evidenced-based guidelines: A set of recommendations that can be used by clinicians that outline treatments and care for specific medical conditions (Sox & Stewart, 2015). These recommendations are based on the best research at the time the guidelines are being developed. They should include an accurate representation of the literature (Sox & Stewart, 2015).

Continuing medical education (CME): The process of providing clinicians with resources, knowledge and educational experiences that improve or optimize professional growth and performance. This project is tailored to Medical Doctors (MD), Doctors of

Osteopathic Medicine (DO), Nurse Practitioners (NP) and Physician Assistants (PA). The following describes the current requirements for each of these specialties:

- Physician/DO: (Category 1) Accreditation Council for Continuing Medical Education. 2-year requirement: 100 credits with 20 credits designated to category 1.
- Nurse Practitioner (10 contact hours in pharmacology) American Academy of Nurse Practitioners. 5-year Recertification Requirements-100 contact hours of continuing education (CE) required in the role of the nurse practitioners focus. There is a 25-credit requirement designated for pharmacology only.
- Physician Assistants (Category 1) American Academy of Physician Assistants (AAPA) Two, Four and Six Year Requirement- 50 Category 1 continuing education credits for recertification.

Summary

CPS is a national health issue that requires the attention of all health care providers, across all settings (Von Korff, 2013). Its negative impact on healthcare expenditure and disability compensation is not sustainable over the continuum. Effective and safe evidenced-based care is essential to reduce the overall mortality and morbidity of this chronic disease. Nurse practitioners have a unique role in the successful treatment of patients with CPS. However, evidence-based education needs to be implemented over the continuum. The use of long-acting opioids provides a safe and cost-effective means of managing patients with CPS. The pharmacological properties of these drugs decrease the possibility of diversion and abuse and provide the clinician with reasonable safeguards. A

change in the way clinicians prescribe these medications will only come with an increase in knowledge that can be used in the clinical setting. This additional knowledge is expected to help change the way clinicians think about and respond to patients with complaints of chronic pain and thus increase the access this population has to effective and efficient care. As is the case for all chronic illnesses, if health care providers turn their backs on these patients and avoid treating them because of barriers, mortality and morbidity will increase over the lifespan. Health care expenditures will continue to rise and disability compensation will skyrocket. The expansion of practice allows the nurse practitioner to be actively involved in the prescribing of opioid analgesics, while participating in the development of evidenced-based and regulatory policies, ultimately helping to change the social fabric.

Section 2: Review of the Scholarly Evidence

A review of the literature was conducted using the following databases: CINAHL Plus with Full Text, ProQuest Nursing & Allied Health Services, Medline with Full Text, Health and Medical Complete, Ovid Nursing Journals Full Text and PubMed with Full Text. The following search terms were used: *nursing knowledge, chronic pain, narcotics,* and *extended-release (long-acting), short-acting (instant release)* and *chronic pain syndrome*. These search terms revealed 1,552 articles using the databases listed above. An additional exclusion criterion was implemented to prevent out of date articles and to ensure each article was peer-reviewed. The two limiters set included: a 2008–2015 time frame and only peer-reviewed articles. This limited search yielded 484 articles of which 30 met the literature specific criteria and were analyzed. It is important to note the CDC, APS and the AAPM documents are primarily the sources being used to develop the educational module.

General Literature

The treatment of chronic pain requires a comprehensive and multimodal approach to be successful in achieving adequate pain control (Von Korff, 2013). The use of short- and long-acting opioid analgesics continue to be the predominant treatment method by primary care health care providers and pain specialists. The AAPM and The APS view the use of these medications as an essential element in the management of chronic pain (Chou et al., 2009). A national review of these medications is occurring, specifically due to the concerns related to education and training. The use of the short-term analgesics is

becoming less attractive in the chronic pain community. Education about both agents is lacking (Gudin, 2013).

Gudin assessed the value of long-acting agents in the chronic pain population. Gudin (2013) demonstrated the effectiveness of these agents while demonstrating the ineffectiveness of the shorter-acting version. The pharmacodynamic properties and clinical advantages of long-acting analgesics are highlighted throughout the literature. The delayed onset of these medications can produce a delayed systemic response, therefore reducing the risk of addiction and tolerance. Additionally, the research outlined the clinical advantages of these medications, including dosing, administration, decreasing adverse events and minimizing of end-of-dose failure. The narrow fluctuations in overall plasma concentrations compared to the short-acting version contribute to these clinical advantages and improve the clinical effectiveness of the long-acting preparation.

Chou et al. (2009) published clinical guidelines that focused on the use of opioid analgesics including the long-acting version. These guidelines and recommendations were published after a panel concluded that long-acting agents are the best approach in the management of chronic pain (Chou et al., 2009). The authors recognized standards set by the AAPM and APS and each organization fostered the new recommendations identified in the clinical guidelines presented. These guidelines were later updated and research gaps were identified. Chou et al. (2009) revealed the need for adequate research to clarify the importance of long-acting agents in the chronic pain population. The uncertainty and confusion surrounding the use of long-acting agents continues to exist

despite the available research. This continues to lead to clinician confusion and inappropriate prescribing of short-acting agents.

The Institute of Medicine's report, "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research," recognized the need for improvement in all these areas and included a timeline that required recommendations for these improvements (IOM, 2011). This report is considered a comprehensive roadmap in the chronic pain community and exhibits commitment to addressing the shortfalls in pain assessment and treatment. Additionally, this report focuses on the need to transform the way our current health-care system deals with chronic pain patients and clinician education (IOM, 2011). While the report is extensive and lengthy, it fosters the need for additional education within the clinical setting. The report focuses attention on the use of long and short-acting medications in the clinical practice (IOM, 2011). It establishes the need for additional support for the use of both of these medications in all clinical setting. The report did not directly support the use of a particular preparation, but it does support a diagnosis-driven treatment plan. This includes the need for chronic medications for chronic conditions (IOM, 2011). The authors recognize the limitations within this recommendation and express the need to increase the literature base and clinician knowledge before a full recommendation can be asserted (IOM, 2011).

In contrast, Fine, Mahajan & McPherson (2009) found that while the benefits of long-acting analgesics revealed promise in the chronic pain population, short-acting medications were still needed in some patients experiencing breakthrough pain (Fine et al., 2009). This recommendation was revealed using the subjective behavior of the

sample and the researches recognized this limitation within the study (Fine et al., 2009). Research conducted by Rauck (2009) refuted this concept by demonstrating the improvements in patient's quality of life and improved treatment response with the use of long-acting agents versus the short-acting preparation. In addition, this research found an improvement in patient focus of daily activities and improved mental dexterity (Rauck, 2009). According to Rauck (2009), " The body of data that supports the role of long-acting opioids in chronic pain management and their beneficial effects on function, as well as quality of life, and sleep, is more robust than that for short acting opioids" (p.476). This research demonstrates the value within the medical community of the use of long-acting opioid agent.

Specific Literature

The knowledge of health care professionals has a direct impact on how chronic pain patients are treated in all settings (IOM, 2011). Although the literature is limited in regards to what current knowledge exists among these professionals, there are concerns that current knowledge in the outpatient and inpatient setting may be inadequate (IOM, 2011). A cross sectional study of over five hundred primary care physicians was conducted at 12 academic medical centers throughout the United States (O'Rorke, Chen, Genao, Panda, & Cykert, 2007). 572 primary care physicians responded to surveys that were distributed in these each of these settings (O'Rorke et al., 2007). The sample consisted of both female and male participants with a mean age of 35, while having a mean of 7.6 years of practice (O'Rorke et al., 2007). A staggering 35% of the physicians surveyed felt uncomfortable managing the chronic pain population (O'Rorke et al.,

2007). Education was noted as the primary reason for the lack of comfort within the sample (O'Rorke et al., 2007). The researchers concluded that additional education and training increased the comfort of physicians and improved their willingness to provide care to patients suffering from chronic pain symptoms (O'Rorke et al., 2007).

In contrast, the John Hopkins Pain Curriculum Development Team conducted research in 2011 that examined current curriculum requirements of 117 U.S. and Canadian medical schools regarding pain management education. Using the Association of American Medical Colleges' CurrMit database and 201 learning objectives developed by pain experts, the researchers collected and analyzed data the findings using a descriptive statistics approach (Mezei et al., 2011). Regression analysis was implemented to compare and contrast the schools characteristics, while a standard T-test compared CurrMit participants and non-participants (Mezei et al., 2011). Eighty-three (79.8%) of U.S medical schools provided some education in pain management, however these educational programs were general in nature and very limited in content and substance (Mezei et al., 2011). In comparison, 92.3% of Canadian medical schools incorporated pain management programs in their educational sessions (Mezei et al., 2011). The researchers also found that each of these courses lacked substance and content that would be reasonable to adequately prepare medical students for the treatment of chronic pain (Mezei et al., 2011). The researchers concluded that significant gaps between pain curricula and educational content existed (Mezei et al., 2011). Additionally, they found that most of the courses reviewed in the research were short, limited and often fragmented (Mezei et al., 2011). This resulted in a clear recommendation for a more

organized and formal approach to education for pain management and care, including lectures, workshops, learning labs, guest speakers and multidisciplinary panels (Mezei et al., 2011).

Upshur, Luckmann and Savageau (2006) revealed a lack of knowledge and training among health care professional in the community clinic population. The aim of their research was to assess the provider satisfaction and knowledge for professionals treating chronic pain. A total of 111 nurse practitioners, physician assistants, attending physicians and residents were surveyed (Upshur et al., 2006). The survey questions used were drawn from prior studies and validated by primary care providers, researchers and board-certified pain specialists (Upshur et al., 2006). These questions varied in regards to depth and included issues related to chronic pain management, opioid prescribing and satisfaction with training and knowledge base for the delivery of care (Upshur et al., 2006). The results of the research revealed a significantly low amount of health care professional, 54.5%, who felt "prepared or knowledgeable" to prescribe opioids and treat chronic pain appropriately (Upshur et al., 2006). This represents a large section of the population and has significant implications in the treatment of chronic pain. Specifically, the research indicated that education should be developed in a comprehensive setting with a focus on patient-centered approaches, while aiming to improve providers' concerns regarding substance abuse and addiction (Upshur et al., 2006).

Research conducted by Lewis, Corley, Lake, Brockopp and Moe (2015) used professionally directed small group discussions to improve the knowledge of, and remove barriers among, critical care nurses treating pain. The research used a quasi-experiment

approach and was conducted in a 383-bed Magnet hospital in the southeastern United States (Lewis et al., 2015). The sample size was relatively low at 34 participants, all of whom were registered nurses that graduated from associate and baccalaureate degree programs (Lewis et al., 2015). The experience among these nurses in managing pain varied (0.25 to 23.0 years) with a mean of 7.92 years (Lewis et al., 2015). The Warden Pain Knowledge Questionnaire (PKQ) was provided to participants and completed prior to their designation to selected small groups (Lewis et al., 2015). This scale consisted of a total of 24 true/false questions regarding the assessment and management of pain. A 5-point Likert scale measured the time and energy nurses spent managing pain of patients within the unit (Lewis et al., 2015). The intervention consisted of 10 small groups with approximately 2 to 6 participants each, which met over a span of 2 weeks (Lewis et al., 2015). Following the 2 weeks of small group discussions, the PKQ was administered again to each participant (Lewis et al., 2015). Descriptive and inferential statistics were used to calculate difference in knowledge within the groups pre-intervention and post-intervention (Lewis et al., 2015). The researchers found a significant difference in knowledge scores pre and post intervention (Lewis et al., 2015). The pre-intervention mean was 18.28 (*SD*=2.33) while the post-intervention mean was 22.16 (*SD*=1.70) (Lewis et al., 2015). This data revealed an increase in knowledge resulting from a basic small group discussion educational technique, while reducing bias among the participants (Lewis et al., 2015). The research had several implications for the hospital setting that included the development of a pain steering committee and an increased awareness among the nursing leadership regarding the lack of knowledge present in nursing units

(Lewis et al., 2015). Lewis et al., (2015) recognized that clinical outcomes would only improve once nurses increased their knowledge in a consistent and in-depth manner.

Finally, in one of the most comprehensive reports, The Institute of Medicine's report, titled "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research", identified three key recommendations regarding the education and knowledge needed to transform the treatment of patients experiencing pain symptoms (IOM, 2011). These recommendations include the need to redesign and expand educational programs that focus on understanding pain, while improving curriculums and continuing education programs for healthcare professionals (IOM, 2011). In conjunction with the American Society of Pain Management Nursing and The Institute of Medicine, researchers recognized two key principles for the use of this education to enhance the treatment of the chronic pain population (Lewis et al., 2015). These two principles are to improve the clinician's education and resources available to support the clinicians practicing pain management and to offer ongoing education support and research for widespread dissemination of evidenced-based analgesic practice (IOM, 2011). This comprehensive report illustrated the need for early education in pain management as well as ongoing high-quality continuing education for physicians, advanced practice nurses and ancillary staff that may be involved in the care of patients suffering pain, especially those requiring opioid analgesics (IOM, 2011).

Conceptual Model

Malcolm Knowles introduced the theory of adult learning in the 1980's and outlined six principles that continue to be used today (Curran, 2014). Given the nature of

the project, this theory is best suited to address the needs of the clinicians being targeted. The six principles recognize that adults are internally motivated and self-directed; bring life experiences and knowledge to learning experiences; are goal oriented, relevancy oriented, and practical; and finally that adult learners like to be respected (Curran, 2014).

Malcolm Knowles's Theory of Adult Learning

1. Autonomous & Self-Directed-The adult learner will be actively involved in the learning process, and the facilitator will guide the process of learning with a focus on the motivations and knowledge of the respective audience.
2. Life Experiences & Knowledge-The facilitator will provide the educational modules in a manner that correlates with the learners' current clinical or "life experiences. Content will be driven toward real life situations.
3. Goal-Oriented-The facilitator understands the learners are enrolling to achieve certain goals. The facilitator will ensure those goals are outlined and met.
4. Relevancy Oriented-Clinical situations and common clinical issues will provide a focus that will make the educational module relevant to the learners interest
5. Practical-Information that lack interest will be outlined in a manner that demonstrates its importance in the clinical setting.
6. Respected-The prospective learner will be treated as equals and their knowledge and experience will be respected in the development of the project (p. 233)

Additionally, these principles explore the adult learning process and the adult's ability to relate to the information provided (Curran, 2014). The course of education relies on the clinicians' (adults') ability to learn, and if these principles are not observed the project is likely to be unsuccessful in its attempts to expand the knowledge of the targeted population (Curran, 2014).

Cox, Roche and Wynen (2011) used this theory to facilitate the examination of retention of knowledge regarding pressure ulcers, using a lecture and computer-based educational platform to present information to critical care and medical-surgical nurses. A sample of 60 ($N = 60$) staff nurses from both units was obtained from a 500 bed Magnet designated hospital in the northeastern of United States (Cox et al, 2011). The theory's principles were integrated into the lecture and computer based learning modules (Cox et al, 2011). Each of these principles provided the researchers with structure to optimize the learning in the critical care and medical-surgical units (Cox et al, 2011). The use of this particular theory provided value to the nurses functioning within the units, while allowing them the opportunity to apply the knowledge directly to clinical practice (Cox et al, 2011).

In similar research, Schneiderman and Corbridge (2009) used the framework in the evaluation of a computer-based learning module for arterial blood gas analysis. A pretest and posttest design was implemented to assess the nurse's abilities to interpret arterial blood gas results before and after engaging in computer-based learning (Schneiderman & Corbridge, 2009). A sample of 58 ($N = 58$) staff nurses from two community hospitals in northern Illinois completed the educational modules and

completed the appropriate pretest and posttest (Schneiderman & Corbridge, 2009). The researchers followed the principles of the theory, and recognized that a better learning experience would occur when the learner has a need to know and motivation for learning (Schneiderman & Corbridge, 2009). According to Schneiderman and Corbridge, "Nurses have a professional responsibility to maintain and update their knowledge, skills and ability with regards to this activity to deliver safe, competent care and timely intervention" (p.152). They also demonstrate that the use of continuing education allows learners to build upon their previous clinical and educational experiences. The theory is present throughout the literature and maintained in the computer-based educational module (Schneiderman & Corbridge, 2009).

Finally, research conducted by Harne-Britner et al. (2009) applied this theory to develop educational strategies to improve the medication calculation skills of nurses (N = 22) and senior nursing students (N = 31) at PinnacleHealth System and Messiah College. The researchers reinforced the participants' involvement by providing feedback following their pretests, before implementing a 10-minute educational presentation (Harne-Britner et al., 2009). The researchers furthered the use of the theory by providing the participants the ability to choose the specific style of learning that most represented their learning styles (Harne-Britner et al., 2009). The participants were also given national benchmark data points regarding medication errors nationally and within the organization itself (Harne-Britner et al., 2009). This provided the relevance needed to enhance the learner's education process (Harne-Britner et al., 2009). To further the educational strategies following the research, self-study modules were provided to

nursing educators and implemented within both organizations to enhance the learning experiences and improve patient outcomes (Harne-Britner et al., 2009)

Summary

According to the literature, improvement in the education of all health care providers is needed. Several gaps in the literature exist; these include the current knowledge of physicians, nurse practitioners and physician assistants regarding the current up-to-date treatments in pain management. There is a focus on curriculum adjustments to ensure that new providers develop the necessary skills to treat the pain population.

Malcolm Knowles's Theory of Adult Learning is an appropriate theory for the projects development. The principals of this theory focus on the adult learner and integrate the life experiences of the learner. In addition to the focus on the adult learner's life experiences there is a level of respect that is maintained for the learner. The educational module will be developed in a fashion that fosters the primary principals of this theory and will be maintained throughout the dissemination process.

Section 3: Methodology

Project Design/Methods

The educational module's content drew on the clinical guidelines established by the APS and the AAPM in 2009. This joint project brought together some of the leaders in pain management, and consisted of 21 experts whose goal was to review evidence and formulate recommendations for the use of opioids in chronic noncancer pain. The APS and AAPM made several recommendations regarding patient selection, informed consent, management plans, initiation and titration, short-acting medications use, monitoring, and the treatment of high-risk patient populations (IOM, 2011). Additionally, the panel offered strong recommendations on dosing, opioid rotation, and discontinuation of therapy. These recommendations should be reflected in the practice of pain management clinicians, but the pain management and primary care community recognize the lack of knowledge of and adherence to these recommendations (IOM, 2011).

The continuing educational module was developed using a committee whose members had extensive experience in the field of chronic pain management. Yeshvant Navalgund, MD, Kimberly Jacob, NP-C, and myself were actively involved in the planning, development, and implementation of the education module. Navalgund is a national leader in the pain management community, with over 15 years of experience. He is the chief executive officer of two separate chronic pain management centers, with over 17 offices under his direction. He holds board certifications from the American Academy of Anesthesiologist and the American Academy of Pain Physicians. Dr. Navalgund is actively involved in the pain community and spends several hours a week providing

clinical and didactic education across multiple settings. Dr. Navalgund played an important role in the development of content and guidance related to the pharmacological aspects of the education. Additionally, Kimberly Jacob served in a role that supported the development of the material that was presented to the experts. She was actively involved in the development of topic selection and end product review. The development of the content was under the direction of Dr. Navalgund and the committee chair.

As the principal educational project developer, I have the experience necessary to ensure the validity of the project. I am a board-certified nurse practitioner in both family practice and pain management, with over 15 years' experience in the treatment of the chronic pain population. As adjunct faculty at the University of Pittsburgh, I am actively involved in the development and implementation of educational lectures for undergraduate and graduate nursing students in anesthesia administration. My clinical experience is significant. I continue to practice in the clinical setting, with an average of 20-30 patients under my care on a daily basis. My responsibilities include developing, implementing, and monitoring plans for chronic pain patients who require narcotic analgesics. Thus, I am well versed and up-to-date on the barriers and restrictions seen in the treatment of this patient population.

As illustrated in the literature review, the need for education in the area of pain management is well documented among all health care providers. This project is tailored to medical doctors, doctors of osteopathic medicine, nurse practitioners and physician assistants. The literature review demonstrated gaps in the knowledge of all these professionals. One of the most successful approaches identified by experts in education is

the use of continuing educational modules. This process allows educators the opportunity to reach a vast array of medical providers in large numbers across multiple specialties. There are several formats available for the development of continuing education. The format chosen for this project was a standard written document. This format provides a constructive, organized and easily referenced document that can be used by clinicians throughout the health-care spectrum. However, if the content is not evidenced-based and clinically relevant, the continuing educational module will not be approved for continuing education credit. The content of the presentation focused on the treatment of chronic pain with appropriate long-acting opioid analgesics. This included educational instructions that align with the current standards of practice and clinical guidelines offered by the APS and AAPM (see Appendix G and Appendix H).

Experts were chosen to review and evaluate the finished continuing educational module and asked to provide feedback using the expert-rating tool. The committee developed this expert tool since no current standardized tool exists in the educational or clinical setting. Each expert was asked to complete a Likert scale (rating tool) to confirm the appropriateness and validity of the project. The following criteria were needed to deem the evaluator an expert:

1. Experts must be board-certified in a selected specialty (i.e. Pain Management, Family Practice, Physical Medicine and Rehab)
2. Experts must be involved in the daily care of chronic pain syndromes (i.e. Chronic Pain Syndrome, Complex Regional Pain Syndrome and Lumbar Laminectomy Syndrome).

3. Experts must have prescriptive authority and be actively involved in the maintenance of short and long-acting opioid analgesics.
4. Experts must have experience in academia or be involved in continuing education in some capacity.

Population and Sample

Given the nature of the project, the sample population were experts in the field of various medical disciplines that are responsible for the daily care of patients suffering CPSs. Ten experts in total participated. Seven of these experts were specific to pain management as a specialty. The remaining experts were chosen from outside the specialty to ensure other specialties are represented in the evaluation of the educational module. The aim is to evaluate the content and presentation of the module and determine its worthiness for submission for CME accreditation.

Data Collection

The experts were provided the educational module for review. A detailed description of the intended focus of the project was provided to each expert before his or her enrollment. The experts were asked to review the module and return the expert tool once the review is completed. The tool consisted of questions that focused on the content of the educational module to ensure its appropriateness and quality (See appendix B for more information regarding expert tool). The experts were asked to return the responses within 30 days of receiving the educational module and response form. They were provided return pre-stamped envelopes for their convenience. Once a form was received, it was labeled with the appropriate response number and locked in a secured location.

The responses were not opened until all responses were returned. This observation was reasonable for ensuring the correct data is extracted and recorded appropriately. This ensured the answers are inputted as they appear on the response form. Each answer was uploaded into an Excel file that was secured with password protection.

Protection of Human Subjects

Protection of human subjects was not an issue with this project given the educational focus, however strict protocols were observed for the experts reviewing the project. The expert review process occurred without the use of any personal information and no information was retained following the return of the rating tool. No patients were used, since the study is specific to improving the knowledge of health care providers. IRB approval was still obtained according to the policy and a procedure of Walden University The IRB approval number is 07-13-16-0495977.

Data Analysis

The data analysis was completed once all the experts completed their -rating of the educational module. A standard descriptive analysis was used to summarize the data obtained from the experts' evaluations of the educational module.

Project Evaluation

The project was evaluated based on the responses of the chosen experts in the selected specialties. The aim of this project was to design and develop a quality educational module that is suitable for submission to a licensed organization that can provide CME accreditation. The responses from the experts served as a foundation that guided changes to the project. The expansion of knowledge for clinicians is an important

goal of continuing education. This expansion of knowledge can only be obtained with quality, evidenced-based education. The success of this project hinged on the approval and acceptance of the content from the experts in the field. The evaluation occurred in phases that include a formative evaluation, process evaluation, impact evaluation and outcome evaluation (Friis & Sellers, 2009). The formative evaluation allowed for modifications and improvement during the course of the development stages (Friis & Sellers, 2009). This occurred over the course of the educational module. The process evaluation allowed for reflection on the target population and the validity and consistency of the information being provided (Friis & Sellers, 2009). This phase was emphasized by the experts' responses in the project. As for the impact evaluation, this measured the impact on the clinicians that receive the educational module and the expansion of knowledge that may occur (Friis & Sellers, 2009). Identification of this process occurred once the content was established and the experts agreed that the module was worthy of submission (Friis & Sellers, 2009). Finally, the outcomes evaluation focused heavily on the experts' feedback on the educational module (Friis & Sellers, 2009). This included any recommendations that were made during the course of the evaluation. Collectively, this information serves as an evaluation plan that works over the continuum and expands beyond the academic setting.

Summary

The need for quality education on the use of opioids is needed in all healthcare specialties. The use of evidence-based guidelines and treatment protocols should be used to develop these educational modules. This project focused on the development and

implementation of a high quality, evidenced-based educational module that can be used in all specialties. A knowledge expansion is expected to occur with this module while further expanding the nursing profession and help negate the risk involved with the use of chronic opioid therapies in patients. The use of experts ensures the project meets the goals of a high-quality, evidenced based module. The finished product is expected to expand beyond the academic setting and be submitted to CME distribution companies.

Section 4: Findings, Discussion and Implications

Summary of Findings

The goal of this project was to develop a comprehensive educational module on opioid usage as a written document. This educational module was developed collaboratively to expand the knowledge of clinicians who may encounter patients suffering chronic pain and in need of opioid analgesics. This project is a peer-reviewed educational module on the use of opioids in clinical practice. The need for quality evidenced-based educational modules is highlighted in the literature, particularly in the specialty of pain management (IOM, 2011). I ensured that the training being developed would be clear and concise and that it represented up-to-date evidence. The educational module was developed and provided to experts for assessment. A Likert scale was used to assess the content and usability of the module (Appendix I). The Likert scaling system for this project was as follows: 1 (*complete disagreement*), 2 (*disagree*), 3 (*neutral*), 4 (*agree*), 5 (*strongly agree*).

The 10-question evaluation form was designed to examine the project's content and instructional method (Appendix I). The data obtained from evaluation tool confirmed the validity of the project while illustrating its importance in the education of health care professionals.

Five physicians, four nurse practitioners and one physician assistant made up the expert panel. All ten met the criteria listed in the previous section. All ten evaluations were returned within 30 days. Table 1 lists the questions, the question type, median value, and the experts' rating for each question (as a percentage).

Table 1
Expert Responses to Evaluation of Educational Module

Question	Question type	Median	1 (*complete disagree-ment*) %	2 (*disagree*) %	3 (*neutral*) %	4 (*agree*) %	5 (*strongly agree*) %
The content is clear and concise	Content	4.5	0	0	0	50	50
The content is capable of expanding the knowledge of clinicians	Content	4.5	0	0	0	50	50
The content is appropriate for clinicians in general and specialist	Content	4.0	0	0	20	50	30
As an expert in pain management, Would you recommend this education to your colleagues?	Content	5.0	0	0	0	40	60
The content demonstrates the importance of using long-acting analgesics in the CPS	Content	4.0	0	0	10	50	40
The content clearly outlines the medical and legal implications to practice and community when opioids are used	Content	3.0	0	30	30	30	10

The instructional methods were well organized	Methods	5.0	0	0	0	20	80
The instructional methods illustrate the concepts well	Methods	5.0	0	0	0	20	80
The teaching strategies were appropriate for the activity	Methods	5.0	0	0	0	10	90

Expert Evaluation Data

Content. The content questions one though seven measure the experts (*N* =10) opinion on the educational modules effectiveness and appropriateness for clinical practice and knowledge expansion. Five of the ten experts 50% (*N* =5) responded that they *agreed* that the educational was clear and concise and capable of expanding the knowledge of clinicians. The remaining five experts or 50% (*N*=5) responded with an opinion that they *strongly agreed* with the modules ability to expand the knowledge and viewed it as clear and concise. Question three demonstrated a different distribution in the answers and included an opinion that were *neutral* in two 20% (*N* = 2) of the experts, while (*N* = 5) 50% of the experts *agreed* that the content was consistent with the current practice standard and treatment guidelines. The remaining 30% (*N* = 3) experts *strongly agreed* in their responses. Questions four and five demonstrated a correlation in the responses with 40% (*N* = 4) *agreeing* with the contents appropriateness for general and specialty practice and their willingness to recommend the educational module to colleagues. The remaining

60% (*N* = 6) experts *strongly agreed* with this assertion. Question six and seven of the evaluation tool demonstrated a significant variation in the opinions provided by the experts. Question six examined the expert's opinion on the educational modules ability to demonstrate importance of using long-acting analgesic in the chronic pain setting. One expert 10% (*N* = 1) rendered the opinion as *neutral;* while 50% (*N* = 5) rendered the opinion that they agreed that the education demonstrated the importance of the long-acting agent. Four 40% (*N* = 4) opined that they *strongly agreed* with the educational modules ability to demonstrate the importance of these medications. The seventh and final question provided incite on the improvements that may be needed within the educational project. The question addresses the medical and legal discussion within the educational module and weather the implications are clearly outlined. The experts provided opinions that demonstrated a need for additional improvements in this area of the content. A total of 30% (*N* = 3) of the experts provided opinions in that fell below the level of acceptance and *disagreed* with the modules ability to clearly state the medical and legal implications. In contrast, only 10% (*N* = 1) of the experts *strongly agreed* with the modules ability to state this content, while 30% (*N* = 3) *agreed* the module was adequate in this content section. The remaining 30% (*N* = 3) experts opined that the module was neutral in this regard.

Methods. A total of three questions were dedicated to the instructional methods of the educational module. Questions one and two provided similar data from the experts and 20% (*N* = 2) revealed *agree* with the organization and concepts of the module, while the remaining 80% (*N* = 8) *strongly agreed* with the modules organization and concepts

as it was presented. The final question addressed the overall teaching strategies used for the education. A total of 90% ($N = 9$) *strongly agreed* that the strategies used were appropriate for the module and content. Only 10% ($N = 1$) responded with an *agreed* response in this section of the data.

In summary, the experts provided data that demonstrated the validity and appropriateness of the pain management educational module. With the exception of question seven, the experts overall agreed or strongly agreed with the content of the educational module. The experts did not deem the medical and legal implication content adequate and additional revisions will be needed prior to the implementation of the final project planned after the academic setting. The data analyzed supports the content of the module in all other aspects and support the education moving forward to the CME process.

Implications

Policy impact. The DNP-prepared nurse practitioner is in a unique position to guide and disseminate the need for improved health care policies in the chronic pain arena (IOM, 2011). Their ability to critically evaluate the literature, health care policy and clinical practice can be used to formulate the best practices and steer the health care policies being developed. The ability to disseminate this information using the totality of the evidence, while meshing daily clinical practice, provides a perceptive that has a direct impact on how this policy should be developed. Several states across the country are lacking the necessary health care policies that improve the pain management community and the patient they serve (IOM, 2011). In the Institute of Medicine report titled

"Relieving pain in America: a blueprint for transforming prevention, care, education, and research" experts and policy makers recognize the need for quality evidenced-based continuing education (IOM, 2011). This project is the first step in that process and provide a foundation for lawmakers and state representatives as they consider health care policy changes in pain management. Ensuring that clinicians are educated in the most up-to-date approach and materials is imperative for the improvement of patient outcomes, specifically in opioid prescribing (IOM, 2011). Given the current health concern and mortality associated with opioid use, it is imperative that health care clinicians are provided quality education and supported with appropriate health care policy (Friis & Sellers, 2009).

In several states there are licensure requirements that require the clinician undergo a required amount of hours of continuing education for selected topics including child abuse, pain management and drug abuse before renewal of their license can occur, however several states continue to lack the health policy needed to mandate this very important process (Friis & Sellers, 2009). The national attention and the abundant literature base surrounding education in pain management, specifically opioids, illustrate the need for quality state mandated continuing educational modules (IOM, 2011). I will disseminate the project to state and federal health care policy makers to demonstrate the need for health care policies that support the mandate nationally. The educational module will be used as a framework for the states that don't currently have an opioid specific educational mandate. This will shape the health care policy arena and shift the political

awareness toward the education of the clinicians prescribing these medications on a daily basis.

Clinical practice. The clinical practice of pain management continues to evolve with the recent changes in the practice guidelines established by the CDC and AAPM (Glowacki, 2015). The uses of continuing educational modules allow clinicians to educate themselves on practice techniques that have proven to improve patient outcomes (Glowacki, 2015). It is the clinician's responsibility to translate the education into the clinical practice (IOM, 2011). This project applies the most up-to-date evidenced based guidelines and presents them in an expert-reviewed educational module that can be applied directly to the clinical practice of pain management.

In a recent study conducted by The National Database of Nursing Quality Indicator (NDNQI) titled "Coordinating Center for Dissemination and Implementation of Evidenced-Based Methods to Measure and Improve Pain Outcomes" a total of 400 hospitals in the United States surveyed patients regarding their pain management while being hospitalized (Glowacki, 2015). This research occurred in March of 2011 and involved two phases that ended in December 2011 (Glowacki, 2015). Phase one resulted in the development of interdisciplinary teams to manage the pain of patients while hospitalized regardless of the pathology involved (Glowacki, 2015). One of the main focuses of this interdisciplinary team was to provide evidenced-based staff education for clinicians involved in the treatment of the pain population (Glowacki, 2015). The direct result of this education, along with the implementation of pain management daily rounds, improved patient outcomes and increased patients positive pain responses by 42.1 percent

(41.2% to 83.3%) (Glowacki, 2015). The researchers recognized the significant benefit in evidenced-based pain education and clinical practice changes occurred in 85% of the hospitals involved in the two-phase research (Glowacki, 2015). These changes included mandatory clinician and staff education for the treatment of pain in the inpatient population (Glowacki, 2015). This research further illustrates the need for this education in the pain community in order to implement quality practice changes

Research. Evidenced-based research in the pain management community started to advance following the AAMP clinical guidelines offered in 2009, however prior to the 2009 report there was very limited effort placed on the proper prescribing of opioids (Chou et al., 2009). In 2011, the Institute of Medicine's report determined that a lack of education was one of the primary reasons for prescription medication abuse, diversion and addiction (IOM, 2011). The IOM linked this to several factors in the research, however one of the most significant findings was the limited education and knowledge possessed by the prescribers, before and during, the administration of these medications (IOM, 2011). This project provides a comprehensive educational module with a focus on opioid prescribing and procedures that are necessary to provide safe, effective an efficient care.

Research will need to continue once the project is completed and the academic requirements are met. This includes the implementation and evaluation of the projects content in a sample of clinicians. Research will examine if the module stimulates learning and improves the knowledge of clinician (learner). Once this research is completed and demonstrates an expansion in knowledge in the health care setting these findings will be

disseminated to federal and state lawmakers. The intent and goal again will be to have this educational module distributed as a mandatory continuing educational module for clinicians with prescriptive authority, however without further research it is unlikely this will be credible to persuade lawmakers. The additional research will also allow for the perspective of the clinicians versus the current experts view. Additional adjustments may be needed before wider distribution occurs.

Social change. The misuse, abuse and diversion of opioid analgesics are at an all-time high in the United States (Compton & Volkow, 2006). The social impact of opioid misappropriation has created concern at both the state and federal levels (Compton & Volkow, 2006). Mortality and morbidity continues to rise as a result of this misappropriation (Compton & Volkow, 2006). Clinicians need to be prepared and educated on the most up--to-date evidence to ensure these medications are not being misappropriated by their patient (IOM, 2011). The assessment and identification of potential problems prior to the initiation of opioids is essential and without proper education this identification process can be complicated (IOM, 2011). If the clinician does not recognize these potential problems it can place the clinician, patient and society at further risk. The expansion of knowledge allows the clinicians the opportunity to make decisions regarding the patient pain without the feeling of fear and apprehension (Lewis et al., 2015). The education of our peers has proven over decades to improve patient outcomes and create a shift in mortality and morbidity in other chronic illness including heart disease, diabetes and cancer (IOM, 2011). This project, once fully implemented, provides the foundation needed to achieve the expansion of knowledge to protect

clinicians, patients and society as a whole.

Project Strengths and Limitations

Strengths. The evidenced-based educational module is easy to read and can be accessed on any device that supports a Microsoft Word and PDF format. Experts in the field of pain management have reviewed the module and the content was affirmed. Therefore, the educational module demonstrates the content needed to improve the knowledge of clinicians. The evaluation process allowed the experts to review the module anonymously. This prevented any bias in the answers and allowed them to fill out the evaluation tool without any preconception. This process allows the project to move toward the next level and evaluate the impact in the clinical setting that will be implemented post academic setting.

Limitations. The main limitation in the project's development was its inability to evaluate a sample of clinicians that are not considered experts. It does not examine the actual knowledge expansion that is expected to occur in this population. This project only demonstrates viewpoints of the expert and how they perceive the content of the project. The measurement of knowledge expansion is going to be an important part of the next phase of the projects success. The actual measurement of knowledge expansion will further prove the validity of the project and reaffirm the projects benefit.

Recommendations for Remediation of Limitations in Future Work

The future work will need to include a separate measurement of the non-experts opinion of the educational module and its content. Measurements will also need to include pre and post testing of knowledge to accurately establishes the modules validity

and worth in the from the non-experts standpoint. The data collected during this process will further affirm the modules ability to improve the knowledge base of clinicians prescribing opioid analgesics on a regular basis.

Analysis of Self

Practitioner. The conclusion of the DNP project offered areas of improvement for me as a practitioner. The use of evidenced based practice is essential to ensure patient outcomes are maximized (IOM, 2011). This project allowed me the opportunity to take evidence-based guidelines and apply them to the educational process, which in turn, resulted in a change in practice within the clinical setting. The translation of evidence into practice is only achievable when the practitioner takes the necessary steps to review the literature and recognize the changes that need to be made (Curran, 2014). This is something that became very evident during this initial phase of the project development. During the course of the project, I was able to translate the most up-to-date evidenced based guidelines into my daily practice. The augmentations in my knowledge base translated to the treatment of my patients and further research will be needed to determine the direct impact.

Scholar. As a scholar, the DNP project presented me with an opportunity to learn and grow during this 3-year process. The ability to evaluate the literature and translate it into evidenced-based knowledge and education was an essential part of this projects development. The scholarly inquiry necessary to produce a quality educational module cannot be understated. This inquiry process led to an additional knowledge base in my field and directly affects my patient's outcomes and health.

As project developer

As a scholar, the DNP project presented me with an opportunity to acquire leadership skills during the development phase; implementation phase and evaluation of the DNP project cannot be understated. The project development required vigorous leadership and organizational skill. The leadership needed to manage and align all the stakeholders, project members and content reviewers was one of the biggest accomplishments of the entire project. This process defined me as a leader and without proper leadership this process could not have been achieved. During the entire project development, my hands on approach provided stakeholders, project members and content reviewers with the support and leadership needed to ensure a successful project outcome.

Future Professional Development

The advancement of the DNP project has already had a significant impact on my personal professional development. The growth of the proposal and educational module provided a significant learning experience for me professionally. The enhancement in my own education and understanding of pain management process was augmented by the evidenced-based literature reviews. This process made me attentive to some of the most up to date evidence that can now be applied directly to patients suffering CPS. In addition, during the process of completing the DNP project there was an increased awareness of the gaps and barriers present in the pain population. These gaps and barriers are addressed in the educational module which will be disseminated to a larger audience moving forward cannot be understated. This inquiry process led to an additional knowledge base in my field and directly affects my patient's outcomes and health.

Section 5: Dissemination Plan

Introduction

The dissemination of the DNP project will be a process that occurs once the project is implemented fully. One of the observed weaknesses of the project in its current form is its inability to measure the actual knowledge expansion from the non-expert clinician perspective. The larger portion of the project will occur following the academic setting and will be implemented on a much larger scale, yielding a larger data set. This data will be analyzed in similar fashion as the expert reviewed portion of the project. Ultimately, The project will be dissemination using a written document format to state and federal lawmakers in a face-to-face presentation. The intent and goal of this presentation will be to make continuing education, regarding opioid management, a state and federal requirement for any clinician with prescriptive authority that is wishing to renew their license.

Furthermore, the project will be presented to multiple continuing educational suppliers. This would include organizations such as Pri-Med Medical, American Nursing Association, The American Academy of Nurse Practitioners and American Nurses Credentialing Center. If accepted, this educational module will be disseminated to multiple clinicians throughout the health care setting. This will provide the education needed to enhance the pain management community.

Summary and Conclusions

The DNP project presents an evidenced-based educational module that focuses on the use of opioid analgesics in the clinical setting. The experts in pain management

reviewed this project and the content was affirmed by their responses on the evaluation tool provided. The median score for questions 1 and 2 was 4.5, while questions 4, 5, 8, 9 and 10 scored a median score of 5.0. The lower of the two median scores (4.5 and 3.0) occurred on questions 3, 6, and 7, which will be addressed in the next phase of the project. The median and raw scores demonstrate a clear understanding of the content while enhancing the validity of the projects purpose.

In summary, the DNP project will provide value to the health care community and the clinicians treating patients that suffer chronic pain. This patient population is often complex and may require the use of opioids analgesics throughout their care. Without a proper knowledge base, patient outcomes can suffer, leading to a further burden on society (IOM, 2011). Continuing education and the expansion of knowledge have proven to improve patient outcomes in other chronic conditions including heart disease, diabetes and several forms of cancer (IOM, 2011). Significant emphasis is being placed on clinicians treating chronic pain and the need to practice with the most up-to-date evidence has never been more imperative. The use of a quality evidenced-based educational module will assist the clinicians in their clinical practice and allow them to practice within the current guidelines while maintaining a standard of care (IOM, 2011). Thus, producing a more informed clinicians base while improving patient outcomes though the duration of their treatment.

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Appendix A: An Evidenced-Based Pain Management Module to Improve the Knowledge of Clinicians

Patient Selection and Diagnosis:

Physical Examination and History

A. Complete assessment of physical health

1. Complete medical history-pain specific.
2. Identification of co-morbidities
3. Appropriate Diagnostic Testing (Ordering/Obtaining)
4. Complete physical examination, including documentation of painful elements and findings
5. Clarifying and establishing opioid appropriate diagnosis

Physiological Assessment and History

A. Complete assessment of psychological health

1. Identification of pre-existing psychological disorders
    a. Personal history of abuse/addiction
    b. Family History of abuse/addiction
    c. Psychosomatic Underpinning
2. Risk Assessment Tools
    a. Screener and Opioid Assessment for Patient with Pain (SOAPP)
    b. Opioid Risk Tool
    c. Diagnosis, Intractability, Risk, Efficacy (DIRE) Tool
    d. CAGE

II. Informed Analgesic Consent/Management Plans:

1. Risk/Benefit Analysis:

a. Documentation
b. Patient Awareness.
c. "RED FLAGS"

2. Goal Setting/Planning

a. Functional Improvements
b. Physiological Improvements
c. Social Indications

3. **Monitoring**
    a. Urine Drug Screening
    b. Random Pill Counts
    c. Genetic Testing-New Technology
    d. High-Risk Populations

4. **Opioid Treatment Agreement**
    a. Documentation Standards
    b. Patient Requirements
    c. Frequency of renewal

III. Drug Selection and Appropriate Use for Chronic Non-Malignant Pain

1. Short-Acting Analgesics
a. Literature Review/Diagnosis Appropriate Care
b. Efficacy
c. Pharmacokinetics/Pharmodynamics
d. Side Effects/Adverse Reactions
e. Initiating Therapy
d. Outcome Measures

2. Long-Acting Analgesics
a. Literature Review/Diagnosis Appropriate Care
b. Efficacy
c. Pharmacokinetics
d. Side Effects/Adverse Reactions
e. Initiating Therapy
d. Outcome Measures

3. Maintenance
a. Follow up Consultations/Documentation
b. DEA Reporting
c. Pharmacy Reporting
d. State Databases

IV. Legal Implications for Advanced Practice
a. Current Federal Law
b. Current State Law
c. Prescribing Implications
d. Case Studies/Legal Examples

V. Current Clinical Guideline Review
a. American Pain Society

1. Opioid Treatment Guidelines

b. American Academy of Pain Medicine

1. Opioid Treatment Guidelines

c. Centers for Disease Control and Prevention

Appendix B. Opioid Analgesic Educational Module

Introduction:

The use of opioid analgesics for the treatment of CPSs continues to be controversial in the absence of cancer related pathology (Compton & Volkow, 2006). It is imperative that direct and indirect health care providers treating chronic pain utilize the most up-to-date literature and guidelines available to develop and manage the treatment plans in this patient population (Chou et al., 2009). In 2015, it is estimated that 20% of patients presenting to health care providers reporting pain received opioid analgesics prescriptions (Dowell, Haegerich & Chou, 2016). In the United States, opioid prescriptions have escalated significantly over the last several years. In 1991 it is estimated that roughly 40 million prescriptions were written compared to 259 million in 2012 (Dowell et al., 2016). This is enough for every man, women and child in the United States to have their own prescription bottle (Dowell et al., 2016). The escalation in opioid prescribing undoubtedly had an impact on the increase of addiction and non-medical uses of these prescriptions (Dowell et al., 2016). While there is limited literature to directly relate the two, several statistical trends appear problematic. In the time period between 2004-2008 emergency room visits increased by 111% for non-prescription opioid related uses, overdose deaths became the second leading cause of death in America and an estimated 7 million Americans were abusing some form of prescription opioids (Dowell et al., 2016).

These problematic statistics reinforced the need for clinical guidelines, stricter regulations and formative treatment protocols for clinicians treating patients with chronic pain. In 2009, The APS and The AAPM published guidelines titled “Clinical Guidelines

for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain". This joint document serves as a nationally recognized set of guidelines for clinicians that treat chronic pain (Chu et al., 2009) In 2011, The White House Office of National Drug Control Policy echoed the recent guidelines and emphasized the need to maintain legitimate medical treatment of pain while reducing the risk of opioid abuse and death (Dowell et al., 2016). Shortly after the White House published their initiative, The U.S Food and Drug Administration released the Risk Evaluation and Mitigation Strategies in 2012, commonly referred to a REMS, which focused on the education of clinicians as it relates to the use of extended-release (ER) and long- acting (LA) opioid analgesics (Dowell et al., 2016). Most recently, The Center for Disease Control (CDC) released a new set of guidelines titled "CDC Guideline for Prescribing Opioids for Chronic Pain, United States, 2016. These guidelines are the most comprehensive to date and included input from stakeholders, experts, public representatives, peer reviewers and federal advisory committees (Dowell et al., 2016). The CDC intended to bridge the communication gap between clinicians and patient regarding the risk and benefits of long term opioid therapy, while improving the safety and effectiveness of pain treatments (Dowell et al., 2016). The value of these guidelines remains to be seen but are being reared as some of the most comprehensive and in-depth published opioid guidelines (Dowell et al., 2016).

Local, state and federal officials identified education and training as being one of the most effective avenues to facilitate and combat the current opioid crisis (Institute of Medicine, 2011). This CME exposition will provide clinicians with a structured foundation to practice with vigilance when opioid prescriptions are needed to control pain

chronically. It will serve as the first step in defining and furthering the education of clinicians interested in the safe, effective and efficient treatment of the chronic pain population.

Patient Assessment, History and Physical Examination

Assessing patients for the use of chronic opioid therapy in noncancerous chronic pain is a process that all clinicians should be well versed and fluent in preforming (Jamison, Serraillier & Michna, 2011). This process is multifactorial and requires a significant documentation process in order to comply with state and federal regulation. The inherent risk of prescribing opioid medications can only be reduced when clinicians are provided education that represents the most current clinical guidelines available (Jamison et al., 2011). The current published clinical guidelines demonstrate a need for particular elements that include a complete documented assessment and medical history, verification of all current medications, detailed physical examination, current psychological status and substance abuse history (Dowell et al., 2016). Each of these will be addressed in detail, ensuring a complete understanding of the elements needed to be in compliance.

Patient Assessment

A comprehensive approach needs to be taken when addressing the assessment and medical history of a patient suffering from noncancerous related pain, especially when opioid analgesic is being considered in the treatment plans (Jamison et al., 2011). Ancillary staff and clinicians practicing pain management should be aware of the necessary elements needed to meet the minimal standards set forth in the clinical

guidelines offered by The American Academy of Pain Medicine and The Center for Disease Control (Jamison et al., 2011;Dowell et al., 2016). These minimal standards include a detailed description of the following (Jamison et al., 2011;Dowell et al., 2016):

A. Locality of pain symptoms

1. Current location of the pain including any areas that the pain may radiate to.
2. Multiple pain complaints to be address individually.

B. Onset of pain

1. When the pain started (post-surgical, motor vehicle accident ect)
2. Duration of symptoms (short term intermittent, long term continuous)
3. Timing (When it is better or worse)

C. Characteristics of pain (detailed description, i, e., aching, throbbing, sharp or shooting)

1. Throbbing
2. Aching
3. Sharp
4. Shooting
5. Burning

D. Pain scoring/Intensity (current pain, best pain, worst pain)

1. Numeric Pain Scale (0 to 10 scaling system)
2. Verbal Descriptor Scale (utilizes six phrases starting with no pain to worst pain)

3. Visual Analogue Scale (VAS) (Rating system using patients marking on a line)
4. Oucher Scale (culturally sensitive pediatric scaling system)
5. Comprehensive McGill Pain Questionnaire (sensory component)

Several scoring systems currently exist and consideration must be given for cultural, development stage, cognitive function and language barriers of the patient.

E. Exacerbating/Alleviating factors

1. What activities make the pain worse?
2. What activities make the pain better?
3. What medications reduce the pain?
4. What interventional treatments improve the pain?
5. What holistic treatments improve the pain?

F. Associated Symptoms

1. Sleep Disruptions
2. Mood alterations
3. Appetite
4. Socialization and family relationships
5. Sexual activity
6. Activities of daily living

G. Current and Past Treatment

1. Interventional treatments (injection therapy, surgeries, holistic care)
2. Physical therapy/chiropractic care (document number of sessions)

3. Past medication usage (NSAID's, opioid's, muscle relaxants)

Aside from compliance, these assessment elements will assist the clinician in defining the etiology of the patient's painful symptoms (Kulich &Stone, 2012). Clinicians must be cautious when treating painful symptoms with opioid analgesics and ensure that the diagnosis they are treating is appropriate (Kulich &Stone, 2012). There are two main pain categories that are clearly defined in the literature. These two categories include nociceptive and neuropathic pain processes (Allen et al., 2013)

Nociceptive pain is best described as pain that results from damage to an area or areas of body tissue (Atluri, Akbik & Sudarshan, 2012). It is due to the activation of specific neural pathways that sense damage to the tissue or the possibility of potentially damaging stimuli (Atluri et al., 2012). The activation of C fibers, A-delta and A-beta neurons transmit the painful signals to the brain (Atluri et al., 2012). It is typically a benign process, however can be related to cancerous involvement. In most cases the pain can be directly related to bony structure, muscle and joint pathology (Martel et al., 2014). Nociceptive pain is usually described as sharp, aching and throbbing, that is persistent and can vary in intensity (Atluri et al., 2012; Martel et al., 2014). This particular pain processes is very responsive to opioid analgesics and is supported in the literature (Atluri et al., 2012; Martel et al., 2014). Given the response to opioids, patients that suffer from nociceptive pain are considered ideal candidates for opioid therapy (Atluri et al., 2012; Martel et al., 2014).

In contrast, neuropathic pain can be directly related to damage to a specific nerve or a group of nerves (Atluri et al., 2012). This damage occurs at the level of the neurons

in the human body that has become injured or damaged (Atluri et al., 2012). This insult/damage results in abnormal messages of pain being sent to the central nervous system and brain (Atluri et al., 2012). These abnormal signals travel in the nerve pathway that result in sensations of pain that are consider dysfunctional. The pain is typically described as shooting, burning, tingling and numbness (Atluri et al., 2012; Martel et al., 2014). In chronic noncancerous pain, this process can be related to co-morbidities and diagnoses including diabetes, previous surgery, infection and trauma (Atluri et al., 2012; Martel et al., 2014). It is noted in the literature that the use of opioids in this patient population should be avoided and they are minimally responsive when neuropathic pain is present (Atluri et al., 2012; Martel et al., 2014).

Appropriate management techniques can only be developed when the differentiating factors are properly assessed. There is a clear distinction between nociceptive and neuropathic pain symptomology and the clinician should be clear when documenting these differences (Von Korff, 2013). It is well established in the current guidelines that pain evolving from the neuropathic pain processes is minimally responsive to opioid analgesics (Chou et al., 2009; Dowell et al., 2016). There are several theories as to why the responsiveness of opioid analgesics is reduced in the neuropathic process, but one continues to be most predominant in the literature. The functional change that occurs at the level of the dorsal horn of the spinal cord during neuropathic pain processes causes a noted downregulation or desensitization of the μ-opioid receptors (Chou et al., 2009). This ultimately leads to a reduced in the overall responsiveness of the opioids and reduces ability of the μ-opioid receptors to be affected by the opioid

medication (Chou et al., 2009). This is not to say that they should not be used, however it should be considered second or third line treatment option.

Physical Examination:

The physical examination that focuses on the pathology of noncancerous pain must comprehensive and systematic (Sox & Stewart, 2015). The standard physical examination should apply and the clinician should exam the basic systems involved in a complete examination. This includes documentation of the cardiovascular, respiratory, abdominal, musculoskeletal and neurological systems (IOM, 2011). A focused evaluation should include an in depth assessment of the motor and sensory function of the patient to include documentation of any painful or decreased sensory response to testing (Sox & Stewart, 2015). The documentation should reflect correlation with pain patterns and the suspected or known pathological processes (Sox & Stewart, 2015). The patient complaints should direct the clinician to perform a focused examination while narrowing the differential pain diagnosis. Careful observation of verbal and non-verbal pain behaviors should be examined and documented (Sox & Stewart, 2015). These include the patient's ability to sit in a chair, gait, position changes and use of assistive devices (Sox & Stewart, 2015). Each clinician should utilize their own structured examination; however the documentation should reflect the appropriate examination of the painful areas. There are no clinical guidelines for the specific physical examination requirements nevertheless a detail examination should occur (Chou et al., 2009).

Co-morbidity/Medical History Assessment:

The assessment of a patient's medical history and comorbidities is particularly important when deciding on the integration of opioids analgesics into the treatment plans (IOM, 2011). Aside from the assessment of these conditions, it is imperative that documentation reflects all of these conditions and the clinician must address how they will be managed. Assessment of prior medical history can occur via patient report or previous medical record reviews (IOM, 2011). The importance of obtaining and reviewing a patient's prior medical history with primary care, specialist and hospitalizations cannot be understated (IOM, 2011). These records will often reveal a patient's previous history that may be a contributing factor in the decision making process (IOM, 2011).

The clinician should use extreme caution when prescribing in patients that suffer from any sleep-disordered breathing (IOM, 2011). This would include patients with heart failure, sleep apnea and obesity (IOM, 2011; Sox & Stewart, 2015). It is essential that clinicians monitor the titration of opioids in patents that suffer altered respiratory function. Opioid analgesics should be avoided in all cases that are classified as moderate to severe in nature. This includes uncontrolled congestive heart failure and sleep apnea requiring continuous positive airway pressure (CPAP, IOM, 2011; Sox & Stewart, 2015). In milder cases, opioids can be used, however very careful titration should occur and continuous monitoring is crucial in order to minimize the potential for overdose and death (Sox & Stewart, 2015).

Obesity is a major health risk and concern when treating chronic noncancerous pain with opioid analgesics (Lewis et al., 2015). The respiratory insufficiency and respiratory depression that occurs in patients presenting with a body mass index (BMI) of 30 or greater pose the greatest risk (Lewis et al., 2015). It is estimated that patients that fall into this classification have a 45% greater chance of developing a significant respiratory insufficiency in comparison to patient that present with a BMI of 25-29 (Lewis et al., 2015). The risk is negated further when patient present with a BMI of less than 25 (Lewis et al., 2015). Caution and careful attention should be taken when starting and titrating opioid analgesic of any kind in this population. Consideration for weight loss evaluation or pulmonary testing may be needed prior to the initiation of these medications (Lewis et al., 2015).

Patients with renal and hepatic function insufficiency also pose a risk when opioids are being prescribed or considered (IOM, 2011). Clinicians need to use extreme caution when prescribing opioids in this population given the inability of the body to excrete the drug efficiently (IOM, 2011). If renal or hepatic excretion is not optimized accumulation of opioids may occur, reducing therapeutic windows and causing respiratory depression and overdose situations (IOM, 2011). Routine lab values should be obtained in any patient that has a history or concern for renal or hepatic insufficiently (Lewis et al., 2015). Hepatic and renal function panels should be ordered prior to the initiation of the selected opioid and routine follow up testing should be performed every 3 months (Lewis et al., 2015). Documentation should present a complete review of these laboratory values with notation of any abnormal values prior to and throughout treatment

(Lewis et al., 2015). This is especially the case in combination medications including Hydrocodone/Acetaminophen (Vicodin) and Oxycodone/Acetaminophen (Percocet)(Lewis et al., 2015). These two opioids analgesic have been linked in the literature to significant damage to the hepatic system is patients requiring regular frequencies and dosing (IOM, 2011).

Advanced age is a significant factor when deciding if opioid analgesics are appropriate and safe for a patient suffering pain symptoms (IOM,2011). Clinical guidelines recommend that any patient over the age of 65 years be closely monitored and all alternatives be considered prior to implementing the use of opioids (IOM, 2011). There is an inherent risk given the reduced renal function and medication clearance that occurs in advanced age (IOM, 2011). This is true even in the absence of underlining renal disease. There is a very thin line when renal function declines in advanced age, making the therapeutic window small making normally safe doses unsafe in this population (IOM, 2011).

Additionally, cognitive function needs to be assessed prior to considering opioid therapy in the older adult. Education and counseling should be provided to negate the risk associated with declining cognitive function (IOM, 2011). Clinicians should be concerned with cross interaction with multiple medication use, constipation and incorrect dosing schedules (IOM, 2011). Interventions should be implemented to avoid and combat these issues prior to starting opioids in a patient of advanced age. Fall risk assessments should be conducted to ensure the use of the opioid wouldn't further exacerbate an already unsafe situation (IOM, 2011).

Finally, the female adult population needs to be evaluated for the possibility of pregnancy prior to and during treatment with opioid analgesics (Chou et al., 2009; Dowell et al., 2016). Mother and fetus are at increased risk should opioids be continued during the development stages of pregnancy (Chou et al., 2009; Dowell et al., 2016). The literature demonstrates a clear correlation of stillbirth, poor fetal development, pre-term delivery and early child defects when opioid analgesics are used during pregnancy (Chou et al., 2009; Dowell et al., 2016). Current guidelines from the AAMP and CDC suggest the use of opioids in pregnancy should be avoided unless the benefits outweigh the risk (Chou et al., 2009; Dowell et al., 2016). It is estimated that 50% of opioid dependent mothers will have a child with opioid-induced withdraw (Dowell et al., 2016). Should opioids be absolutely required, a specialist with experience in neonatal withdrawn should be present for delivery (Dowell et al., 2016). It is imperative that clinicians provide and document that a discussion occurred regarding these inherent risk and potential complications (Chou et al., 2009; Dowell et al., 2016). Birth control techniques should be addressed with each adult female of childbearing age during initial assessment (Chou et al., 2009; Dowell et al., 2016).

Physiological Assessment:

It is imperative that a thorough evaluation and documentation of the psychological impact of pain on the patient be conducted (Bussing, Ostermann, Neugebauer, & Heusser, 2010). Clinical depression, anxiety and stress are associated with chronic pain in the literature (IOM, 2011; Bussing et al., 2010; Arteta et al., 2016). If left unaddressed it can undermine the treatment of the patient and exacerbate the

current symptomology (Arteta et al., 2016; Bussing et al., 2010). Several evaluation tools that address and identify these potential psychological conditions exist in the literature and practice. Clinicians should avoid using a single tool or method when conducting a psychological evaluation of a patient to avoid biases and manipulation of the testing (Arteta et al., 2016; Bussing et al., 2010). The inclusion of spouses/partners, family member and close friends is critical and valuable to the assessment of the psychological health state of the patient suffering chronic pain and should be implemented whenever possible (Arteta et al., 2016; Bussing et al., 2010).

The most common and tested tools include Personal Interviews, Psychosocial Pain Inventory, Pain Assessment Report, The Minnesota Multiphasic Personality Inventory (MMPI) and The Patient Health Questionnaire (PHQ-4)(Arteta et al., 2016; Bussing et al., 2010). The personal interview process is one of the most commonly used approaches to identifying and obtaining psychological information (Bussing et al., 2010). This process includes very directed question with the patient and family that focus on the identification of potential problems areas that may require further evaluation. The clinician should pay particular attention to the input from other sources during the personal interview (Bussing et al., 2010). The relationships and interactions with others can provide valuable information into the psychological state of the patient during everyday interactions and periods of stress and pain (Bussing et al., 2010). Theoretical perspective of the clinician plays a role in this process and the variables need to be considered during the patient-clinician interaction (Bussing et al., 2010).

The Psychosocial Pain Inventory is a 25-question interview process that allows the participant and interviewer the opportunity to expand of topics that may affect treatment (Arteta et al., 2016; Bussing et al., 2010). The primary psychosocial factors evaluated in this instrument include pain behavior, social reinforcement, lifestyle changes, secondary gain (litigation), economic status, alcohol/drug use, prescription medication use, coping strategies, social environment and interaction, current stressors (Arteta et al., 2016; Bussing et al., 2010). The assessment also addresses the patient's personal, family and medical histories over the course of the lifespan. Additionally, it evaluates the reactions and coping with current pain related treatments and outcomes (Arteta et al., 2016; Bussing et al., 2010).

The Pain Assessment Report is another valuable interview process that is semi-structured and quantifiable (Arteta et al., 2016; Bussing et al., 2010). The information is obtained in a specific format and the questions are coded in measureable terms. Each of these questions focus on a specific domain that includes history, presumed diagnosis of pain, patient factors influencing the pain experience, illicit substance/alcohol use and cognitive, behavioral and physical means of coping strategies (Arteta et al., 2016; Bussing et al., 2010). Additional information is obtained regarding pain related changes in relationships with family, friends and significant others (Arteta et al., 2016; Bussing et al., 2010). A larger emphasis is placed on social and psychological functioning including mood, sleeping patterns and previous psychological treatments (Arteta et al., 2016; Bussing et al., 2010).

The Minnesota Multiphasic Personality Inventory (MMPI) is another commonly used assessment tool that aims to parallel pain and personality (Arteta et al., 2016; Bussing et al., 2010). The MMPI is currently being administered is two separate formats. This includes the MMPI-2 that contains 567 questions that are answered in true or false format and address 10 clinical scales, 10 subscales that measure abnormal psychological behavior (Arteta et al., 2016; Bussing et al., 2010). Built in validity testing is present within the assessment and allows the clinician the opportunity to measure general test taking attitudes (Arteta et al., 2016; Bussing et al., 2010). In 2008, the MMPI-2-RF was published and is considerably shorter and only consists of 338 true/false questions (Arteta et al., 2016). The subsections are limited in the newer version and the typical time of testing is roughly 30-40 minutes (Arteta et al., 2016). The MMPI-2 is well established in the literature and is the used frequently considering the familiarity in the medical and psychological community despite its length of time it requires to administer (Arteta et al., 2016).

Finally, The Patient Health Questionnaire (PHQ-9) is one of the widely recognized depression assessment tools for the use in the clinical setting (Arteta et al., 2016). It provides clinicians with a multipurpose tool that can be used for screening, diagnosing, monitoring, and measuring the severity of depression symptoms (Arteta et al., 2016). This tool is scored with ease and can be administered several times throughout treatment to establish improvements and setbacks (Arteta et al., 2016). The questions focus on the patient symptoms, within the prior 2 weeks to testing, and include suicide related questions (Arteta et al., 2016). In recent months, the first two question of the

assessment have been incorporated into several quality improvement measures including the Physician Quality Reporting System (PQRS)(Arteta et al., 2016). This national program recognizes the importance of early identification of depression in the pain population and all health care population seeking treatment (Arteta et al., 2016).

The above psychological assessments are just a guide and each individual clinician should decide on the best tool for their patient population and medical practice (Arteta et al., 2016). Whenever possible, it is recommended that the clinician treating non-cancer chronic pain align themselves with mental health professionals that have experience in the treatment of pain related psychological disorders (Arteta et al., 2016). Given the complexity and chronicity of this population; it is important that the clinician treating the painful symptoms also involve these specialists to manage the ongoing and concurrent psychological issues that exist or continue beyond the initial evaluation and treatment period (Arteta et al., 2016). If the clinician feels appropriate, the management can be concurrent and effective.

Culture plays a very important role in the treatment of chronic pain, especially when opioid analgesics are being considered. The clinician has a unique role in identifying, assessing and maintaining cultural influence that may create barriers for the patient and treating clinician. It is well established in the literature that culture influences both the expression and perception of pain is certain populations, making the identification imperative during the initial assessment period. Some very basic assessment components should be evaluated during this period. They include (Arteta et al., 2016):

A. Family and affiliation systems

1. Family system structure (nuclear or extended)

2. Role definition (each family member's individual role in the family)

B. Social Patterns

1. Daily routine (social functions)

2. Nutritional considerations (dietary patterns-individual and family)

C. Language and family traditions

1. Current language spoken

2. Verbal and nonverbal communication techniques

3. Major cultural traditions

D. Religion

1. Religion beliefs and current practices

2. Health Practices and religion's role

E. Health practices and health beliefs

1. Health and illness attitude

2. Health Care decision makers

3. Define any remedies, folk medicine, rituals and healers

Cultural assessment is imperative to have a complete evaluation of the patient suffering chronic pain. Opioid analgesics are considered taboo is some cultural settings and early identification is crucial to ensure an appropriate treatment planning occurs (IOM, 2011). Again, the clinician should use personal judgment when determining the

assessment needed for their individual patients, however these basic concepts should be considered.

Risk Assessment and Risk Tools

Risk assessments imperative in the treatment of patients suffering chronic noncancerous pain when opioids are being considered (Kulich & Stone, 2012). This assessment provides a means of applying a risk level to each patient and allows the clinician the opportunity to tailor monitoring techniques to each treatment plan. Each clinician should determine which assessment technique and tool suits their patient population best. The current guidelines identify patients into three risk categories including low risk, medium risk and high right. These categories, regardless of screening tool use, should be used and the criteria should be assessed. Below are the current criteria for each classification.

Low risk classification	**Medium risk classification**	**High risk classification**
Known pathological pain processes with objective findings	Known pain pathology with subjective and objective findings, but no more than three painful areas	Unknown pain pathology with subjective complaints and no objective findings
Clinical correlation with available testing (MRI, EMG), physical examination and diagnostic interventional procedures (facet blocks, nerve root block)	Confirmed diagnostic evidence of pain pathology	Pain in more than three body regions
Limited psychological comorbidity	Moderate psychological and comorbidities that are controlled by medical treatment	Abnormal drug behaviors (multiple request)
No personal or family history of alcohol or prescription drug abuse	Personal and family history of alcohol or prescription drug abuse	Major or untreated medical and psychological conditions

Well –defined coping strategies	Agreeable and willing to participate in interventional and multimodality approaches to treatment	Age < 45
Age of >45 years	Attempting to perform activities of daily living and normal daily function despite pain	Minimal or no coping strategies with magnification of symptoms
Agreeable and willingness to participate in interventional pain treatments		Unwilling or refusal of available interventional modalities

Risk Assessment Tools

The opioid risk tool (ORT), as explained by Kulich and Stone (2012), is a self-reporting, five-item assessment tool that helps predict the potential for uncharacteristic drug-related behaviors Scoring is simple and practical in the clinical setting (Kulich & Stone, 2012). Scoring can be completed within minutes and typically occurs during the initial assessment period. Content areas include personal and family history of drug abuse including illicit drugs, alcohol use and prescription drug history (Kulich & Stone, 2012). Other scored items include current age, history of preadolescent sexual abuse and psychological diseases (Kulich & Stone, 2012). Each of these items are given a numeric value and totaled at the end of the assessment. Scores at 3 and below represents a low risk of opioid abuse, while a score of 4 to 7 represent moderate risk and a score of 8 or higher represents a much higher risk level (Kulich & Stone, 2012).

The Screener and Opioid Assessment for Patients is another comprehensive self-reporting tool for any patient being considered for long-term opioid therapy (Kulich & Stone, 2012). This 24-item screening is used to predict potential aberrant behaviors (Kulich & Stone, 2012). The content is geared toward identify factors that are correlated

with the misuse and abuse of opioid analgesics such as alcohol abuse, substance abuse, cravings and mood. Scoring is completed at the time of the assessment and any patient receiving a score of 18 or more are considered high risk (Kulich & Stone, 2012). In fact, this assessment is accurate in 90% of the population when determining the eventual misuse of opioid analgesics (Kulich & Stone, 2012). This screening tool has been validated in several literature sources and cross validated in over 600 patients throughout the United States (Kulich & Stone, 2012).

Conversely, the Diagnosis, Intractability, Risk and Efficacy (DIRE) rating tool is comparable to the ORT, however it is a clinician-rating tool. It is used to predict compliance and appropriateness in patients that require long-term opioids in less than seven minutes (Belgrade, Schamber & Lindgren, 2006). The content consists of questions that explore diagnosis, patient care involvement, psychological history, dependability, social support and previous opioid drug efficacy (Belgrade et al., 2006). Scoring from 7 to 13 would represent a candidate that is not suitable for long-term opioids and scores ranging from 14-21 would be more appropriate for the long-term use of opioids (Belgrade et al., 2006).

The final screening tool that has been used in chronic pain and serves an important role in evaluating patient for chronic opioid therapy is the CAGE-Aid. This screening tools original design was primarily for alcohol use, however the redesign format adds question about drug abuse to the questioning set (Kulich & Stone, 2012). This screening is easy to perform and takes little time to administer. The content consist of 4 pointed questions following the acronym:

C Have you ever felt that you ought to cut down on your drinking or drug use?

A Have people annoyed you by criticizing your drinking or drug use?

G Have you ever felt bad or guilty about your drinking or drug use?

E Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?

Answer of two or more yes answer is considered positive and extreme caution should be taken with this patient population (Kulich & Stone, 2012). There is current literature that suggests that the positive screening should be considered with one yes answer to the screening (Kulich & Stone, 2012). This is still being considered and the current recommendation remains at two yes responses. Clinicians should use preference while remaining consistent when administering this screening (Kulich & Stone, 2012). An example of each risk assessment tool is available at http://www.aafp.org/fpm/toolBox/viewToolBox.htm

Patient Monitoring and Compliance

Patient suffering CPSs that do not have an underlining cancerous process require regular monitoring and follow up care when opioid are being used as a part of the treatment plans. The current guidelines identify several helpful monitoring strategies that should be implemented by clinicians prescribing opioids or considering them in their treatment plans (Haffajee, Jena & Weiner, 2015).

Urine Toxicology

Urine toxicology screening is vital for the identification of the potential unauthorized use of prescription and illicit drugs, diversion and non-compliance

(Haffajee et al., 2015). There are several types of urine drug testing that can be used in practice and the least complex and basic is immunoassay testing (Haffajee et al., 2015). This test provides a belief overview that can be easily administered in the clinical setting, however it fails to quantify the result. It also limits the testing to positive and negative results and doesn't provide specific drug information. In recent studies the use of gas chromatography/mass spectrometry urine toxicology has proven to be the most effective way to quantify the extent of current drug usage, both prescription and illicit (Haffajee et al., 2015). Additionally, the use of gas chromatography/mass spectrometry can provide values related to drug metabolites, which is particularly important to avoid alteration of the testing (Haffajee et al., 2015). It is imperative that clinicians become familiar with the common drug and metabolite pathways to ensure accurate interpretation (See appendix A)(Haffajee et al., 2015). Misunderstandings can occur since the metabolites may be different then the parent drug (Haffajee et al., 2015). Patients that are prescribed hydrocodone may show positive for oxycodone or hydromorphone and clinicians may discontinue the patient's medications without cause (Haffajee et al., 2015).

Current guidelines offered by the CDC recommended that urine screening be completed prior to the initiation of opioid analgesics and at minimal annually (Dowell et al., 2016). In patients that are identified as medium or high risk, testing should be completed every three months or monthly should the clinician feel appropriate (Dowell et al., 2016). Random testing is also essential when performing urine screening. Random testing should be completed in all risk categories, however should occur more frequently on populations falling in the medium and high-risk categories (Dowell et al., 2016).

Opioid Agreements

Opioid agreements play a vital role in the relationship between patient and provider, particularly when opioids analgesics are a part of the treatment plans. The AAMP and CDC guidelines recommend opioid agreements be completed prior to the initiation of opioids for all patients (Dowell et al., 2016; Chou et al., 2009; Payne et al., 2010). These agreements should contain specific information regarding the clinician's expectations of the patient while receiving opioid analgesics (see appendix B) Basic opioid agreements should include the following (Payne et al., 2010):

- Patient and clinician's responsibilities
- Overall treatment and function goals.
- Risk and benefits of opioid analgesics
- Filling and refilling expectations and requirements
- Specific information regarding early refills, emergency appointments and missed appointments.
- Criteria for discharge from practice

The opioid agreement should be read and signed by the patient or representative, clinician and witness (Payne et al., 2010). Once the initial agreement is signed it should be kept in the patient chart for reference (Payne et al., 2010). A copy should be provided to the patient after the signature is obtained (Payne et al., 2010). The agreement and signatures should be updated yearly to ensure the patient is up-to-date with any changes that may occur.

Pill Counting

Pill counting can be an easy and effective means of avoiding diversion, while increasing compliance This process requires the patient to bring their prescribed medications into the office for a physical count, usually by a licensed professional. Clinicians should consider developing a relationship with pharmacies that have experience with opioid analgesics and offer bubble packing of all opioid analgesics. This package method prevents the possibility of patients buying medications identical to those being prescribed or altering the pill bottles prior to counting. Typically, the process would be done at random, but in patients with a classification of medium to high risk it is recommended that they bring their pills to every scheduled visit. For random testing, the clinician must set an expected timeframe for which the patient must show up to prevent an extended period of time passing after initiating the call for random testing. Usually this ranges from 12 to 24 hours. There is specific documentation that should occur when a pill count is conducted. This would include documentation of the time, date, number of pills, person or persons conducting the count and any inconsistencies. This documentation should reflect any action taken as a result of the count. Patient should be made aware that this is a part of their treatment and is a requirement in order to receive ongoing prescriptions.

Prescription Drug Monitoring Programs

The use of prescription drug monitoring programs is gaining traction nationally. It is estimated that 49 states have either a monitoring program in place or legislation supporting the use of these programs (Haffajee et al., 2015). These monitoring programs

are designed to assist the clinician with monitoring the filling and dispensing of opioid analgesics for each patient they are considering for long-term opioid management (Haffajee et al., 2015). The purpose is to identify patients that may be filling multiple prescriptions with multiple providers. Each state differs in regards to the information that is collected and stored in the respective database. Some basic information is collected throughout most states (Haffajee et al., 2015). Here are some examples of collected data

- Patient demographic (Name, date of birth, address, phone number and gender)
- Prescriber Information (Clinician name, address and phone number and DEA number)
- Detailed Medication Information (Dose, frequency, date written and filled)
- Pharmacy Information (Pharmacy name, address and phone number) (Haffajee et al., 2015, p.122):

The AAMP and CDC recommend that clinicians review and document the patients opioid prescribing record prior to the initiation of any opioid treatment (Dowell et al., 2016; Chou et al., 2009; Payne et al., 2010). Additionally, it is recommended that an updated report be reviewed every 3 months during treatment (Dowell et al., 2016; Chou et al., 2009; Payne et al., 2010). In patients that are identified as medium and high risk reports should be reviewed monthly (Dowell et al., 2016; Chou et al., 2009; Payne et al., 2010). Any discrepancy should be documented and include any action that may be taken.

The monitoring of patients being considered for opioid therapy for chronic pain is an imperative part of ensuring compliance (Dowell et al., 2016; Chou et al., 2009; Payne

et al., 2010). Clinicians and providers should identify the most useful means of monitoring for their practice, however it is strongly recommended in the literature that monitoring should include more than one monitoring technique (Dowell et al., 2016; Chou et al., 2009; Payne et al., 2010). Documentation is a crucial part of this process and clinicians should develop policies to ensure all staff is compliment with the monitoring process (Chou et al., 2009).

Opioid Initiation/Escalating and Discontinuation

Initiating opioid analgesics

The initiation of opioid analgesics should only occur once a definitive diagnosis and pathology is established and nonpharmacologic therapy is exhausted (Chou et al., 2009; Dowell et al., 2016). A complete risk assessment should be performed and all benefits should be clearly stated. Therapy goals should be developed and all expected functional improvements should be outlined prior to the initiation of opioids. The use of nonpharmacologic therapies such as epidural injections, nerve root blocks, facet injections physical therapy and chiropractic care should be considered and implemented prior to the consideration of opioid analgesics (Chou et al., 2009; Dowell et al., 2016). Additionally, the use of non-opioid medications including acetaminophen, nonsteroidal inflammatory drugs should be considered if no contraindication exists (Chou et al., 2009; Dowell et al., 2016). The AAPM (appendix C) and CDC (appendix D) developed guidelines that focus on the initiation and titration of opioids (Chou et al., 2009; Dowell et al., 2016). All clinicians considering opioid analgesic for their patients should observe these guidelines.

The initiation of opioid analgesics for chronic non-cancer pain symptoms should be treated as a short-term trial, which can last for as short as a few weeks and last for a few months (Chou et al., 2009; Dowell et al., 2016). Initially the use of short-acting opioids (SA) /immediate release (IR) (see appendix E), which includes formulations such as Hydrocodone, Oxycodone and Oxymorphone, should be used in the opioid-naïve patient (Chou et al., 2009; Dowell et al., 2016). The shorter half-life lessens the risk of overdose during the initial phases. The lowest available dose should be used in all populations (Brown, Swiggart, Dewey, & Ghulyan, 2012). The rapid onset (10-60 mins) and short duration (2-4hrs) is best for acute and short-term pain pathologies (Chou et al., 2009; Dowell et al., 2016). The clinician should reassess the patient's response in 4 weeks or sooner depending on the individual clinician's comfort level with the patient and their current health state (Brown et al., 2012). Examination and documentation should reflect the patient's response, any side effects/adverse reactions, functional improvements and any therapeutic goals that may have been met. No opioids should be started without an adequate exit strategy, should the risk outweigh the benefit at anytime during treatment (Brown et al., 2012). The evidence and guidelines recommend a minimal waiting period of five half lives before any titration occurs to get a reasonable assessment of the previous doses effect. The clinician should use extreme caution when initiating SA/IR opioids in patients $\geq$65 years of age and patients with renal and hepatic dysfunction to avoid the possibility of overdose/death (Chou et al., 2009; Dowell et al., 2016). This opioid preparation is not to be used as a long-term option and should be reserved for pain that is acute in nature, intermitted and expected to resolve within 3

months (Chou et al., 2009; Dowell et al., 2016). Using these medications for extended periods has been known to produce extended tolerance, abuse and higher incidence of addiction (Brown et al., 2012).

In contrast the use of extended release (ER) or long-acting (LA) version of these medications should only be considered in patients that have previous exposure to the IR version and now require around the clock dosing. Patients that continue to suffer pain beyond a 3-month period should be considered for the ER/LA version of opioid treatment (Chou et al., 2009; Dowell et al., 2016). The literature demonstrates a reduced incidence of tolerance, abuse and addiction in this patient population. This ER/LA class of medication includes drug such as OxyContin, Ms Contin, Duragesic and Oxymorphone ER (see appendix F). It is imperative to observe and understand the pharmacological properties of these medications before considering them for patients suffering chronic non-cancer pain symptoms (see appendix F). The onset of LA/ER medications is comparatively longer at 30-120 min and the duration is between 7-72hrs when compared to the IR/SA version (Chou et al., 2009; Dowell et al., 2016). The use of these medications should only be initiated when the pain is clearly defined and considered severe and long term (Chou et al., 2009; Dowell et al., 2016). The chronicity of the pain symptoms must be clearly documented before the initiating these medications. Reevaluation must occur within the first 3 weeks of initial dosing and the patient must be given adequate time on the medications before making a decision to titrate dosing. This may require additional time beyond the initial follow up period and the clinician should not prematurely adjust dosing.

Dose titration and escalation

The process of opioid analgesic titration requires vigilance and careful consideration to avoid adverse patient outcomes. Failure to be vigilant and careful in this process has led to serious and unnecessary sequela for patient receiving these medications (Brown et al., 2012). The literature demonstrates a clear link with dose and titration related overdose (Brown et al., 2012). The CDC identifies an increase risk in populations titrated to ≥90 morphine milligram equivalents (MME) a day (Dowell et al., 2016). Specifically, the risk factors increased by 1.9 to 4.6 percent in doses ≥20 MME day and 2.0-8.9 in patient receiving ≥100 MME a day (Dowell et al., 2016). Therefore, the safest dosing recommendation is ≤50 MME a day and the risk is drastically reduced in this population (Dowell et al., 2016). The current literature also demonstrated that doses ≤50 not only increased the risk of negative patient outcomes, but also did not show clinical benefit (Dowell et al., 2016). Any clinician exceeding the recommended <50 MME should clearly document the need to adjust beyond this clinical recommendation (Dowell et al., 2016). Each clinician should take into account the patients diagnosis and functional improvements as it relates to the risk once the titration exceeds the clinical recommendation. Any patient receiving opioids at or above the clinical recommendation should consider increasing the observation of the patient, increasing the amount of urine drug screening and making the appropriate referrals to pain management (Dowell et al., 2016). The clinician should also consider prescription Naloxone (Narcan) for the patient for any dose exceeding the clinical recommendation. It is imperative for the clinician to be familiar with their current state regulations regarding the care of patients receiving

opioids. In some states once a patient reaches levels beyond the recommended threshold referral must occur or the clinician is in violation of state law and is subject to disciplinary action.

Continuous titration and escalation of opioid analgesic is not recommended and is strongly discouraged in the guidelines offered by both the CDC and AAPM (Chou et al., 2009; Dowell et al., 2016). Patients that do not receive adequate relief >50% from opioid analgesic of ≥50 MME should consider alternative treatments and consideration should be given to performing a drug holiday (Chou et al., 2009; Dowell et al., 2016). This process would include a complete cessation of opioid use and allowing the mu receptors an opportunity to regenerate to pre-opioid status. If the receptors are unresponsive it is unlikely that any additional titration of the opioid would be beneficial and further damage may occur. Additionally, it is important to have a clear understanding of paradoxical hyperalgesia when escalation and titration is failing (Chou et al., 2009; Dowell et al., 2016). This condition occurs when the mu receptors are over used and overestimated by the chronic and continuous use of opioid analgesics. Continuous titration and escalation of doses should alert the clinician to the possibility of this phenomena and appropriate action should be implemented (Chou et al., 2009; Dowell et al., 2016). Typically, this would require a cessation or rotation of all opioid analgesics for a period of 3 months.

Discontinuation of Opioid Therapy

The discontinuation of opioid therapy should occur if aberrant drug behavior is noted, diversion is occurring, side effect/adverse reaction develop and when there is minimal clinical or functional improvements seen (Chou et al., 2009; Dowell et al.,

2016). The initial tapering of opioids should be slow and can be as little as 10% per week, however a more aggressive taper can occur at a rate of 25% to 50% every week (Chou et al., 2009; Dowell et al., 2016). The clinician should account for withdraw symptoms should the taper be aggressive. Pre-planning and patient education is imperative during this process. The patient should be instructed that withdraw may occur and should be made aware of the signs and symptoms. Depending on the patients dosing, referral may be needed to an addiction or opioid rehabilitation specialist (Brown et al., 2012). It is imperative the clinician recognize that a failure to properly taper a patient receiving opioid analgesics can lead to civil and licensure penalties. Abandonment of the patient can be implied if the proper steps are not taken and proper discontinuation occurs (Brown et al., 2012).

Patient Education

Patient education is an imperative process in the prescribing and maintain of opioid analgesics. The process will require the clinician to identify any barriers that may exist prior to the development and structuring of the education. This would include any language, educational and cognitive issues the patient demonstrates. Clinicians will need to individualize the materials to ensure the education is conveyed in an appropriate context. In any case, a few very important points should be addressed with each patient. The following are key components that should be addressed (Brown et al., 2012):

1. Patients should be instructed to review all prescription packaging and contact the provider if label is incorrect.

2. Ensure all prescriptions are not expired and never use medications beyond the expiration date.
3. Instruct the patient that they should never use alcohol or sedatives while on opioid analgesics.
4. Never alter the tablets including crushing, breaking or chewing, especially with ER/LA preparations.
5. Never share or provide medications to others including family or friends.

Safe Disposal and Storage

Patients need to be adequately trained on the proper storage and disposal of opioid analgesics (Brown et al., 2012). Proper storage should be in a locked and secure location with only very few that has access to the secured place. They should be out of the reach of children and pets at all times (Brown et al., 2012). Patient should be instructed that they should never be left in a motor vehicle or unsecure location even for a short period of time (Brown et al., 2012). If disposal is needed each state has specific laws regarding disposal and clinicians should become familiar with their individual states guidelines for disposal (Brown et al., 2012). There is some commonly used method of disposal including returning to the pharmacy, returning to the physician's office and flushing down the toilet (Brown et al., 2012). Additionally, several police and fire departments offer take-back programs which patients can take advantage of locally. Patients can contact their local municipalities for additional information regarding these take-back programs. Safe disposal and storage is an essential part of prescribing opioid and

clinicians need to be aware of all the resources patients have at their disposal (Brown et al., 2012):

Naloxone Prescribing

The use of take home Naloxone, an opioid antagonist, has been gaining a significant amount of national exposure within recent years. The increase in prescription drug overdose related deaths have reached an all-time high (Dowell et al., 2016). From 2000-2014 over 500,000 deaths have occurred and this number continues to grow yearly. Interventions must be considered when opioids are being used as a part of a treatment plan for patient suffering chronic pain (Dowell et al., 2016). Most recently, Evzio (Naloxone) was approved by the Federal Drug Administration for the use in the home by non-licensed caregivers (Dowell et al., 2016). This hand-held auto-injectable device is easy to use and delivers pre-set dosing that can reverse an overdose situation before first responders arrive (Dowell et al., 2016). Patients receiving any opioid exceeding ≥90 MME should be considered a high risk for overdose and consideration must be given for take home Naloxone (Dowell et al., 2016). There are a few other delivery systems including intranasal which are slowly making their way to the market. Federal, state and local community leaders are developing programs designed to assist caregivers and family members with the tools and training needed to prevent overdose and death in the home (Dowell et al., 2016).

Conclusion

The use of opioid analgesic may be necessary in the treatment of chronic non-cancer pain and clinicians need to have a detailed understanding of the current guidelines.

This continuing educational module provides an overview of the current and most recent up-to-date guidelines and recommendations for the assessment, examination, dosing, monitoring and patient education needed to ensure a safe, efficient and effective care. Clinicians need to strike a balance between safe and effective care and the potential harm that opioid pose to the patient and society as a whole. This educational module will assist in the development and implementation safe and effective policies to guide the clinician in any setting.

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Appendix C: ER/LA Opioid Analgesics

ER/LA Opioid Analgesics	
MS Contin (Morphine Sulfate ER tablets)	Duragesic (fentanyl transdermal system)
Opana ER (Oxymorphone HCI ER tablets)	Butrans (buprenorphine transdermal system)
OxyContin (Oxycodone HCI ER tablets)	Zohydro ER (hydromorphone HCI ER capsule)
Exalgo (Hydromorphone HCI ER tablets)	Nucynta ER (tapentadol HCI ER tablets)
Avinza (morphine sulfate ER capsule)	
Hysingla ER (hydrocodone ER tablets)	

MS Contin/Avinza	Morphine Sulfate ER Tablets
Dosing Preparations	15 mg, 30 mg, 60 mg 100 mg 200 mg
Dosing Frequency	Every 8 or Every 12 Hours
Current Guidelines	• Start at lowest dose of 15 mg and titrate to maximum effectiveness without side effect • Not to be used in opioid naïve patients • Titration to occur only after 1-2 week period • <50 MME daily dosing recommended
Pharmacology	Morphine Sulfate binds to opioid

	receptors (mu) producing analgesic. Metabolism occurs in the liver and GI tract with 10-20% bioavailability. Excretion is primary urine (85%) with half life of 2-4hrs

Opana ER	**Oxymorphone HCI ER tablets**
Dosing Preparations	5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg
Dosing Frequency	Every 12 Hours
Current Guidelines	Opioid naïve patients should be started at 5 mg every 12 hrs Avoid usage in patients with impaired hepatic/renal function. (CrCl<50ml/min) Titrate by 5-10 mg with a minimal of 3-7 days between titrations Avoid alcohol: Increases oxymorphone levels leading to fetal overdose
Pharmacology	Oxymorphone (semi-synthetic) is an opioid that exerts its affect in the central nervous system. Binds with mu-receptors and inhibits GABA altering the descending pain pathway. There is direct action at the level of the brain stem, which can lead to respiratory depression. Half-life 7.3-11.3 hrs respectively. Metabolizes though the hepatic system while excretion via urine and feces.

OxyContin	Oxycodone HCI tablets
Dosing Preparations	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg
Dosing Frequency	Every 12 Hours

Current Guidelines		Opioid naïve patients should be started at 10 mg every 12 hrs Avoid usage in patients with impaired hepatic/renal function. (CrCl<50ml/min) Titrate by 5-10 mg with a minimal of 1-2 days between titrations 40 mg, 60mg and 80mg to be reserved for Opioid-tolerant patients.
Pharmacology		OxyContin binds to opioid receptors (mu) producing analgesic. About 60% to 87% of an oral dose of OxyContin reaches the central compartment in comparison to a parenteral dose. This high oral bioavailability is due to low pre-systemic and/or first-pass metabolism. Primarily metabolized in the liver and excreted via urine. Half-life 4.5 hrs.
Exalgo		Hydromorphone HCI ER tablets
Dosing Preparations		8 mg, 12 mg, 16 mg, 32 mg
Dosing Frequency		Once Daily
Current Guidelines		All dosing should to be reserved for Opioid-tolerant patients only Renal impairment (moderate): 50% normal starting dose Renal impairment (severe): 25% normal starting dose Hepatic impairment (all levels) 25% normal starting dose. Titrate by 4 mg with a minimal of 3-4 days between changes.

Pharmacology	Binds to a variety of opioid receptors including mu and k-receptors. Metabolized in the liver and plasma levels gradually increase over 6 to 8 hours, and subsequently concentrations are maintained for approximately 18 to 24 hours post-dose. Excretion occurs in the urine (75%) and feces (1%). Half-life 11hrs, 40 hrs with renal impairment.

Hysingla ER/Zohydro ER	Hydrocodone ER tablets
Dosing Preparations	Hysingla ER: 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, 120 mg. Zohydro ER: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg 50 mg
Dosing Frequency	Hysingla ER :Once Daily Zohydro ER: Every 12 hours
Current Guidelines	• Non-tolerant patients starting dose 20 mg for Hysingla and 10 mg for Zohydro • Titrate 10 mg at single time with minimal of 3 days between titrations. • 50% normal starting dose with hepatic and renal impairment • 80 mg, 100mg, 120 mg reserved for opioid-tolerant patients population only • Monitor for QTc prolongation on EKG (Hysingla)
Pharmacology	Binds to a variety of opioid receptors including mu and k-receptors. Metabolized in the liver active metabolite (hydromorphone). Excreted in the urine with a half-life of 7-9 hrs

Butrans	Buprenorphine Transdermal System

Dosing Preparations	5 mcg/hr., 7.5 mcg/hr., 10mcg/hr., 15 mcg/hr., 20 mcg/hr.
Dosing Frequency	Every 7 days
Current Guidelines	• Initial dosing for non-tolerant patient should be 5 mcg/hr. • Titration should occur by 5 mcg/hr with a minimal 72-hour • Maximum daily dosing: 20 mcg/hr. (risk of QTc prolongation in higher doses) • Avoid exposure to heat or activities that increase body temperature. • Observe for hepatotoxicity (liver function testing should be performed every 3 months)
Pharmacology	Butrans produces agonism at delta receptors, partial agonism at the mu receptors and antagonism at the k-receptors. Primary metabolism occurs in the liver with a half-life of 26hrs.

Duragesic	**Fentanyl Transdermal System**
Dosing Preparations	12 mcg/hr., 25 mcg/hr., 37.5 mcg/hr. 50 mcg/hr., 62.5 mcg/hr., 75 mcg/hr., 87.5 mcg/hr., 100 mcg/hr.
Dosing Frequency	Every 72 hours
Current Guidelines	• Lowest possible starting dose should be considered (12.5 mcg) • Not to be used as a first line therapy and all strengths should be used in patients that have prior exposure high dose opioids • Avoid in hepatic and renal function • Avoid exposure to heat or activities that increase body temperature.
Pharmacology	Binds to primary mu receptors with little affinity to k-receptors. Primarily metabolized in the liver and excreted in urine and feces. 17 hour half-life

Nucynta ER	Tapentadol ER tablets
Dosing Preparations	50 mg, 100 mg, 150 mg, 200 mg 250 mg
Dosing Frequency	Every 12 hours
Current Guidelines	• Opioid naïve patients should be started on 50 mg every 12 hrs • Titrate by 50 mg with a minimal of 3 days between increases • Contraindicated with MAOI therapy • Avoid usage in hepatic and renal impairment (max 100 mg once daily)
Pharmacology	Nucynta ER attaches to mu-opioid receptor and inhibit reuptake of norepinephrine (central opioid agonist). Primarily metabolized in the liver with excretion occurring in the urine. Half-life: 4-5 hrs

Appendix D: IR/SA Opioid Analgesics

IR/SA Opioid Analgesics

Hydrocodone/acetaminophen (Hycet, Lortab, Norco, Vicodin, Xodol)

Hydromorphone (Dilaudid)

Morphine (MS IR)

Oxycodone (Oxy IR, Roxicodone)

Oxycodone/acetaminophen (Endocet, Percocet, Roxicet)

Oxymorphone (Opana IR)

Tapentadol (Nucynta IR)

Hydrocodone/acetaminophen	Hycet, Lortab, Norco, Vicodin, Xodol
Dosing Preparations	2.5 mg/325 mg, 5 mg/325 mg, 5 mg/300 mg 7.5 mg/300 mg, 7.5 mg/325 mg, 10 mg/300 mg, 10 mg/325 mg
Dosing Frequency	Every 4-6 hours as needed
Current Guidelines	• Use in acute pain and initial opioid trial only • >3 months: consider long-acting • Hepatic function testing every 3 months • Limit daily amount due to acetaminophen intake (4000 mg acetaminophen/day) • Observe and monitor for hepatotoxicity • Caution in hepatic function impairment.

Pharmacology	Activates mu-receptors in the central nervous system. Onset is typically 10-20 mins with peak effects in 30-60 mins. Metabolized in the liver extensively. Excreted in the urine with a half-life of 3.8-4.9 hrs.

Hydromorphone	Dilaudid
Dosing Preparations	2 mg, 4 mg, 8 mg
Dosing Frequency	Every 4-6 hrs as needed
Current Guidelines	• Opioid naïve patients should be started on 2-4 mg • Caution in elderly and debilitated patients. (Consider lowest dose).
Pharmacology	Hydromorphone interacts with mu-receptors with a lower affinity for kappa-receptors. Primary effects occur in the central nervous system Derivative of morphine with better absorption. Metabolized in the liver and excreted in the urine Half-life 2.6 hours.

Morphine	Morphine IR
Dosing Preparations	15 mg, 30 mg
Dosing Frequency	Every 6 hours as needed
Current Guidelines	• Opioid naïve patients initial dosing 10-30 mg every 6hrs • Caution in elderly and debilitated patients • Max dosing≥50 daily

Pharmacology	Morphine Sulfate binds to opioid receptors (mu) producing analgesic. Metabolism occurs in the liver and GI tract with 10-20% bioavailability. Excretion is primary urine (85%) with half life of 2-4hrs

Oxycodone	OxyIR, Roxicodone
Dosing Preparations	5 mg, 10 mg, 15 mg, 20 mg, 30 mg
Dosing Frequency	Every 4-6 hrs as needed
Current Guidelines	• Opioid naïve patients initial dosing 5-10 mg every 4-6hrs • Avoid the use of 20 mg and 30 mg tablets in all patient populations (consider ER version) • Usage beyond 3 months need reevaluated for ER version • Caution in patients <30 years of age and >50 years of age.
Pharmacology	Oxycodone primarily affects mu-receptors with a weaker affinity for kappa and delta receptors, working in the central nervous system. Semisynthetic opiate with derivatives of hydrocodone and morphine. Primarily metabolized in the liver and excreted in the urine. Well absorbed with bioavailability of 60-87% Half-life 4.5 hrs

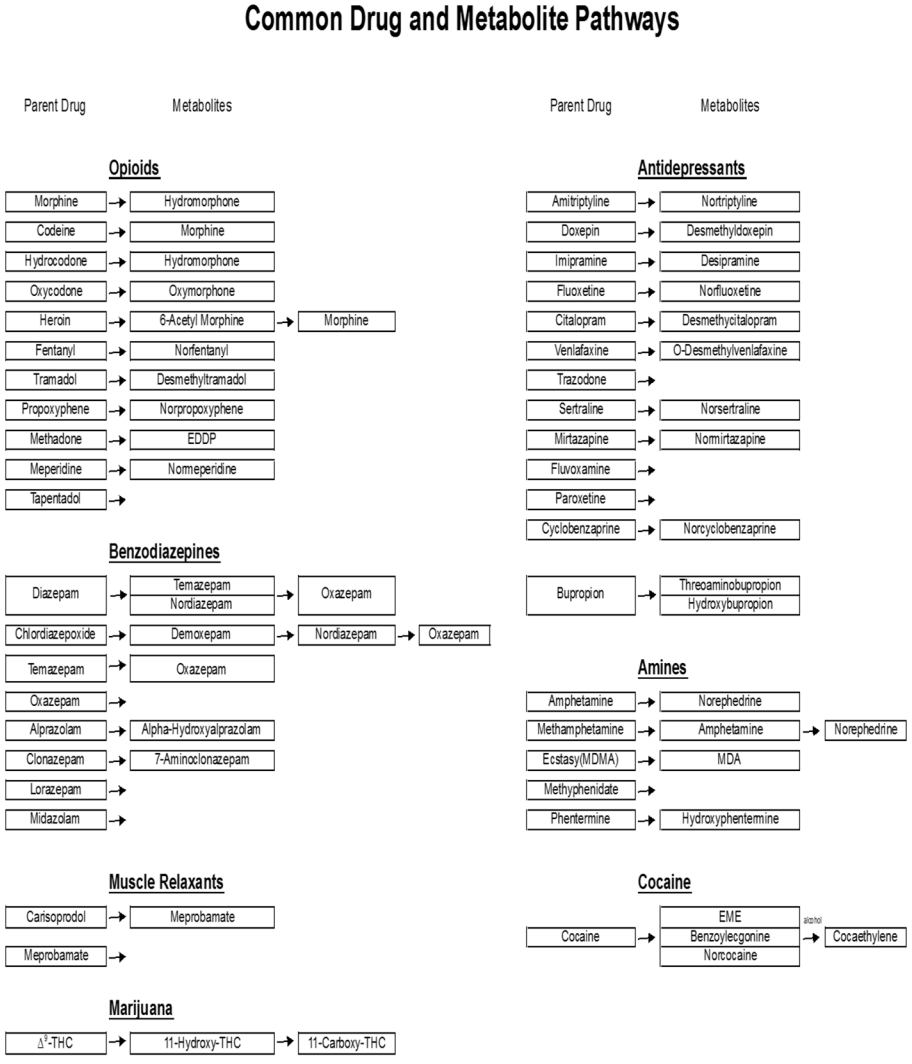
Oxycodone/acetaminophen	Endocet, Percocet, Roxicet
Dosing Preparations	2.5 mg/325 mg, 5 mg/325 mg, 7.5 mg/300 mg, 7.5 mg/325 mg, 10 mg/325 mg
Dosing Frequency	Every 4-6 hrs as needed
Current Guidelines	• Opioid naïve patients initial dosing 5-10 mg every 4-6hrs • Hepatic function testing every 3 months • Limit daily amount due to

	acetaminophen intake (4000 mg acetaminophen/day) • Observe and monitor for hepatotoxicity • Caution in hepatic function impairment
Pharmacology	Oxycodone primarily affects mu-receptors with a weaker affinity for kappa and delta receptors, working in the central nervous system. Semisynthetic opiate with derivatives of hydrocodone and morphine. Primarily metabolized in the liver and excreted in the urine. Half-life 4.5 hrs

Oxymorphone	Opana IR
Dosing Preparations	5 mg, 10 mg
Dosing Frequency	Every 4-6 hrs as needed
Current Guidelines	• Opioid naïve patients initial dosing 5-10 mg every 4-6hrs • Avoid usage in patients with impaired hepatic/renal function. (CrCl<50ml/min) • Titrate by 5-10 mg with a minimal of 3-7 days between titrations • Avoid alcohol: Increases oxymorphone levels leading to fetal overdose
Pharmacology	Oxymorphone (semi-synthetic) is an opioid that exerts its affect in the central nervous system. Binds with mu-receptors and inhibits GABA altering the descending pain pathway. There is direct action at the level of the brain stem, which can lead to respiratory depression. Half-life 4.5 hrs. Metabolizes though the hepatic system while excretion via urine and feces.

Tapentadol	Nucynta
Dosing Preparations	50 mg, 75 mg 100 mg
Dosing Frequency	Every 4-6 hrs as needed
Current Guidelines	• Opioid naïve patients initial dosing 50-75 mg every 4-6hrs • Avoid usage in patients with impaired hepatic/renal function. (CrCl<50ml/min) • Titrate by 5-10 mg with a minimal of 3-7 days between titrations • Max daily dosing: 600 mg total • Avoid alcohol: Increases oxymorphone levels leading to fetal overdose
Pharmacology	Tapentadol attaches to mu-opioid receptor and inhibit reuptake of norepinephrine (central opioid agonist). Primarily metabolized in the liver with excretion occurring in the urine. Half-life: 4-5 hrs

Appendix E: Common Drug and Metabolite Pathways



Appendix F: Opioid Agreement Example

Opioid Agreement

- I understand that the treatment I receive by the (Name of Service) includes opioid and/or sedative medications. I also agree to the following while receiving these medications:
- I understand that the goals of my treatment with medications are to increase my activities at home and/or work a decreased my pain symptoms and behavior within the time specified in my treatment plan.
- I understand that opioid medications are only one part of my therapy and agree to follow all parts of my treatment program (ex. Physical therapy, behavioral pain management, etc) and office appointments.
- I will not obtain any opioid or sedative medications from any source other than the (Name of Service). In the event of an emergency that requires treatment with opioid or sedative medications, I will notify a staff member at (Name of Service) the following business day.
- (Name of Service) requires that all opioid or sedative medications prescribed for me by the Center must be filled by the following pharmacy:
  _____
- If I do not agree to this provision, I have been informed that the Center may not write for opioid or sedative medications and this may constitute termination of my patient status at the Center.
- In the event that I am prescribed opioid or sedative medications by another physician, I understand that I must notify the (Name of Service) within 24 hours.
- I understand that lost or stolen medications and/or prescriptions will not be replaced under any circumstance Any adjustments to my medications will be initiated by the (Name of Service).
- No increase in medication doses should be made without the approval of the prescribing physician.
- I understand that I must provide at least 7 business days for ALL refills. No prescriptions will be refilled early under any circumstance. If you are going out of

town, arrangements will be made for delivery of your medication I will call the pharmacy with any questions about DELIVERY of my medication.

- I will call the pharmacy and notify them myself of any address or phone number changes before my refill.

- No opioid medications will be adjusted over the phone. I will not call the pharmacy or the Pain Center requesting more medication. If needed, I will call the Clinic for a follow up appointment or go to the nearest emergency room.

- I will make/attend follow up appointments at the specified day/time. If I do not show for 3 or more appointments, I may be discharged from the Pain Center.

- I understand that I must provide pills for random pill counts and/or provide urine for random urinalysis upon physician request. This urine screen must be done within 24 hours, unless otherwise specified by the physician or nurse. Failure to provide the urine screen within the specified amount of time may result in discharge from the clinic.

- I understand that if results of my urine screen indicate the use of alcohol, illicit drugs of any kind, or narcotics not prescribed by the (Name of Service), this will result in my immediate discharge from the Center.

- I understand that failure to follow these guidelines may require cessation of opioid and/or sedative therapy, referral to a substance abuse specialist, and possible termination of my patient status at the (Name of Service).

- I understand that other physicians involved in my medical care will be notified of my discharge from the (Name of Service).

- I understand that unruly behavior is not tolerated, and it is grounds for immediate discharge.

- I understand that I am not to remove medications from the bubble pack until the time when it is necessary to take them. I understand that I should count my medication when I receive it from the pharmacy and notify the pharmacy and (Name of Service) if it is not what it should be.

- CAUTION: Opioid medications may cause drowsiness. Alcohol should not be consumed while taking these medications. Use care when operating a car or machinery. Federal law prohibits the transfer of these drugs to any other person other than the patient for whom they were prescribed.

- The terms of this agreement are to ensure patient safety when on opioid therapy.

Patient: _____Date: _____

Clinician: _____Date: _____

Witness: _____Date: _____

Appendix G: AAPM Opioid Initiation and Titration Guidelines

3.1. "Clinicians and patients should regard initial treatment with opioids as a therapeutic trial to determine whether COT is appropriate"

3.2. "Opioid selection, initial dosing, and titration should be individualized according to the patient's health status, previous exposure to opioids, attainment of therapeutic goals and predicted or observed harms"

7.1 "When repeated dose escalations occur patients on COT, clinicians should evaluate potential causes and reassess benefits relative to harms"

7.2. "In patients who require relatively high doses of COT, clinicians should evaluate for unique opioid-related adverse effects, changes in health status, and adherence to the COT treatment plan on an ongoing basis and consider more frequent follow up visits"

7.3. "Clinicians should consider opioid rotation when patients on COT experience intolerable adverse effects or inadequate benefit despite dose increases."

7.4. "Clinicians should taper or wean patients off of COT who engage in repeated aberrant drug-related behaviors or drug abuse/diversion, experience no progress

toward meeting therapeutic goals, or experience intolerable adverse effects."

12.1. "In patients on around-the-clock COT with break-through pain, clinicians may consider as needed opioids based upon an initial ongoing analysis of therapeutic benefit versus risk.

Appendix H: CDC Opioid Initiation and Titration Guidelines

#4. "When starting opioids therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long acting"

5. "When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dose, should carefully reassess evidence of individual benefits and risk when considering increasing dosage to ≥50 milligram equivalents (MME)/day or carefully justify a decision to titrate dosage to≥90 MME/day.

#7 "Clinicians should evaluate benefits and harms with patient within 1 to 4 week of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioid to lower dosages or to taper and discontinue opioids

Appendix I: Continuing Education Activity Evaluation Form

An Evidenced-Based Pain Management Module to Improve the Knowledge of Clinicians

Activity Title: Comprehensive Pain Management Education
Date:

As an expert in the field of pain management, Please review the educational material and answer the following questions to the best of your ability. The comment section is to only be used should an answer to the question fall below# 3.

	Disagree			Agree
Content				
1. The content is clear and concise	1	2	3	4
2. The content is capable of expanding the knowledge of clinicians....	1	2	3	4
3. The content is consistent with the current practice standards and treatment guidelines	1	2	3	4
4. The content is appropriate for clinicians in general and specialist practice……	1	2	3	4
5. As an expert in pain management, I would recommend this education to my colleagues……	1	2	3	4
6. The content demonstrates the impotence of utilizing long-acting analgesic in the chronic pain setting…….....	1	2	3	4
7. The content clearly outlines the medical and legal implications to practice and community when opioids are used……	1	2	3	4 5
Instructional Methods				
1. The instructional material was well organized.....	1	2	3	4
2. The instructional methods illustrated the concepts well.....	1	2	3	4
3. The teaching strategies were appropriate for the activity.....	1	2	3	4 5

Comments:

Appendix J: Recruitment Letter

Mark A. Wells, NP-C
164 Stratford Court
New Stanton, PA 15672

To Whom It May Concern:

My name is Mark Wells and I am currently a doctoral student at Walden University. I am in the process of completing the university requirements, which includes a final DNP project. This project focuses on the development of an educational module that looks to improve the knowledge of health care clinicians utilizing an evidenced-based model. The title of the project is "An Evidenced-Based Pain Management Module to Improve the Knowledge of Clinicians". You have been identified as an expert in the field of pain management and I am writing to see if you would be willing to take part in evaluating this projects content. The process will require that you review the educational module and return a pre-paid stamped envelop containing the "expert-rating tool". This rating tool will be used to provide descriptive statistics in the body of the project. No further data collection will be needed once this rating tool is completed and returned. I would be happy to discuss the project further should you have any questions or concerns. I can be reached at mark.wells@waldenu.edu or via phone at 724-454-8800. I appreciate your time and consideration in this matter. I look forward to your response.

Sincerely,

Mark A. Wells