EVALUATION OF ACUTE CARE PROVIDERS' OPIOID PRESCRIBING PRACTICES IN CHRONIC NON-CANCER PAIN

by

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ABSTRACT

KIMBERLY BETH PAYNE BUCKNER. Evaluation of Acute Care Providers' Opioid Prescribing Practices in Chronic Non-Cancer Pain. (Under the direction of DR. ALLISON BURFIELD).

Over 760,000 people have died from an opioid overdose since 1999. In 2019, the opioid epidemic claimed more than 70,000 lives, with over 1.6 million having an opioid use disorder. Literature suggests an association between increased opioid prescribing and increased opioid addiction; limiting the number of opioid prescriptions written may reduce opioid addiction. There is variation in opioid prescribing practices among acute care providers and opioid prescribing education has been proven to optimize prescribing in the acute care setting. This quality improvement project sought to minimize the use of opioids for chronic non-cancer pain by adhering to the Centers for Disease Control Guideline for Prescribing Opioids for Chronic Pain.

Twenty-five acute-care providers including medical doctors, nurse practitioners, and physician assistants participated. This project included a pre-test to measure providers baseline pain management knowledge, an educational module, and a post-test. Retrospective chart audits were performed on records of patients discharged from the acute care setting from July to August 2020 with an opioid for chronic non-cancer pain prior to implementation of educational intervention and again January to February 2021 post-implementation.

Comparison of the pre-and-post-test surveys revealed learning in several areas. Though not statistically significant, (Pre: 40.4; Post: 41.3, p=.276), efficacy of the educational session was evident by improved test scores, pre-test (M = 40.4, SD = 3.5) and post-test (M = 41.3, SD = 4.7). The average number of opioid prescriptions by provider decreased significantly in the post-intervention period (Pre: 3.4; Post: .24, p<.000). Results suggest that implementing opioid-

prescribing guidelines can reduce sub-optimal opioid prescribing in the acute care setting, thereby reducing the number of available opioids in the community for diversion and abuse.

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LIST OF ABBREVIATIONS

AHRQ Agency for Healthcare Research & Quality

APPs Advanced Practice Providers

CDC Centers for Disease Control and Prevention

CHG Carolinas Hospitalist Group

CITI Collaborative Institutional Training Initiative

CINAHL Cumulative Index of Nursing and Allied Health Literature

DAWN Drug Abuse Warning Network

EBP Evidence Based Practice

ED Emergency Department

FSMB Federation of State Medical Boards

IDUs Injection Drug Users

IOM Institute of Medicine

IRB Internal Revenue Board

JCAHO Joint Commission on Accreditation of Healthcare Organizations

MDs Medical Doctors

NIDA National Institute on Drug Abuse

NPs Nurse Practitioners

OUD Opioid Use Disorder

PAs Physician Assistants

QI Quality Improvement

SWOT Strength, Weaknesses, Opportunities, and Threats

UNCC University of North Carolina at Charlotte

Chapter 1: Introduction

Opioid use and abuse, and its adverse consequences, including death, has escalated at an alarming rate since the 1990s (Manchikanti et al., 2017). In an attempt to control opioid abuse, numerous regulations and guidelines for responsible opioid prescribing have been developed by various organizations (Manchikanti et al., 2017). However, the United States' opioid epidemic is continuing, and drug dose deaths tripled between 1999 and 2016 (Manchikanti et al., 2017). In 2016, there were over 63,600 drug overdose deaths, and of these, opioids played a role in 42,249 (Ratycz et al., 2018). Despite representing only 5% of the global population, Americans consume 80% of the world's oxycodone and 90% of the world's hydrocodone (Grounder, 2013). This trend peaked in 2012 when approximately 259 million prescriptions were written for opioids, more than enough to provide one bottle for every adult in America (American Society of Addiction Medicine, 2016).

In North Carolina, where this project was implemented, the numbers are devastating. More Powerful NC (2019), a campaign dedicated to raising awareness about the opioid epidemic, reported that five people die from opioid overdoses every day in North Carolina. In addition, their figures showed that between 1999 and 2017 more than 13,169 North Carolina residents lost their lives to unintentional opioid overdoses, and there was a 32% increase in opioid overdose deaths in 2017 compared to the previous year, with more than 2,000 deaths. Because of the appreciable mortality risk with opioids, there has been a call for increased clinical guidance, training, and mandates for practitioners prescribing opioids for pain (Barth et al., 2016).

The opioid crisis has not only taken a profound human toll, but has also had an enormous economic impact. The estimated total economic burden of the opioid crisis in the United States

from 2015 through 2018 was at least \$631 billion. In 2018 alone, the total cost came to \$179 billion (Davenport et al., 2019). Those costs are borne by all Americans, both by governments providing taxpayer-funded services (estimated to be about a third of the cost) and by individuals, families, employers, private insurers and more (Simmons-Duffin, 2019). The annual cost from the opioid crisis is estimated to exceed 2% of the nation's Gross Domestic Product. Estimates at the individual state level experience a cost approaching 15% of Gross State Product. The economic effects, as measured through the loss in productivity, dominate the costs in addition to previously measured explicit expenses for healthcare, including substance abuse treatment, and additional expenses for policing, courts, jails, and prisons (Ropero-Miller & Speaker, 2019).

Background

Opioid prescriptions for chronic non-cancer pain skyrocketed in the late 1990s with the shift toward more compassionate treatment for all patients suffering chronic pain (Manchikanti et al., 2014). Deaths involving opioids began to rise following a sharp increase in the prescribing of opioid and opioid-combination medications for the treatment of pain. The increase in opioid prescriptions was influenced by reassurances given to prescribers by pharmaceutical companies and medical societies claiming that the risk of addiction to prescription opioids was very low (Liu et al., 2020). With data from 1990 to 1996, Joranson et al. (2000) concluded that the trend of increasing medical use of opioid analgesics to treat pain did not appear to contribute to increases in health consequences of opioid analgesic abuse. During this time, pharmaceutical companies also began to promote the use of opioids in patients with non-cancer related pain even though there was a lack of data regarding the risks and benefits in these patients. By 1999, 86% of patients using opioids were using them for non-cancer pain. Communities where opioids were

readily available and prescribed liberally were the first places to experience increased opioid abuse and diversion (Liu et al., 2020).

The lifting of the restrictions on opioid prescribing by state medical boards was the primary driver of the opioid epidemic (Federation of State Medical Boards [FSMB], 1998). Ironically, these guidelines seem to have had the effect of absolving prescribers from responsibility for their actions and promoted more prescriptions under the guise of appropriate medical treatment (Manchikanti et al., 2014). Further, these guidelines state, "no disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed" (FSMB, 1998). Unfortunately, the revised version of guidance from FSMB (2013) continued to provide inappropriate information about the cost of chronic pain, undertreatment, and other issues based on inadequate or biased evidence synthesis.

Other factors leading to runaway opioid prescriptions were the standards for both inpatient and outpatient pain management, implemented in 2000 by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) with pain as the fifth vital sign and the concept of a patient's right to pain relief resulting in the validation of a physician's need to increase their opioid prescribing (Phillips, 2000). The legislation of the right to pain relief was enacted without the understanding of the consequences of inappropriate opioid use in chronic non-cancer pain, overuse, and inappropriate use. During the same period, many physicians and many organizations also called for increasing opioid treatment for patients with chronic non-cancer pain (Manchikanti et al., 2014). The pharmaceutical industry took advantage of physicians and unleashed their marketing machine, promoting all types of opioids for all types of pain, ignoring safety and inappropriate use (Manchikanti et al., 2014). However, the majority of the positions taken by organizations and physicians, though well-meaning on occasion, were

based on misinformation and unsound science for the justification of increased opioid prescribing, with an omen that opioid prescribing was safe and effective so long as the opioids were prescribed by a physician. As of today, there is no strong scientific evidence that opioids are effective for chronic non-cancer pain (Manchakanti et al., 2014).

In a review of literature conducted by Meyer et al. (2014), eight studies examined resource utilization and found that when compared to non-abusers, opioid abusers were generally more likely to utilize medical services, such as the emergency department (ED), physician or mental health outpatient visits, and inpatient hospital stays. Compared to non-abusers, opioid abusers were also found to be four times as likely to visit the ED, eleven times as likely to have had a mental health outpatient visit, and twelve times as likely to have had an inpatient hospital stay (Meyer et al., 2014). Opioid abuse or dependence is strongly related to ED utilization. The Drug Abuse Warning Network (DAWN) estimated that the number of ED visits involving non-medical use of opioids increased 111% from 2004 (144,644 visits) to 2008 (305,885 visits) (Meyer et al., 2014). In North Carolina in 2017 alone, there were nearly 125 unintentional opioid-related overdose ED visits per week on average (More Powerful NC, 2019).

Given the current opioid epidemic, it is vital to use consistent evidence-based practice (EBP) when treating chronic non-cancer pain. Acute care settings are a major source of opioid prescriptions, often for minor conditions and chronic non-cancer pain (Del Portal et al., 2016). Opioids are commonly used for the treatment of acute pain in hospitalized patients, often at high potency with long half-lives. Recent reports highlight that hospital use of opioids impacts downstream use (Herzig et al., 2018). Among opioid-naïve patients admitted to the hospital, 15-25% fill an opioid prescription in the week after hospital discharge, 43% of such patients fill another opioid prescription 90 days post-discharge, and 15% meet the criteria for long-term use

at one year (Herzig et al., 2018). With about 37 million discharges from U.S. hospitals each year, these estimates suggest that hospitalization contributes to the initiation of long-term opioid use in millions of adults each year (Herzig et al., 2018). In a retrospective cohort study by Herzig et al. (2014), there was considerable hospital opioid variation in opioid use, severe opioid-related adverse events occurred more frequently with higher opioid prescribing rates, and the relative risk of a severe adverse event per patient prescribed opioids was also higher in the hospital.

Opioid prescribing practices vary between providers and hospitals, highlighting the need for prescribing standards and guidance. There are no existing guidelines for improving the safety of opioid use in hospitalized patients outside of intensive care or immediate peri-operative settings (Herzig et al., 2018). Manchikanti et al. (2012) found a common theme that this crisis is rooted in misinformation and a lack of education, leading to overprescribing. The majority of cases involving injury and death occur in those using opioids as prescribed, not just those misusing or abusing them. Despite adequate relief and improvement in function with modalities other than opioids, patients continue on opioids (Manchikanti et al., 2012).

Clinical Question

The PICO question is, "Do acute care providers who participate in opioid prescribing education, compared to providers without additional education, demonstrate a difference in opioid prescribing practices among patients who have chronic non-cancer pain?"

Problem Statement

Providers continue to inconsistently prescribe opioids for chronic non-cancer pain despite the high risk of addiction, opioid-use disorder, or opioid overdose deaths. The prescriber's role in generating and sustaining opioid abuse has been made clear by studies that link a practitioner's prescribing patterns to a patient's likelihood of long-term opioid dependence (Meisenberg et al.,

2018). Calcaterra et al. (2015) found that 25% of opioid-naïve patients who received an opioid at hospital discharge were more likely to become chronic opioid users and had an increased number of opioid refills one-year post-discharge, compared to patients without an opioid receipt. This link between prescribing patterns and opioid dependency formed the rationale for a targeted initiative to reduce opioid prescribing (Meisenberg et al., 2018).

The opioid epidemic has been responsible for hundreds of thousands of lives lost over the past two decades, and millions more individuals and their families have been negatively affected by the misuse or abuse of prescription opioids. Although the origins of increased opioid use were well-intended attempts at optimal pain management, the result has become a costly increase in opioid use disorders (OUDs) and death, with little evidence of improvement in chronic non-cancer pain (Hagemeier, 2018). In summary, pain contributes to substantial morbidity, mortality, and disability for millions of Americans. When inadequately or inappropriately treated or managed, the consequences extend beyond the individuals experiencing pain, impacting families, healthcare systems, work performance, and society (Institute of Medicine [IOM], 2011).

Purpose

In an attempt to follow the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain, the purpose of this scholarly quality improvement (QI) project was to evaluate acute care providers' opioid prescribing practices in chronic non-cancer pain. Acute care providers consist of medical doctors and advanced practice providers in the hospitalist population. Hospital-based physicians, described as hospitalists, are physicians who work exclusively in the hospital and care for the majority of hospitalized patients (Calcaterra et al., 2017).

The challenge of effective pain management, coupled with exponentially rising opioid-related deaths, is further compounded by inadequate provider education regarding opioid prescribing (IOM, 2011). A multifaceted federal effort aims to address this crisis through significant increases in funding to multiple opioid-related programs and opioid-prescribing educational initiatives, specifically the Centers for Disease Control (CDC) guidelines for opioid prescribing for non-cancer, non-palliative chronic pain (Dowell et al., 2016).

The CDC (2018a) urges clinicians to prevent opioid overdoses by following best prescribing practices. Calcaterra et al. (2015) states, "these guidelines are not easily integrated into current hospital practice due to a focus on pain control and the acute problem, rather than high-risk patient characteristics for opioid abuse or chronic use" (p. 483). The guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death (Dowell et al., 2016). Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the risk of an opioid use disorder, overdose, and death (CDC, 2018b).

Objectives

This project had several related objectives. The first was to evaluate acute care providers' baseline prescribing practices of opioids in acutely ill patients admitted to the hospital who suffer from chronic non-cancer pain. Baseline prescribing practices of opioids for chronic non-cancer pain among acute care providers was evaluated by administration of a pre-test to assess baseline prescribing knowledge.

The second objective was to develop and implement an educational and quality improvement course to improve opioid prescribing practices in line with current EBP opioid prescribing guidelines (specifically, those set forth by the CDC). Education in line with the CDC's opioid prescribing guidelines was provided electronically via voice over PowerPoint format to each provider.

Finally, the third objective was to evaluate the change in knowledge and practices before and after completing the education, and to identify barriers to adhering to the CDC guidelines. A post-test was provided to re-evaluate acute care providers' opioid prescribing practices after completion of the educational session.

The immediate objective of this project was to identify acute care providers who inappropriately prescribe opioids as a result of inadequate training and education, to provide education, and finally, to determine if the education was effective as evidenced by appropriate opioid prescribing in conjunction with the CDCs guidelines. The long-term objective is to reduce the current opioid burden of addiction and overdose, as well as the economic impact, with adherence to CDC opioid prescribing guidelines.

Chapter 2: Literature Review

An integrative literature review was conducted using Cochrane, Cumulative Index of Nursing and Allied Health Literature (CINAHL), and Medline (via ProQuest) databases.

Keywords included opioid prescribing hospital, opioid abuse, opioid epidemic, opioid prescribing practices, opioid prescribing in chronic non-cancer pain, opioid prescribing guidelines, opioid education, and opioid prescribing practices hospitalist. Results were filtered to include the years 2014-2019, peer-reviewed articles, full-text publications, and only articles in English.

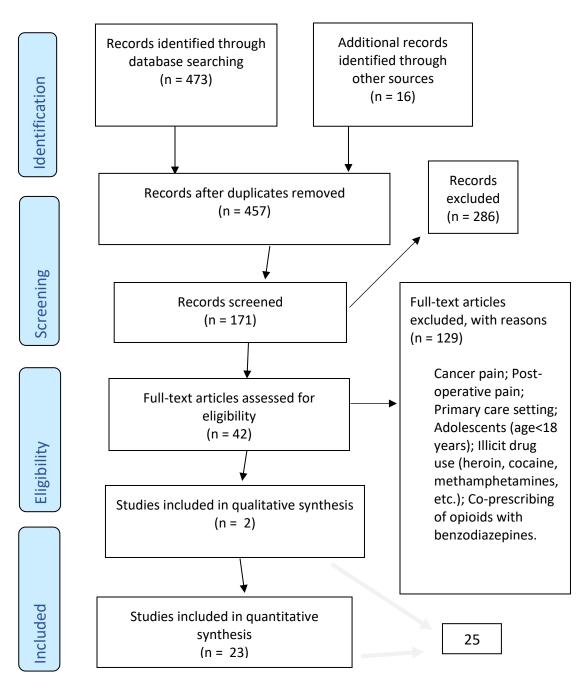
Figure 1 summarizes the literature included and excluded in this QI project. The search yielded 473 articles; 25 met the inclusion and exclusion criteria for the topic. Articles were excluded if they were focused on illicit drug use (i.e. heroin, cocaine, methamphetamines, etc.), included post-operative pain, sickle cell pain, cancer pain, current opioid addiction, or coprescription with benzodiazepines. Articles were included if they described the clinical and/or economic burden of prescription opioid abuse. The clinical burden consisted of opioid addiction, opioid overdose, and quality of life. The economic burden consisted of health care utilization costs, treatment costs, and other financial consequences. In addition to the above search, a review of the reference lists of articles was conducted to identify additional publications relevant to this topic, providing two additional articles.

Of the studies included (Table 1), thirteen discussed opioid prescribing practices in the hospital, five discussed both opioid prescribing practices and opioid prescribing guidelines, three discussed the clinical burden of prescription opioid abuse, one discussed a pain management survey, and two discussed organizational change as related to Lewin's Theory of Planned Change. One study did discuss benzodiazepine prescribing, though this was not in conjunction

with opioid prescribing, thus making it appropriate for this project in opioid prescribing practices.

Figure 1

Prisma Flow Diagram



(Moher et al., 2009)

Table 1

Literature Review Table

Year	Author	Title	Journal	Purpose	Research Design	Level of Evidence	Result
2018	Herzig et al.	Safe opioid prescribing for acute noncancer pain in hospitalized adults: A systematic review of existing guidelines.	Journal of Hospital Medicine	Evaluate quality/ content of existing guidelines for acute, non- cancer pain management.	Systematic Review	ı	Guidelines, based largely on expert opinion, recommend judicious prescribing of opioids for severe, acute pain. There are no guidelines identified that focus on acute pain management in the general hospital population.
2019	Hopkins et al.	Prescriber education interventions to optimize opioid prescribing education in acute care: A systematic review.	Pain Physician Journal	Identify impact of educational interventions on opioid prescribing in the acute care setting.	Systematic Review	I	All 9 significantly reduced at least one of the following: highrisk agent use, total or daily dosage of opioids at discharge, no increase in pain complaints or prescription refill requests. The longest study looked at prescribing 15 months after education reporting sustained practice changes.
2017	Manchikanti et al.	Responsible, safe, and effective prescription of opioids for chronic non-cancer pain: American society of interventional pain physicians (ASIPP) guidelines.	Pain Physician Journal	Guidance for opioids in management of chronic non-cancer pain, develop consistency in prescribing opioids, improve treatment/red uce likelihood of drug abuse/diversi on.	Systematic Review	I	Chronic opioid therapy should only be provided with proven medical necessity and stability with improvement in pain and function.
2012	Manchikanti et al.	Opioid epidemic in the United States	Pain Physician	Describe various aspects of the opioid use in the United States.	Systematic Review	I	Over the past 20 years there has been escalation in therapeutic use of opioids and other psychotherapeutic s as well as their

Year	Author	Title	Journal	Purpose	Research Design	Level of Evidence	Result
							abuse and nonmedical use.
2014	Meyer et al.	Prescription opioid abuse: A literature review of the clinical and economic burden in the United States.	Population Health Management	Synthesize current findings and understanding of the clinical and economic burden of prescription opioid abuse.	Systematic Review	ı	Future quality improvements to prevent and minimize abuse, misuse to include educational programs for both health care providers and the community.
2006	Midmer et al.	Effects of a distance learning program on physicians' opioid and benzodiazepin e-prescribing skills.	The Journal of Continuing Education in the Health Professions	Determine effectiveness of e-mail case discussions in improving physicians' attitudes/ clinical performance in prescribing opioids and benzodiazepin es	Randomized Control Trial	II	E-mail case discussions facilitated by addictions expert are effective in improving physicians' performance in prescribing opioids.
2019	Roy et al.	Utilizing a faculty development program to promote safer opioid prescribing for chronic pain in internal medicine resident practices.	Pain Medicine	Implement skills-based faculty development program to improve Internal Medicine faculty's clinical skills about safe opioid prescribing.	Quasi- experimental Study	III	A didactic session followed by examination can improve faculty Internal Medicine safe opioid prescribing knowledge, attitudes, and clinical and teaching confidence.
2015	Calcaterra et al.	Opioid prescribing at hospital discharge contributes to chronic opioid use.	Journal of General Internal Medicine	Characterize opioid prescribing at hospital discharge in "opioid naïve" patients/quan tify risk of chronic opioid use and opioid refills 1-year postdischarge.	Retrospective Cohort Study	111	Opioid receipt at hospital discharge among opioid naïve patients increased future chronic opioid use.
2014	Herzig et al.	Opioid utilization and opioid-related adverse events in non- surgical patients in U.S. hospitals.	Journal of Hospital Medicine	Investigate patterns and predictors of opioid utilization in non-surgical admissions to U.S. hospitals, variation in	Retrospective cohort study	III	Majority of hospitalized non- surgical patients exposed to opioids, often at high doses. Hospitals that used opioids most frequently had

Year	Author	Title	Journal	Purpose	Research	Level of Evidence	Result
				use, and the association between hospital-level use and rates of severe opioid-related adverse events.	Design	Evidence	increased risk of severe opioid- related adverse events per patient exposed.
2018	Meisenberg et al.	Assessment of opioid prescribing practices before and after implementati on of a health system initiative to reduce opioid overprescribin g.	JAMA Network Open	Measure the effects of multilevel interventions on opioid prescribing within a healthcare system.	Quasi- experimental Study	III	Opioid overprescribing was reduced with multifactorial interventions creating prescriber awareness and accountability.
2015	Gordon et al.	Development of the KnowPain-12 pain management knowledge survey.	Clinical Journal of Pain	Develop a brief survey about chronic non-cancer pain to be used as a reliable and valid measure of providers' pain management knowledge.	Cross- sectional Study	IV	Total scores across all 12 items significantly higher among pain specialists compared to non- pain specialists.
2016	Alford et al.	scope of pain: An evaluation of an opioid risk evaluation and mitigation strategy continuing education program.	Pain Medicine	Describe the Safe and Competent Opioid Prescribing Education program and its impact on clinician knowledge, confidence, attitudes, and self-reported clinical practice.	Cohort Study	IV	Significant increase in correct responses to knowledge questions immediately; continued to have significant increase at 2 months post-program with 86% reported implementing practice changes. There was also improvement in alignment of desired attitudes toward safe opioid prescribing.
2016	Del Portal et al.	Impact of opioid prescribing guideline in the acute care setting.	The Journal of Emergency Medicine	Evaluate a voluntary opioid prescribing guideline to see if there is a decrease in	Retrospective observational study	IV	Decrease in number of opioid prescriptions prescribed 0-6 months after: 1229

Year	Author	Title	Journal	Purpose	Research Design	Level of Evidence	Result
				the number of patients prescribed opioids for pain.			6-12 months prior: 2392
2014	Cobaugh et al.	The opioid abuse and misuse epidemic: Implications for pharmacists in hospitals and health systems.	American Journal Health-System Pharmacists	Describe the current epidemic of opioid abuse and misuse and the pharmacist's role in ensuring safe and effective opioid use.	Literature Review	IV	Pharmacists in hospital and health systems can play a role in recognizing opioid toxicity and in preventing inappropriate prescribing and diversion of opioids.
2016	Barth et al.	Targeting practitioners: A review of guidelines, training, and policy in pain management.	Drug and Alcohol Dependence	Literature on physician guidelines & training, and government payer policies that have merged in response to rise in opioid overdoses.	Literature Review	V	Need for more research on safe and effective treatments for chronic pain as well as an increased focus on improving training and access to evidence-based treatment for opioid use disorder.
2017	Kim et al.	Addressing the prescription opioid crisis: Potential for hospital- based interventions?	Drug and Alcohol Review	To highlight potential hospital-based interventions to address opioid crisis.	Literature Review	v	Hospitals have been overlooked as a prime location for impactful interventions in addressing opioid crisis.
2018	Ratycz et al.	Addressing the growing opioid and heroin abuse epidemic: A call for medical school curricula.	Medical Education Online	Propose ways to incorporate opioid education into medical school curricula to better prepare future doctors to prevent and recognize opioid addiction.	Literature Review	V	Incorporating opioid addiction topics into medical school curriculum better prepares future physicians to be capable of preventing and recognizing addiction.
2019	Wyse et al.	Setting expectations, following orders, safety, and standardizatio n: Clinicians' strategies to guide difficult conversations	Journal General Internal Medicine	Identify and describe clinicians' strategies for managing prescription opioid misuse and aberrant behaviors.	Qualitative Study	V	Primary theme: clinicians' struggles to navigate and successfully manage conversations regarding opioids. Challenges: pts object to change

Year	Author	Title	Journal	Purpose	Research	Level of Evidence	Result
		about opioid prescribing.			Design	Evidence	in prescribing & clinicians' ambivalence in altering their practice to conform to new
2017	Calcaterra et al.	A qualitative study of hospitalists' perceptions of patient satisfaction metrics on pain management.	Hospital Topics	Evaluate hospitalists' perceptions on satisfaction metrics for pain control in hospitalized patients and understand if the metrics impact clinical practice.	Qualitative Study	V	guidelines. Themes identified: Institutional pressures to obtain high satisfaction scores; increased time spent at bedside usually resulted in improved patient satisfaction, but time was limited in busy hospital practice; patient satisfaction metrics incorrectly interpreted as quality healthcare delivery.
2013	Shirey, M. R.	Lewin's theory of planned change as a strategic resource.	Journal of Nursing Administratio n	Explores change management strategies that may be successful in planning and executing organizational change initiatives.	Expert opinion	V	Lewin's framework is best used with change that is planned where initiative starts at the top and where there is stability and time to produce change.
2014	Batras et al.	Organizational change theory: Implications for health promotion practice	Health Promotion International	Reviews organizational change models to identify the most pertinent insights for practitioners.	Expert Opinion	V	Theory-informed research is needed to identify targets of change, and effective strategies and implementation processes needed to address these.
2012	Zgierska et al.	Patient satisfaction, prescription drug abuse, and potential unintended consequences	The Journal of American Medical Association	Discusses patient satisfaction as a driving force behind changes in healthcare delivery.	Expert Opinion	V	Patient dissatisfaction may not always reflect lower- quality medical care. Unintended consequences may result from inappropriate use of patient satisfaction scores, and it is importance to ensure incentives for clinicians are consistent with

Year	Author	Title	Journal	Purpose	Research Design	Level of Evidence	Result
							good medical practice.
2018	Hagemeier, N. E.	Introduction to the opioid epidemic: The economic burden on the healthcare system and impact on quality of life	The American Journal of Managed Care	Discusses burden of pain and impact of opioid abuse on individuals, families, and society; attempts to remedy this burden through prescription opioid use; overview of opioid analgesics and opioid use disorder and the rise in opioid-related deaths.	Expert Opinion	V	Opioid epidemic responsible for hundreds of thousands of lives lost over past 2 decades, and millions of individuals and their families have been negatively affected by the misuse or abuse of prescription opioids; Origins of increased opioid use intended to achieve optimal pain management resulting in increase in OUDs and death, with little evidence of improvement in chronic noncancer pain.
2004	Kalso et al.	Opioids in chronic non- cancer pain: Systematic review of efficacy and safety	Pain	Evaluate effectiveness and safety of opioids long- term use in chronic non- cancer pain.	Literature Review	V	Opioids reduce pain in patients with chronic noncancer pain by average 30%; long-term use of opioids in patients with chronic noncancer pain is not associated with improvements in health-related quality of life assessment scores.

Year	Author	Title	Journal	Purpose	Research	Level of	Result
					Design	Evidence	
2018	Krebs et al.	Effect of opioid versus nonopioid medications on painrelated function in patients with chronic back pain or hip or knee osteoarthritis pain.	The Journal of the American Medical Association	Evaluate and compare pain-related function among opioid and non-opioid users.	Randomized Clinical Trial	II	Opioid users experienced more adverse events but did not differ from nonopioid users in pain- related function. Furthermore, pain intensity was significantly better for nonopioid users.

(Melnyk & Fineout-Overholt, 2019)

Opioid Use

Opioid analgesics are commonly used to treat acute and chronic pain in acute settings; however, they are associated with dependence and addiction, and were implicated in 47,600 American fatalities in 2017. Poisoning deaths in the United States nearly doubled from 1999 to 2006, from 20,000 to 37,000 (Cobaugh et al., 2014). This was largely due to deaths from prescription opioid analgesics, with methadone, oxycodone, and hydrocodone more frequently implicated. This increase in deaths coincided with a nearly fourfold increase in the use of prescription opioids nationally (Cobaugh et al., 2014). In 2016 alone, more than 60 million patients had at least one prescription for opioid analgesics filled or refilled (Hagemeier, 2018).

Despite the ubiquitous use of these agents, the effectiveness of long-term use of opioids for chronic non-cancer pain management is questionable, yet links among long-term use, addiction, and overdose deaths are well established (Hagemeier, 2018). Although evidence indicates prescription opioids do reduce pain intensity in patients with chronic noncancer pain by 30% on average, evidence also indicates that the long-term use of opioids in patients with chronic noncancer pain is not associated with improvements in health-related quality of life

assessment scores (Kalso et al., 2004). A recent study by Krebs et al. (2018) evaluated painrelated function among 234 opioid and nonopioid users. After 12 months, opioid users experienced more adverse events but did not differ from nonopioid users in pain-related function. Furthermore, pain intensity was significantly better for nonopioid users (Krebs et al., 2018).

Provider Inconsistencies

Guidelines are intended to improve safe opioid prescribing for chronic pain but incorporating them into patient care can be challenging. Studies have demonstrated that providers inconsistently adhere to guideline recommendations (Roy et al., 2019). Clinician education is a necessary strategy for improving adherence to safe opioid prescribing guidelines and addressing the crisis of overprescribing opioid analgesics (Roy et al., 2019). Pain management education remains inadequate and is a key strategy to address the prescription opioid misuse problem (Alford et al., 2015). Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the risk of opioid use disorder, overdose, and death (CDC, 2018a). In a systematic literature review, Hopkins et al. (2019) found the available evidence demonstrates that delivering face-to-face education to clinicians significantly and positively impacts the opioid prescribing in hospital and on discharge, reducing opioid dosages and quantities, and influencing prescribers to avoid agents, routes, and doses associated with increased risk.

Opioids in the Acute Care Setting

Hospitals have been identified as an environment that significantly contributes to the challenges faced by prescription opioid misuse. This largely stems from the fact that initial opioid use often occurs in hospital settings, and patients with OUD often frequent hospitals to access medical care (Kim et al., 2017). Past research has documented inappropriate opioid

prescribing practices in hospitals and their potential effects after discharge, including the development of an OUD and overdose. More specifically, one study demonstrated that hospitals' prescribing of opioids among opioid-naïve patients was associated with almost a five times increased risk of chronic opioid use one-year post-discharge, compared with patients who did not receive opioids (Kim et al., 2017).

Acute opioid prescribing must be optimized to reduce the risk of potential long-term addiction, while ensuring acute pain is well-managed. However, evidence suggests that prescribing remains highly variable, with a call for improving prescribing through different approaches, including better opioid education in training (Hopkins et al., 2019). In a systematic review by Hopkins et al. (2019), significant positive changes in opioid prescribing practices were noted after education interventions.

Clinical Practice Guidelines

There is a pressing need to improve clinician opioid prescribing skills to ensure that patients with chronic non-cancer pain receive safe and effective opioid therapy (Midmer et al., 2006). Improving the way opioids are prescribed through clinical practice guidelines can ensure that patients have access to safer, more effective chronic pain treatment, while reducing the number of people who misuse or overdose from these drugs (CDC, 2018a). The CDC (2016a) has published the CDC Guideline for Prescribing Opioids for Chronic Pain, which can be utilized as a tool to prevent opioid overdose deaths by improving opioid prescribing, reducing exposure to opioids, preventing misuse, and treating opioid use disorder (CDC, 2016a).

Theoretical Framework

Kurt Lewin's Theory of Planned Change was selected as the conceptual framework for this project. This theoretical framework provides the structure and guidance required to evaluate change in acute care prescribers' opioid prescribing practices. The theoretical framework identifies the forces to achieve change as well as barriers that prevent change (Batras et al., 2014). The project involved evaluating opioid prescribing practices of acute care providers, specifically hospitalists, in patients with chronic non-cancer pain. Lewin's approach postulated that behavior is a function of the group environment or field. Lewin's view was "that if one could identify, plot and establish the potency of (driving and restraining) forces, then it would be possible not to only understand why individuals, groups, and organizations act as they do, but also what forces would need to be diminished or strengthened to bring about the change" (Shirey, 2013, p. 69).

This framework consists of three phases: unfreezing, moving, and refreezing. Unfreezing is the realization that the potential benefits of change outweigh the potential negatives associated with the process. Moving is the implementation and trialing aspect of change, involving research, action and learning. Refreezing occurs when organization norms, culture, practices, and policies become realigned to support the continuation of change (Batras et al., 2014).

The long-held belief that prolonged opioid therapy for chronic pain is a safe and effective treatment was the most significant factor for the evaluation of acute care providers' opioid prescribing practices. Utilizing Lewin's Theory of Planned Change, the unfreezing stage consisted of initiating the project by reaching out to stakeholders, mainly the hospitalists, to evaluate opioid prescribing practices in conjunction with evidence-based guidelines. In the movement phase, the evaluation of opioid prescribing practices was assessed. During the moving phase, opioid prescribing education consistent with current evidence-based guidelines was provided, followed by a post-test for evaluation. Shirey (2013) stated, "This stage necessitates creating a detailed plan of action and engaging people to try out the proposed change" (p. 70). In

the refreezing phase, providers' prescribing practices were evaluated to determine compliance with evidence-based opioid prescribing guidelines. Shirey (2013) explained, "This stage demands stabilizing the change so that it becomes embedded into existing systems such as culture, polices, and practices" (p. 70). The long-term effect of opioid-prescribing education would be adherence to evidence-based guidelines in hopes of curbing the opioid epidemic and appropriately treating pain.

Chapter 3: Project Design

Methods

This project is a QI initiative that addresses the prescribing practices of opioids to patients with chronic non-cancer pain in the acute care setting per the CDC's evidence-based opioid prescribing guidelines. The purpose of this project was to improve the quality of care patients receive and to improve patient outcomes. In order to protect human rights and maintain ethical conduct, mandatory CITI training on data security per UNCC and Atrium Health was completed. This project was registered with the IRB through both Atrium Health and UNCC. This was a QI project in alignment with Carolinas Hospitalist Group (CHG) initiatives to maintain best practices, thus all providers were required to participate and there were no provided incentives.

The UNCC CITI training on human subjects' research was completed January 7, 2020 (Appendix E). This DNP project was registered with the DNP Council at Atrium Health Carolinas Medical Center January 28, 2020. CITI training on data security was completed on 2/3/2020 (Appendix F) and the "QI at Atrium Health" module was completed via Peoplelink 2/1/2020 (Appendix G). The QI project summary template (Appendix H) was submitted to the DNP council 4/10/2020 and was approved on 4/24/2020 (Appendix I). The QI project was submitted to UNCC IRB (Appendix J) on 5/8/2020 and was approved on 5/20/2020 (Appendix K).

All information and data collected was confidential and protected in a locked filing cabinet as well as on a password protected computer. Each provider was assigned a number to maintain anonymity. This project was implemented during employee working hours, thus there was no further compensation beyond normal salary. Though no compensation was provided,

there was the incentive to improve patient care. Each audited patient chart was also assigned a number to maintain confidentiality of the patient's information.

Marketing

Targeting stakeholders, most importantly Atrium Health, was vital to the success of this project. Atrium Health (2020b) created a taskforce in 2017 to "focus on the development of standard tools and resources to support the appropriate use of opioids." The taskforce is comprised of stakeholders from across the system, including medication safety, musculoskeletal, behavioral health, rehabilitation and emergency services. The goal of the taskforce is to develop a standard pain agreement and guidelines to assist providers in the discussion and treatment of patients with chronic pain, as well as a resource list for providers and teammates available on the intranet (Atrium Health, 2020). Particular stakeholders include MDs, APPs, nurses, hospital administrators, and researchers. This project is in alignment with Atrium Health's values and mission, which will allow for greater success.

The cost for introduction of the opioid prescribing education was minimal, as it was incorporated into an existing hospital service. Financial projections are based upon marketing costs to include paper, ink, and nurse practitioner time spent compiling the educational tools. There was no estimated extra cost for provider salaries as the education was introduced during scheduled monthly hospital meetings. Incorporating a plan that is cost-effective allowed for greater success.

Implementation Site

This project was conducted from September 2020 through February 2021 at Atrium

Health Carolinas Medical Center, a Level 1 trauma center in Charlotte, North Carolina. In a

Level 1 trauma center, patients are provided with care for every aspect of injury, from prevention

through rehabilitation. Specifically, the focus was on internal medicine patients admitted for acute general medical problems. Community-focused services include referrals outside of the hospital in nearby regions, providing leadership in prevention and public education to surrounding communities.

Other elements included in a Level 1 Trauma Center are 24-hour in-house coverage by general surgeons; prompt availability of care in specialties including orthopedic surgery, neurosurgery, anesthesiology, emergency medicine, radiology, plastic surgery, oral and maxillofacial, pediatric and critical care; providing continuing education of team members; incorporating a comprehensive quality assessment program; operating an organized teaching and research effort to help direct innovations in trauma care; programs for substance abuse screening, and patient intervention (American Trauma Society, 2020).

Subjects

This quality improvement project was focused on evidence-based opioid prescribing education using the CDCs Guidelines for prescribing recommendations (CDC, 2016b). This education was disseminated to acute care providers who prescribe opioids to those over the age of 18 who have chronic non-cancer pain. Specifically, acute care providers include medical doctors (MDs) and advanced care providers (APPs) including nurse practitioners (NPs) and physician assistants (PAs) within CHG. Currently, there are a total of 44 providers, including 34 MDs and 10 APPs.

Sample Population

The sample population included adult patients with chronic non-cancer pain admitted to the hospitalist group. More specifically, criteria included patients between 18-60 years of age, currently with chronic pain attributed to a medical condition, neurological pain, or

musculoskeletal pain. The exclusion criteria included patients with cancer pain, sickle cell pain, post-surgical or current opioid addiction.

Intervention

The intervention consisted of a pre-test to evaluate the baseline knowledge of hospitalists' opioid-prescribing practices and was administered before dissemination of opioid prescribing education. This was followed by an educational session per the CDC's evidence-based prescribing of opioids (CDC, 2018b). Approximately six weeks after the educational session, there was a post-test to determine the effectiveness of the education and determine if there was a need for additional education.

The CDC has indicated an intent to evaluate and assess the Opioid Prescribing Guideline as new evidence becomes available, and to determine when research gaps would prompt an update. The CDC is funding the Agency for Healthcare Research & Quality (AHRQ) to conduct systematic reviews of the scientific evidence that has been published since the Guideline was released in March 2016 (CDC, 2019). Results of further reviews will help the CDC address evidence gaps and assess whether the Opioid Prescribing Guideline should be updated or expanded. If an update or expansion occurs, the development process would include results from the ongoing systematic reviews (CDC, 2019).

The prescription opioid prescribing education intervention was implemented over a period of 20 weeks to MDs and APPs within CHG at Atrium Health Carolina's Medical Center. The content was in PowerPoint format and disseminated via e-mail, to include the nationwide and communitywide status of the opioid epidemic and current evidence-based opioid prescribing practice guidelines in alignment with the CDC guideline for prescribing opioids for chronic pain

(2016a). A post-test, disseminated six weeks later, evaluated opioid prescribing practices of the providers to determine if there are any changes in practice.

Data Collection Plan

Measurement Tool

Providers were given a survey before administering evidence-based opioid-prescribing guideline educational material via the KnowPain-12 survey (Appendix A). This is a brief knowledge survey about chronic non-cancer pain that can be used as a reliable and valid measure of a provider's pain management knowledge and attitudes about prescribing (Gordon et al., 2014). The KnowPain-12 is a six-category Likert-type scoring scale that provides for answering and is sensitive to changes in expertise and confidence. Answers range from strongly agree (5 points), agree (4 points), neutral and somewhat agree (3 points) to somewhat disagree (2 points), disagree (1 point), and strongly disagree (0 points). The survey includes eight items with agreement and four with disagreement as correct responses (Gordon et al., 2014). For scoring, items were coded so that the most extreme correct response was assigned 5 points and the most extreme incorrect response 0 points, yielding a possible total scoring of range of 0-60. Items 1, 5, 10, and 11 (for which strong disagreement is the correct response) are coded so that the most correct response, strongly disagree, is assigned 5 points, and the least correct response, strongly agree, is assigned 0 points. The KnowPain-12 score ranges from 0-60, with a higher score corresponding to more correct responses (Gordon et al., 2014). Permission to use this tool was obtained by contacting the developer, Dr. Debra Gordon, via e-mail (Appendix B).

An educational session aligned with the CDC's current evidence-based opioid prescribing practices was administered via PowerPoint presentation via e-mail (Appendix C). The PowerPoint presentation covered the following recommendations: when to initiate or continue

opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; assessing risk and addressing harm (Providers Clinical Support System [PCSS], 2019). A pocket card directly adapted from the CDC guideline, entitled "Prescribing Opioids for Chronic Pain" (CDC, 2016b), was given to each provider (Appendix D).

Following the presentation, the KnowPain-12 survey was again administered to reassess pain management knowledge and attitudes. This was compared to the initial KnowPain-12 survey, and data was analyzed to see if the educational intervention was successful.

Chart Audit Tool

Starting in July 2020, retrospective chart audits of Cerner were performed to determine if providers adhered to the CDC's current evidence-based opioid prescribing recommendations by identifying opioids prescribed for each patient. A random sample of opioid prescriptions written from the clinical site were obtained to determine if opioids were initiated appropriately, meaning selection, dosage, duration, and discontinuation. Data was collected from June 1, 2020 through August 31, 2020.

Method of Data Collection

Data collection began by measuring the current opioid prescribing practices of the hospitalists, including both MDs and APPs, at Atrium Health Carolinas Medical Center. This consisted of 44 providers, including 34 MDs and 10 APPs. Opioid prescribing practices were specifically measured by the number of opioid prescriptions written.

The educational component of this Doctor of Nursing Practice (DNP) project was measured by pre-and post-test scores as well as attendance of the initial training. There was an Excel spreadsheet listing each provider, identified by a number, to identify their chart audits to maintain confidentiality. The identity of each provider was kept separate from the data collected.

Retrospective chart audits were utilized to determine provider compliance with the recommended opioid-prescribing guidelines. Data was collected from the clinical site, Atrium Health Carolinas Medical Center, to determine whether prescribing practices adhere to the CDCs opioid prescribing guidelines to include the dosage and quantity of opioids that were prescribed to patients. The information was taken from the Excel spreadsheet and composed for use in the StataCorp v.16 statistical software.

Timeline for Data Collection

This DNP project was implemented over 20 weeks beginning October 2020. A proposal, including clinical tools, was submitted to the DNP chair, as well as a clinical expert, for review by mid-July 2020 to be ready for implementation. By the end of August 2020, approval for implementation was obtained. Before implementation, chart audits were conducted to determine a baseline of providers' opioid-prescribing practices from June 2020 through August 2020 as well as post-intervention from January 2021 through February 2021. This was used to compare to post-project implementation prescribing practices. The following, as summarized in Figure 3, is a more detailed timeline for this DNP project:

Week 1: The project leader obtained approval and began recruiting providers to participate in the project. Recruitment entailed reaching out to each provider via e-mail (Appendix L) on 9/24/2020 with an introduction to the project as well as its objectives.

Week 4: The pre-test questionnaire was disseminated via e-mail for providers to complete on 10/20/2020. Providers had one week to complete the questionnaire. The date and time of the opioid prescribing education sessions were also provided. Additional reminders to complete the pre-test questionnaire were sent out on 11/2/2020 and 11/17/2020.

Week 8: Results were obtained from the pre-test questionnaire and reviewed prior to implementation of the education. This data was collected and put into an Excel spreadsheet.

Week 12: The evidence-based opioid prescribing guideline educational session was presented to the providers via voice over PowerPoint on 12/15/2020. This was followed by a post-presentation test approximately six weeks later on 1/21/2021, and the results were put into an Excel spreadsheet.

Weeks 16-18: During this period, pre-test and post-test results were evaluated and compared to determine the effectiveness of the educational session. This data was utilized to determine if there were further educational needs.

Week 20: Retrospective chart audits were performed for January and February 2021 to identify the quantity of opioids prescribed and if prescribed in concordance with the CDC opioid prescribing guidelines. This was compared to initial data collected regarding the quantity of opioids prescribed prior to implementation of this project. The project leader compared preproject implementation quantity of opioids prescribed to post-project implementation quantity of opioids prescribed to evaluate effectiveness. This was directly measured by the number of opioid prescriptions written.

Figure 2

Timeline for Data Collection Summary

			201 9			202												202				
Month	8	9	10	11	12	1	2	3	4	5	6	7	8	9	1 0	1 1	1 2	1	2	3	4	5
Research Team Meetings*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
IRB Approval									X	X												
Participant Enrollment												X	X									
Preliminary Research Site													X									
Analyze Preliminary Data														X								
Refine Study Materials														X								
Research Site 1													X	X								
Data entry/Analysi s															X	X						
Prepare final reports																X	X					
Manuscript Preparation																		X	X	X		
Disseminate findings																		X	X			X

Table 2. Timeline to Complete the Proposed Research

SWOT Analysis

The Strength, Weaknesses, Opportunities, and Threats (SWOT) analysis is an assessment tool used to evaluate the strengths and weaknesses of an organization, program, project, or process (Moran et al., 2017). A SWOT analysis, summarized in Figure 2, was conducted to evaluate the strengths, weaknesses, opportunities, and threats that could affect the implementation of the evidence-based opioid prescribing practices in the management of chronic non-cancer pain.

^{*}Bi-monthly with primary mentor, monthly-bimonthly with research mentors, quarterly with mentor team

A major strength of the project was being part of a large healthcare system with access to substantial resources, including finances as well as professional talent and knowledge. Atrium Health (2020a) states, "With 900+ care locations and more than 12 million interactions with patients every year, our approach has the potential to change the trajectory of the opioid crisis throughout our entire region." Another strength is that this project addresses a gap in provider knowledge in prescribing opioids for chronic non-cancer pain, especially during a time in which there is a known opioid epidemic affecting not only the entire nation, but the south-central region of North Carolina in particular. Another strength is the potential impact this project can have on the number of opioid prescriptions written, directly affecting the prescription opioid-related overdoses and deaths. Additionally, there could be potential cost-reduction in utilized medical services.

A limitation of this project is inconsistencies in providers' prescribing practices of opioids for chronic non-cancer pain, as well as a lack of provider participation among the hospitalist group due to personal bias, unwillingness to change current practices, and time constraints. Some providers may view this change as negative as it may make their jobs more difficult or increase their workload. Patient pushback regarding a change in their pain regimen or lack of opioid prescribing could also potentially make work increasingly stressful. Wyse et al. (2018) conducted a qualitative study to identify and describe constraints faced by clinicians in managing and treating misuse among patients. They reported that clinicians found conversations about guideline-recommended opioid practices to be challenging in that some patients resisted changes in ways that were emotionally taxing and time-intensive.

This QI project offers an invaluable opportunity to serve Mecklenburg County's vulnerable patients. This project educates health care providers in making evidence-based

decisions to prevent harmful effects, including, but not limited to, opioid addiction and overdose.

There is an opportunity to use this project to reach out to other services and facilities in an effort to improve opioid prescribing practices across the region.

A viable threat to this project is patient perceptions and risk for decreased patient satisfaction scores. Patients may be frustrated or angry when they do not receive the treatment they want and have the misperception that receiving the treatment they want equals good medical care. Physicians who comply with unreasonable requests may find themselves in the role of "customer service" providers rather than medical professionals, while physicians who do not comply may be recipients of poor ratings and patient satisfaction scores, possibly resulting in emotional, financial, and professional penalties (Zgierska et al., 2012).

An unforeseen threat to this project was the COVID-19 pandemic that resulted in atypical staffing routines posing implementation barriers. The clinical role was shifted to virtual care for some providers as well as redeployment to assist in other areas of the hospital. However, the immediate focus in the acute care setting was directed to providing safe and effective care for all of our patients. Foster and Stack (2020) state,

"When the pandemic started, many active improvement efforts were disrupted as immediate attention was turned to safely providing care for potentially COVID-19-infected patients while maintaining high care standards for all patients...traditional processes required immediate restructuring to mitigate risk to patients and staff, and involved rapid, even daily changes as understanding of the virus evolved."

Figure 3

SWOT Analysis

SWOT ANALYSIS

Strengths

Large healthcare system with access to more resources in regard to finances as well as professional talent and knowledge

Potential impact this project can have on the number of opioid prescriptions written directly affecting the prescription opioid-related overdoses and deaths

Project addresses a gap in provider knowledge in prescribing opioids for chronic non-cancer pain, especially during a time in which there is a known opioid epidemic affecting not only the entire nation, but our region in particular

Potential cost-reduction in utilized medical services

Weaknesses

Inconsistencies in providers' prescribing practices of opioids for chronic non-cancer pain

Lack of provider participation among the hospitalist group in relation to personal bias, unwillingness to change current practice, and time constraints

Patient pushback regarding change in their pain regimen or lack of opioid prescribing

Opportunities

Invaluable opportunity to serve Mecklenburg County and vulnerable patients

Utilize this project to reach out to other services and facilities in an effort to improve opioid prescribing practices across the region

Educate our health care providers in making evidencebased decisions to prevent harmful effects of our actions including but not limited to opioid addiction and overdose

Threats

Patient perceptions and risk for decreased patient satisfaction scores

Patients may be frustrated or angry when they do not receive the treatment they want and have the misperception that receiving the treatment they want equals good medical care

Physicians who comply with unreasonable requests may find themselves in the role of "customer service" providers rather than medical professionals

Physicians who do not comply may be recipients of poor ratings and patient satisfactions scores, possibly resulting in emotional, financial, and professional penalties

Chapter 4: Project Findings

Twenty-five of thirty-five providers (71% response rate) participated in the QI project, including sixteen physicians and nine advanced practice providers. Table 2 describes the respondent sample and clinical role. Respondents were primarily physicians (64%) and remaining respondents were nurse practitioners (16%) and physician assistants (20%). Six of the physicians did not participate since they work nights and only do admissions and do not discharge patients. One physician and one advanced practice provider were out on maternity leave, and thus did not participate in this QI project. One physician retired prior to the completion of this QI project, and thus did not participate. Post-education, twenty-five of the twenty-six providers completed the post-survey. Therefore, both the pre-and post-test scores for this provider were excluded, for a total of twenty-five participants.

Table 2 Demographic characteristics of the respondents (N=25)

Table 3

Clinical Roles	% (N)	
Physician	64 (16)	
Advanced practice providers		
Nurse Practitioner	16 (4)	
Physician Assistant	20 (5)	

Categorical Survey Data: KnowPain-12 Survey Responses Pre- and Post-Intervention

Caregorical Burvey Data. Knov	vi am 12 survey nesp	miscs i ic and	1 OSt THICT VCHILOIT
Question	Response	Preliminary	Post-Intervention
		(n=25)	(n=25)
		% (n)	% (n)
Q1 When I see consistently	Strongly agree	8.0% (2)	4.0% (1)
high pain scores on pain	Agree	8.0% (2)	20.0% (5)
rating scales in the face of	Somewhat agree	52% (13)	28.0% (7)
minimal or moderate	Somewhat disagree	8.0% (2)	28.0% (7)
pathology, this means that	Disagree	20.0% (5)	16.0% (4)
the patient is exaggerating	Strongly disagree	4.0% (1)	4.0% (1)
his/her pain.			

Q2 In chronic pain, the assessment should include measurement of the pain intensity, emotional distress, and functional status.	Strongly agree	20.0% (5)	44.0% (11)
	Agree	64.0% (16)	48.0% (12)
	Somewhat agree	16.0% (4)	8.0% (2)
	Somewhat disagree	0.0% (0)	0.0% (0)
	Disagree	0.0% (0)	0.0% (0)
	Strongly disagree	0.0% (0)	0.0% (0)
Q3 There is good evidence that psychosocial factors predict outcomes from back surgery better than patients' physical characteristics.	Strongly agree Agree Somewhat agree Somewhat disagree Disagree Strongly disagree	8.0% (2) 24.0% (6) 44.0% (11) 16.0% (4) 8.0% (2) 0.0% (0)	4.0% (1) 60.0% (15) 28.0% (7) 4.0% (1) 4.0% (1) 0.0% (0)
Q4 Early return to activities is one of my primary goals when treating a patient with recent onset back pain.	Strongly agree	48.0% (12)	40.0% (10)
	Agree	44.0% (11)	60.0% (15)
	Somewhat agree	8.0% (2)	0.0% (0)
	Somewhat disagree	0.0% (0)	0.0% (0)
	Disagree	0.0% (0)	0.0% (0)
	Strongly disagree	0.0% (0)	0.0% (0)
Q5 Antidepressants usually do not improve symptoms and function in chronic pain patients.	Strongly agree	0.0% (0)	0.0% (0)
	Agree	0.0% (0)	8.0% (2)
	Somewhat agree	12.0% (3)	4.0% (1)
	Somewhat disagree	28.0% (7)	20.0% (5)
	Disagree	32.0% (8)	56.0% (14)
	Strongly disagree	28.0% (7)	12.0% (3)
Q6 Cognitive behavioral therapy is very effective in chronic pain management and should be applied as early as possible in the treatment plan for most chronic pain patients.	Strongly agree	32.0% (8)	24.0% (6)
	Agree	44.0% (11)	40.0% (10)
	Somewhat agree	20.0% (5)	32.0% (8)
	Somewhat disagree	0.0% (0)	0.0% (0)
	Disagree	4.0% (1)	4.0% (1)
	Strongly disagree	0.0% (0)	0.0% (0)
Q7 I feel comfortable calculating conversion doses of commonly used opioids.	Strongly agree	12.0% (3)	8.0% (2)
	Agree	36.0% (9)	56.0% (14)
	Somewhat agree	36.0% (9)	28.0% (7)
	Somewhat disagree	16.0% (4)	4.0% (1)
	Disagree	0.0% (0)	4.0% (1)
	Strongly disagree	0.0% (0)	0.0% (0)

Q8 Long-term use of	Strongly agree	4.0% (1)	0.0% (0)
NSAIDs in the management	Agree	12.0% (3)	12.0% (3)
of chronic pain has higher	Somewhat agree	24.0% (6)	12.0% (3)
risk for tissue damage,	Somewhat disagree	24.0% (6)	36.0% (9)
morbidity, and mortality than	Disagree	32.0% (8)	28.0% (7)
long-term use of opioids	Strongly disagree	4.0% (1)	12.0% (3)
Q9 There is good medical evidence that interdisciplinary treatment of back pain is effective in reducing disability, pain levels, and in returning patients to work.	Strongly agree	44.0% (11)	32.0% (8)
	Agree	40.0% (10)	60.0% (15)
	Somewhat agree	12.0% (3)	8.0% (2)
	Somewhat disagree	4.0% (1)	0.0% (0)
	Disagree	0.0% (0)	0.0% (0)
	Strongly disagree	0.0% (0)	0.0% (0)
Q10 I believe that chronic pain of unknown cause should not be treated with opioids even if this is the only way to obtain pain relief.	Strongly agree	16.0% (4)	8.0% (2)
	Agree	28.0% (7)	28.0% (7)
	Somewhat agree	20.0% (5)	24.0% (6)
	Somewhat disagree	16.0% (4)	16.0% (4)
	Disagree	20.0% (5)	20.0% (5)
	Strongly disagree	0.0% (0)	4.0% (1)
Q11 Under federal regulations, it is not lawful to prescribe an opioid to treat pain in a patient with a diagnosed substance use disorder.	Strongly agree	0.0% (0)	4.0% (1)
	Agree	20.0% (5)	16.0% (4)
	Somewhat agree	12.0% (3)	12.0% (3)
	Somewhat disagree	28.0% (7)	24.0% (6)
	Disagree	32.0% (8)	28.0% (7)
	Strongly disagree	8.0% (2)	16.0% (4)
Q12 I know how to obtain information about both state and federal requirements for prescribing opioids.	Strongly agree Agree Somewhat agree Somewhat disagree Disagree Strongly disagree	24.0% (6) 52.0% (13) 20.0% (5) 0.0% (0) 4.0% (1) 0.0% (0)	36.0% (9) 48.0% (12) 12.0% (3) 4.0% (1) 0.0% (0) 0.0% (0)

Categorical Data Analysis

Answers to survey questions were Likert-style, ranging from strongly agree to strongly disagree. Questions 2, 3, 4, 6, 7, 8, 9, and 12 were numerically coded as Strongly agree (5), Agree (4), Somewhat agree (3), Somewhat disagree (2), Disagree (1), and Strongly disagree (0). Questions 1, 5, 10, and 11 were reverse coded: Strongly agree (0), Agree (1), Somewhat agree (2), Somewhat disagree (3), Disagree (4), and Strongly disagree (5). As such, the higher the

score, the more correct the responses. Total overall scores were calculated for each participant by summing each question item response (Table 4).

Table 4Total Overall Scores per Provider Pre- and Post-Intervention (n=25)

5)			
Provider	Preliminary	Post-Intervention	
	Sum	Sum	
1	41	45	
2 3	41	34	
3	38	43	
4	34	38	
5	37	38	
6	39	43	
7	44	38	
8	41	39	
9	40	43	
10	43	46	
11	42	41	
12	42	44	
13	47	47	
14	40	47	
15	32	35	
16	39	37	
17	40	41	
18	43	43	
19	45	43	
20	42	55	
21	43	36	
22	37	37	
23	35	38	
24	41	42	
25	43	39	

For question 1, the most extreme correct answer is "strongly disagree." Prior to provider education, only one participant responded with "strongly disagree." Twenty percent answered "disagree" and 8% "somewhat disagree." This indicated that about 28% of the respondents had some knowledge and belief that it is incorrect to assume that a patient is exaggerating pain if

they are scoring high on pain rating scales. Therefore, 68% of participants answered incorrectly. Post-education showed some improvement with an additional 16% (44% total) having some knowledge and belief that it is incorrect to assume that a patient is exaggerating pain if they are scoring high on pain rating scales.

For question 2, the most extreme correct answer is "strongly agree." Prior to provider education, 20% chose "strongly agree" and 80% chose "agree" and "somewhat agree." This indicates that all participants had some knowledge that the pain assessment should include pain intensity, emotional distress and functional status. Post-education showed improvement in picking the most extreme correct answer by an increase in 24%, from 20% to 44%.

For question 3, the most extreme correct answer is "strongly agree." Prior to provider education, 8% chose "strongly agree" and 68% chose "agree" and "somewhat agree." This indicates that most participants had some knowledge that there is evidence that psychosocial factors predict outcomes from back surgery than patients' physical characteristics. Even though post-education showed a decrease in picking the most extreme correct answer, from 8.0% to 4.0%, overall there was increase in knowledge that psychosocial factors predict outcomes from back surgery than patients' physical characteristics.

For question 4, the most extreme correct answer is "strongly agree." Prior to provider education, 48% chose "strongly agree" and 52% chose "agree" and "somewhat agree." This indicates that most participants believed that early return to activities is a primary goal when treating a patient with recent onset back pain. Even though post-education showed a decrease in picking the most extreme correct answer from 48.0% to 40.0%, overall there was increase in knowledge that early return to activities is a primary goal when treating a patient with recent onset back pain, as 60% picked "agree" as compared to 44% pre-education.

For question 5, the most extreme correct answer is "strongly disagree." Prior to provider education, seven participants responded with "strongly disagree." Thirty-two percent answered "disagree" and 28% "somewhat disagree." This indicated that 60% of the respondents had some knowledge and belief that antidepressants usually do improve symptoms and function in chronic pain patients. Therefore, 12% of participants answered incorrectly. Post-education showed some improvement with an additional 28% (88% total) having some knowledge and belief that antidepressants usually do improve symptoms and function in chronic pain patients.

For question 6, the most extreme correct answer is "strongly agree." Prior to provider education, 32% chose "strongly agree" and 64% chose "agree" and "somewhat agree." This indicates that most participants believed that cognitive behavioral therapy is very effective in chronic pain management and should be applied as early as possible in the treatment plan. Posteducation showed a decrease in picking the most extreme correct answer from 32.0% to 24.0% but overall, there was no change as there was still only one incorrect response of "disagree."

For question 7, the most extreme correct answer is "strongly agree." Prior to provider education, 12% chose "strongly agree" and 72% chose "agree" and "somewhat agree." This indicates that most participants felt comfortable calculating conversion doses of commonly used opioids. Post-education showed a decrease in picking the most extreme correct answer from 12.0% to 8.0% but overall, there was an increase in knowledge and comfort level of calculating conversion doses of opioids. Incorrect answers decreased by 8% (16% to 8%) post-education.

For question 8, the most extreme correct answer is "strongly agree." Prior to provider education, 4% chose "strongly agree" and 36% chose "agree" and "somewhat agree." This indicates that 40% of participants had some knowledge that the long-term use of NSAIDs in the management of chronic pain has higher risk for tissue damage, morbidity, and mortality than

long-term use of opioids. Post-education scores revealed only 24% of participants has this belief. This low percentage of correct responses could be due to the recent modifications of opioid prescribing to avoid opioid-use disorder and overdose deaths, as NSAIDs are pushed as the first-line therapy for chronic pain.

For question 9, the most extreme correct answer is "strongly agree." Prior to provider education, 44% chose "strongly agree" and 52% chose "agree" and "somewhat agree." This indicates that 90% of participants had some knowledge that there is good medical evidence that interdisciplinary treatment of back pain is effective in reducing disability, pain levels, and returning patients to work. Post-education, 100% of participants had some knowledge that there is good medical evidence that interdisciplinary treatment of back pain is effective in reducing disability, pain levels, and returning patients to work.

For question 10, the most extreme correct answer is "strongly disagree." Prior to provider education, no participants responded with "strongly disagree." Twenty percent answered "disagree" and 16% "somewhat disagree." This indicated that 36% of the respondents believed that it is okay to treat chronic pain of unknown cause with opioids if this is the only way to obtain pain relief. Therefore, 64% of participants answered incorrectly. Post-education showed some improvement with one provider responding with "strongly disagree."

For question 11, the most extreme correct answer is "strongly disagree." Prior to provider education, two participants responded with "strongly disagree." Thirty-two percent answered "disagree" and 28% "somewhat disagree." This indicated that 58% of the respondents believed that it is lawful to prescribe an opioid to treat pain in a patient with a diagnosed substance abuse disorder. There was no change post-education other than an increase in the number of providers choosing the most extreme correct answer, from two to four.

For question 12, the most extreme correct answer is "strongly agree." Prior to provider education, 24% chose "strongly agree" and 72% chose "agree" and "somewhat agree." This indicates that 96% of participants expressed knowledge in knowing how to obtain information about both state and federal requirements for prescribing opioids. There was no significant change post-education, with 96% of participants having the same knowledge, although there was an increase in the most extreme correct answer from 24% to 36%.

Table 5

Continuous Survey Data: KnowPain-12 Survey Responses Pre- and Post-Intervention Wilcoxon Matched-Pairs Signed-Ranks

Wilcoxon Matched-Pairs Signed-Ranks			
<u>Question</u>	Preliminary (n=25)	$\frac{\frac{\text{Post-}}{\text{Intervention}}}{(n=25)}$	p-value – signed ranks test
	Mean (SD) Median	Mean (SD) Median	
Q1 When I see consistently high pain scores on pain rating scales in the face of minimal or moderate pathology, this means that the patient is exaggerating his/her pain.	2.4 (1.3)	2.4 (1.2)	.600
Q2 In chronic pain, the assessment should include measurement of the pain intensity, emotional distress, and functional status.	4.0 (.61)	4.4 (.64)	.040*
Q3 There is good evidence that psychosocial factors predict outcomes from back surgery better than patients' physical characteristics.	3.1 (1.0)	3.6 (.82)	.052
Q4 Early return to activities is one of my primary goals when treating a patient with recent onset back pain.	4.4 (.65)	4.4 (.50)	1.0
Q5 Antidepressants usually do not improve symptoms and function in chronic pain patients.	3.8 (1.0)	3.6 (1.0)	.348
Q6 Cognitive behavioral therapy is very effective in chronic pain management and should be applied as early as possible in the treatment plan for most chronic pain patients.	4.0 (.96)	3.8 (.96)	.109

Q7 I feel comfortable calculating conversion doses of commonly used opioids.	3.4 (.92)	3.6 (.87)	.267
Q8 Long-term use of NSAIDs in the management of chronic pain has higher risk for tissue damage, morbidity, and mortality than long-term use of opioids.	2.2 (1.3)	1.8 (1.2)	.271
Q9 There is good medical evidence that interdisciplinary treatment of back pain is effective in reducing disability, pain levels, and in returning patients to work.	4.2 (.83)	4.2 (.60)	1.0
Q10 I believe that chronic pain of unknown cause should not be treated with opioids even if this is the only way to obtain pain relief.	2.0 (1.4)	2.2 (1.4)	.302
Q11 Under federal regulations, it is not lawful to prescribe an opioid to treat pain in a patient with a diagnosed substance use disorder.	2.9 (1.3)	3.0 (1.5)	.227
Q12 I know how to obtain information about both state and federal requirements for prescribing opioids.	3.9 (.91)	4.2 (.80)	.344
Total Score	40.4 (3.5) 41	41.3 (4.7) 41	.276

Table 6Continuous Survey Data: KnowPain-12 Survey Responses Pre- and Post-Intervention Paired t-test

Question	Preliminary (n=25) Mean (SD)	Post- Intervention (n=25) Mean (SD)	p-value t-test	<u>CI</u> (95%)	
Q1 When I see consistently high pain scores on pain rating scales in the face of minimal or moderate pathology, this means that the patient is exaggerating his/her pain.	2.36 (1.3)	2.44 (1.2)	0.793	-0.570, 0.410	
Q2 In chronic pain, the assessment should include measurement of the pain intensity, emotional distress, and functional status.	4.04 (.61)	4.36 (.64)	0.018*	-0.579, -0.061	

Q3 There is good evidence that psychosocial factors predict outcomes from back surgery better than patients' physical characteristics.	3.08 (1.0)	3.56 (.82)	0.037*	-0.928, -0.032
Q4 Early return to activities is one of my primary goals when treating a patient with recent onset back pain.	4.4 (.65)	4.4 (.50)	1.00	-0.238, 0.238
Q5 Antidepressants usually do not improve symptoms and function in chronic pain patients.	3.76 (1.0)	3.6 (1.0)	0.444	-0.264, 0.584
Q6 Cognitive behavioral therapy is very effective in chronic pain management and should be applied as early as possible in the treatment plan for most chronic pain patients.	4 (.96)	3.8 (.96)	0.17	-0.092, 0.492
Q7 I feel comfortable calculating conversion doses of commonly used opioids.	3.44 (.92)	3.6 (.87)	0.327	-0.490, 0.170
Q8 Long-term use of NSAIDs in the management of chronic pain has higher risk for tissue damage, morbidity, and mortality than long-term use of opioids.	2.2 (1.3)	1.84 (1.2)	0.223	-0.234, 0.954
Q9 There is good medical evidence that interdisciplinary treatment of back pain is effective in reducing disability, pain levels, and in returning patients to work.	4.24 (.83)	4.24 (.60)	1.00	-0.315, 0.315
Q10 I believe that chronic pain of unknown cause should not be treated with opioids even if this is the only way to obtain pain relief.	1.96 (1.4)	2.24 (1.4)	0.356	-0.893, 0.334
Q11 Under federal regulations, it is not lawful to prescribe an opioid to treat pain in a patient with a diagnosed substance use disorder.	2.96 (1.3)	3.04 (1.5)	0.799	-0.721, 0.561

Q12 I know how to obtain information about both state and federal requirements for prescribing opioids.	3.92 (.91)	4.16 (.80)	0.265	-0.674, 0.194
Total Score	40.36 (3.5)	41.28 (4.7)	0.312	-2.758, 0.918

Pre- and post-survey responses were matched, and one observation was dropped from analysis due to lacking a post-test response, resulting in a final count of 25. Survey responses were reported as both categorical (Table 4) and continuous (Tables 5 & 6). There is some debate in the literature on how to best analyze Likert data (Norman, 2010). A long-time statistical debate for Likert data focuses on whether the data generated are ordinal or interval in character (Stratton, 2018). Some argue that application of mean and standard deviation statistical measures is appropriate for Likert data and most agree that ordinal data are appropriately described by mode, median, and quartiles. The common argument against applying parametric statistics (means) to Likert data is that it is "meaningless" to measure a "strongly agree" response and an "agree" response within a set of Likert five-point responses and come up with a meaningful measure (Stratton, 2018). Though there is real data that show use of parametric tests such as means yield answers for Likert ordinal data that are unbiased and acceptable (Norman, 2010). Thus, analysis using both means and medians will allow readers and other researchers to see the data analysis from both sides of the "parametric wall" (Stratton, 2018).

Categorical analysis was reported as frequencies and percentages, and continuous analysis was reported as mean, median, and standard deviation. To assess if significant differences in pre- and post-test scores were present, Wilcoxon matched-pairs signed-ranks test for ordinal data was performed, and exact probabilities were reported due to sample size < 200.

Statistical significance was set at p \leq .05 and all analysis was performed using StataCorp v.16 statistical software (2019).

A two-tailed t-test was run on a sample of 25 medical providers to determine if there was a statistically significant difference in knowledge of evidence-based opioid prescribing practices after participating in an opioid-prescribing educational session. Statistical significance was set at $p \le .05$ and all analysis was performed using StataCorp v.16 statistical software (2019).

Discussion of Results

Wilcoxon Matched-Pairs Signed-Rank

Numerically desired results were seen in questions 2, 3, 7, 10, 11, and 12, where each reported a numerical increase in post-test results. A statistically significant increase in post-test Question 2 ("In chronic pain, the assessment should include measurement of the pain intensity, emotional distress, and functional status.") was reported (Pre: 4.0; Post: 4.4, p=.040). Overall Total Score, while numerically higher, did not achieve statistical significance (Pre: 40.4; Post: 41.3, p=.276) (Table 7).

Table 7

KnowPain-12 Survey Responses Pre- and Post-Intervention Statistical Significance Wilcoxon Matched Pairs Signed-Rank Test

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Question	Wilcoxon	Wilcoxon	<u>p-value</u>	•
	Preliminary	Post-	signed	
	(n=25)	<u>Intervention</u>	<u>ranks</u>	
		(n=25)	<u>test</u>	
Q1 When I see consistently high pain	2.4	2.4	.600	
scores on pain rating scales in the face of				
minimal or moderate pathology, this means				
that the patient is exaggerating his/her				
pain.				
•				

Q2 In chronic pain, the assessment should include measurement of the pain intensity, emotional distress, and functional status.	4.0	4.4	.040*
Q3 There is good evidence that psychosocial factors predict outcomes from back surgery better than patients' physical characteristics.	3.1	3.6	.052
Q4 Early return to activities is one of my primary goals when treating a patient with recent onset back pain.	4.4	4.4	1.0
Q5 Antidepressants usually do not improve symptoms and function in chronic pain patients.	3.8	3.6	.348
Q6 Cognitive behavioral therapy is very effective in chronic pain management and should be applied as early as possible in the treatment plan for most chronic pain patients.	4.0	3.8	.109
Q7 I feel comfortable calculating conversion doses of commonly used opioids.	3.4	3.6	.267
Q8 Long-term use of NSAIDs in the management of chronic pain has higher risk for tissue damage, morbidity, and mortality than long-term use of opioids.	2.2	1.8	.271
Q9 There is good medical evidence that interdisciplinary treatment of back pain is effective in reducing disability, pain levels, and in returning patients to work.	4.2	4.2	1.0
Q10 I believe that chronic pain of unknown cause should not be treated with opioids even if this is the only way to obtain pain relief.	2.0	2.2	.302

Q11 Under federal regulations, it is not lawful to prescribe an opioid to treat pain in a patient with a diagnosed substance use disorder.	2.9	3.0	.227
Q12 I know how to obtain information about both state and federal requirements for prescribing opioids.	3.9	4.2	.344
Total Score	40.4	41.3	.276

Paired t-test

The paired-samples t-test assumes that both variables are at the interval level and are normally distributed. A paired-samples t-test was calculated to compare the mean pretest score to the mean final score. The results from the pre-test (M = 40.36, SD = 3.46) and post-test (M = 41.28, SD = 4.67) KnowPain-12 survey indicate some improvement in knowledge of evidence-based opioid prescribing practices, t(24) = -1.0331, p = .3119, although not statistically significant. A statistically significant increase in post-test Question 2 ("In chronic pain, the assessment should include measurement of the pain intensity, emotional distress, and functional status.") was reported with a p-value of 0.018. There was also a statistically significant increase in post-test Question 3 ("There is good evidence that psychosocial factors predict outcomes from back surgery better than patients' physical characteristics.") with a reported p-value of 0.037 (Table 8). Overall Total Score, while numerically higher, did not achieve statistical significance.

Table 8KnowPain-12 Survey Responses Pre- and Post-Intervention Statistical Significance Paired t-test

Question	<u>Preliminary</u>	Post-	<u>p-value</u>
	(n=25)	<u>Intervention</u>	<u>t-test</u>
	Mean	(n=25)	
		Mean	

Q1 When I see consistently high pain scores on pain rating scales in the face of minimal or moderate pathology, this means that the patient is exaggerating his/her pain.	2.4	2.4	.793
Q2 In chronic pain, the assessment should include measurement of the pain intensity, emotional distress, and functional status.	4.0	4.4	.018*
Q3 There is good evidence that psychosocial factors predict outcomes from back surgery better than patients' physical characteristics.	3.1	3.6	.037*
Q4 Early return to activities is one of my primary goals when treating a patient with recent onset back pain.	4.4	4.4	1.00
Q5 Antidepressants usually do not improve symptoms and function in chronic pain patients.	3.8	3.6	.444
Q6 Cognitive behavioral therapy is very effective in chronic pain management and should be applied as early as possible in the treatment plan for most chronic pain patients.	4.0	3.8	.170
Q7 I feel comfortable calculating conversion doses of commonly used opioids.	3.4	3.6	.327
Q8 Long-term use of NSAIDs in the management of chronic pain has higher risk for tissue damage, morbidity, and mortality than long-term use of opioids.	2.2	1.8	.223
Q9 There is good medical evidence that interdisciplinary treatment of back pain is effective in reducing disability, pain levels, and in returning patients to work.	4.2	4.2	1.00
Q10 I believe that chronic pain of unknown cause should not be treated with opioids even if this is the only way to obtain pain relief.	2.0	2.2	.356

Q11 Under federal regulations, it is not lawful to prescribe an opioid to treat pain in a patient with a diagnosed substance use disorder.	2.9	3.0	.799
Q12 I know how to obtain information about both state and federal requirements for prescribing opioids.	3.9	4.2	.265
Total Score	40.4	41.3	.312

Opioid Prescriptions

Data Analysis

Using the Atrium Health Opioid Dashboard, opioid prescribing in the twelve weeks prior to implementation of this project was compared to opioid prescribing in the eight weeks post education implementation (Table 9). Data from pre- and post-intervention was entered into an Excel spreadsheet. Opioid prescribing practices were summarized using means, standard deviations, standard errors, and upper and lower 95% confidence intervals. Paired t-tests were conducted to assess for any statistical significance with P<.05 as cut-off.

Table 9Number of Opioid Prescriptions Written per Provider Pre- and Post-Intervention (N=25)

(11-23)						
Provider	June Rx	July Rx	August Rx	January Rx	February Rx	
1	5	2	1	0	0	
1	5	3	1	U	Ü	
2	2	2	2	0	0	
3	1	1	5	2	0	
4	0	0	1	0	0	
5	0	0	1	0	0	
6	0	1	0	0	0	
7	0	0	0	0	0	
8	0	0	0	0	0	
9	3	0	1	0	0	
10	3	3	2	0	0	
11	4	3	2	0	0	
12	0	3	2	0	0	
13	1	1	0	0	0	
14	0	0	0	0	0	
15	0	0	0	1	0	

16	0	0	0	0	0
17	0	Ö	0	1	0
18	1	0	1	0	0
19	0	0	1	0	0
20	0	0	0	0	0
21	5	1	0	0	0
22	1	3	3	1	0
23	2	3	0	0	0
24	0	2	2	0	0
25	3	1	3	1	0
Total	31	27	27	6	0

Results

Number of pre and post opioid prescriptions were analyzed by paired t-test, where the months of June, July and August were combined to create the pre-intervention period, and January and February were combined to create the post-intervention period. As shown in Table 10, the average number of opioid prescriptions by provider decreased significantly in the post-intervention period (Pre: 3.4; Post: .24, p<.000).

Table 10Pre- and Post-Intervention Analysis of Opioid Prescriptions

f = f = f = f = f = f = f = f = f = f =					
	Preliminary (n=25) Mean (SD)	Post- Intervention (n=25)	Mean Difference	P value	CI
		Mean (SD)			
Number of Opioid Rx	3.4 (3.2)	0.24 (0.52)	3.16	0.000	1.851, 4.469

Chapter 5: Discussion

Significance and Implications

The national toll of the opioid crisis is evident in the impact on the health and safety of children, their families, and the communities in which they live. Opioid misuse and abuse has many additional repercussions on society, including but not limited to increases in crime, violence, and disruptions in the family, workplace, and educational environments (National Institute on Drug Abuse [NIDA], 2018). It is estimated that 8.7 million children have a parent with a substance abuse disorder. This home environment can cause children to endure stressful or traumatic events, otherwise known as adverse childhood experiences, which may last into adulthood (Lipari & Van Horn, 2017).

Comorbidities are exacerbated by the opioid crisis, including the incidence of Hepatitis B and C, Human Immunodeficiency Virus (HIV), and other diseases caused by injecting drugs with infected needles. In addition to risk for addiction and overdose, injection drug users (IDUs) face the risk of contracting or transmitting viral infections through blood or bodily fluids.

Disease transmission is problematic for both IDUs and the public. Contact with these fluids may easily occur when people inject opioids and share needles or other drug equipment or have unprotected sex with an infected partner (NIDA, 2018).

The opioid crisis also amplifies mortality and morbidity and its costs reverberate into the community and economy. In 2015, the estimated cost of the epidemic was \$504 billion (Council of Economic Advisers, 2017). A contributing cost includes opioid-related care, which continues to burden the capacity of the medical community, including responders and resources to care for this influx of patients. In 2014 alone, the rate of unintentional, opioid-related poisonings resulted in 53,000 hospitalizations and an estimated 92,262 ED visits. As the rate of these hospital-related

treatments rises, communities are increasingly challenged to keep up with this surge (CDC, 2017).

This results of this project have significant implications for patients in the acute care setting by providing evidence-based opioid prescribing education to providers in order to deliver safe and effective care in managing chronic non-cancer pain. This project revealed increased knowledge of evidence-based opioid prescribing in alignment with CDC guidelines. A retrospective chart review of the number of opioid prescriptions written prior to initiation of this QI project, as well as chart review post-implementation, revealed a significant decrease in the number of opioid prescriptions written. This could have a significant positive impact on the mortality rates and financial burdens of the opioid epidemic.

Strengths & Limitations

The limitation in the project design was the delivery of the educational session that was disseminated via email in voice-over PowerPoint form. Face-to-face education with multiple sessions would have provided a more comprehensive approach, but were not feasible in the setting of the COVID-19 pandemic. Hopkins et al. (2019) explains evidence demonstrates that delivering face-to-face education to clinicians significantly and positively impacts the opioid prescribing in hospital and on discharge, reducing opioid dosages and quantities, and influencing prescribers to avoid agents, routes, and doses associated with increased risk. Even so, opioid prescribing education is an effective technique in improving acute care providers knowledge and performance in prescribing opioids in chronic non-cancer pain. This method is easy to implement, cost-effective, and convenient. Not only is this appropriate for the internal medicine specialty but can also be disseminated to other specialties in the acute care setting to address inappropriate opioid prescribing.

This project was also conducted over a short time period of 20 weeks. This only included 3 months of retrospective chart audits and 2 months of post-educational chart audits to determine the number of opioid prescriptions written. Extending the timeframe of the project would have allowed for more comprehensive results as related to provider compliance with opioid prescribing guidelines and the number of opioid prescriptions written over time.

This project also utilized the CDC guideline for prescribing opioids that was specifically developed for the outpatient setting targeting primary care providers. This guideline was implemented in the acute care setting as there is currently no evidence of inpatient opioid prescribing guidelines. A systematic review by Herzig et al. (2018) only identified four existing guidelines that include recommendations on safe opioid practices for managing acute, non-cancer pain and only two offered sparse recommendations specific to the hospital setting. The CDC (2019a) is raising awareness of the misapplication of recommendations to populations outside the Guideline's scope. The guideline is intended for primary care clinicians treating chronic pain for patients 18 and older. Misapplications include applying guidelines to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain (CDC, 2019a). This project's exclusion criteria included patients with cancer pain, sickle cell pain, post-surgical or current opioid addiction.

This project used the KnowPain-12 survey to evaluate providers baseline opioid prescribing knowledge and knowledge post-educational intervention. The KnowPain12 survey does not directly measure clinical endpoints (Gordon et al., 2014). The data are considered relatively low-level educational outcomes and could potentially mislead test-takers about whether their knowledge is actually "pain expert" level (Gordon et al., 2014). Although the KnowPain12

survey does not measure clinical endpoints, the data does effectively measure the extent of expected knowledge and is potentially a more sensitive indicator of educational outcomes than supposedly "higher" measures, such as patient well-being, which may be affected by numerous factors beyond provider education (Harris et al., 2008).

Recommendations for Future Research

Further longitudinal studies would be beneficial to determine the long-term impact of evidence-based opioid prescribing guidelines (del Portal et al., 2016). A study on the impact of an opioid prescribing guideline in the acute care setting by del Portal et al. (2018) revealed a decrease in the number of opioid prescriptions written, but revealed an increase in prescription rates in a later time period, though still significantly lower than pre-guideline levels.

Opioid prescribing was reduced after introduction of opioid prescribing evidence-based practice guidelines to acute care providers. This project is easily adaptable and reproducible for use not only in other hospitals across the healthcare system, but other service lines as well.

Summary

The opioid epidemic is a complex problem with many challenges. Medical providers play a vital and important role in in addressing this public health crisis. Providers are in the unique position to evaluate and interact with patients suffering from chronic non-cancer pain to determine who may be at risk or is currently suffering from an opioid addiction. It would be naive to assume that opioid prescribing education alone will adequately address the epidemic, but is an extremely important tool to use along with other measures. The delivery of opioid education to medical providers will increase knowledge and promote safe prescribing practices, which may mitigate the opioid epidemic by reducing the incidence of opioid use disorder and overdose.

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Appendix A

KnowPain-12 Survey

		•	ng scales in the face of mi s exaggerating his/her pa		
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
2. In chronic pain, emotional distress			neasurement of the pain	intensity,	
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
_		t psychosocial factors sical characteristics.	predict outcomes from b	oack surgery	
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
4. Early return to a onset back pain.	ictivities is	one of my primary go	als when treating a patie	nt with recent	
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
5. Antidepressants	s usually do	not improve symptor	ms and function in chroni	ic pain patients	s.
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
-		• •	chronic pain managemen or most chronic pain pati		e
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
7. I feel comfortab	le calculati	ng conversion doses o	of commonly used opioids	s.	
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
_		n the management of cality than long-term u	chronic pain has higher ri use of opioids.	isk for tissue	
☐ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	

9. There is good medical evidence that interdisciplinary treatment of back pain is effective in reducing disability, pain levels, and in returning patients to work.

□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
10. I believe that of this is the only wa	-		nould not be treated with	opioids even i	if
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
11. Under federal with a diagnosed	_	•	escribe an opioid to treat	pain in a patie	nt
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
12. I know how to prescribing opioid		ormation about both s	tate and federal requiren	nents for	
□ Strongly Agree Strongly Disagree	□ Agree	□ Somewhat Agree	□ Somewhat Disagree	□ Disagree	
(Gordon et al., 201	4)				

Appendix B



Dear Dr. Gordon,

My name is Beth Buckner and I am currently finishing my first year in the doctorate of nursing practice (DNP) program at the University of North Carolina at Charlotte (UNCC). My current clinical practice is at Atrium Health Main in Charlotte, NC as an acute care nurse practitioner with Carolinas Hospitalist Group.

Part of the DNP program requirements include implementing evidence-based interventions into clinical practice and developing a quality improvement project. I am currently working with Atrium Health's hospitalist group to implement an educational intervention for providers (MDs, PAs, NPs) regarding appropriate and evidence-based opioid prescribing in the acute care setting. The clinical question for this DNP project is "do acute care providers who participate in opioid prescribing education, compared to providers without additional education, demonstrate a difference in opioid prescribing practices among patients who have chronic non-cancer pain?"

I have become familiar with your research, particularly your article "Development of the KnowPain-12 pain management knowledge survey." After reading more about the KnowPain-12, I feel like it is a good fit with my project goals. With your permission, I would like to incorporate this into my DNP quality improvement project. The clinical chair for this project is Dr. Allison Burfield at UNCC.

My goal is to implement the DNP project in the fall of 2020, however, with the current pandemic I understand there is great ambiguity. Any feedback and guidance you're willing to provide would be much appreciated. If you have any questions, please feel free to email me at kpayne6@uncc.edu. I look forward to hearing from you.

Thank you,

Beth Buckner

Appendix C

PowerPoint Opioid Prescribing Education



Appendix D

Prescribing Opioids for Chronic Pain Pocket Card



PRESCRIBING OPIOIDS **FOR CHRONIC PAIN**

ADAPTED FROM CDC GUIDELINE

Opioids can provide short-term benefits for moderate to severe pain. Scientific evidence is lacking for the benefits to treat chronic pain.

IN GENERAL, DO NOT PRESCRIBE OPIOIDS AS THE FIRST-LINE TREATMENT FOR CHRONIC PAIN (for adults 18+ with chronic pain > 3 months excluding active cancer, palliative, or end-of-life care)

BEFORE PRESCRIBING

ASSESS PAIN & FUNCTION

Use a validated pain scale. Example: PEG scale where the score = average 3 individual question scores (30% improvement from baseline is clinically meaningful).

- Q1: What number from 0 10 best describes your PAIN in the past week? (0 = "no pain", 10 = "worst you can imagine")
- Q2: What number from 0 10 describes how, during the past week, pain has interfered with your ENJOYMENT OF LIFE? (0 = "not at all", 10 = "complete interference")
- Q3: What number from 0 10 describes how, during the past week, pain has interfered with your GENERAL ACTIVITY? (0 = "not at all", 10 = "complete interference")

CONSIDER IF NON-OPIOID THERAPIES ARE APPROPRIATE

Such as: NSAIDs, TCAs, SNRIs, anti-convulsants, exercise or physical therapy, cognitive behavioral therapy.

TALK TO PATIENTS ABOUT TREATMENT PLAN

- Set realistic goals for pain and function Set criteria for stopping or continuing based on diagnosis.
- Discuss benefits, side effects, and risks (e.g., addiction, overdose).
- opioid. Set criteria for regular progress assessment.
- · Check patient understanding about treatment plan.

EVALUATE RISK OF HARM OR MISUSE. CHECK:

- Known risk factors: illegal drug use; prescription drug use for nonmedical reasons; history of substance use disorder or overdose; mental health conditions; sleep-disordered breathing.
- Prescription drug monitoring program data (if available) for opioids or benzodiazepines from other sources.
- · Urine drug screen to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.
- Medication interactions. AVOID CONCURRENT OPIOID AND BENZODIAZEPINE USE WHENEVER POSSIBLE.

WHEN YOU PRESCRIBE

START LOW AND GO SLOW. IN GENERAL:

- Start with immediate-release (IR) opioids at the lowest dose for the shortest therapeutic duration. IR opioids are recommended over ER/LA
- products when starting opioids. Avoid ≥ 90 MME/day; consider specialist to support management of higher doses.
- If prescribing ≥ 50 MME/day, increase follow-up frequency; consider offering naloxone for overdose risk.
- For acute pain: prescribe < 3 day supply; more than 7 days will rarely be required.
- Counsel patients about safe storage and disposal of unused opioids.

See below for MME comparisons. For MME conversion factors and calulator, go to TurnTheTideRx.org/treatment.

50 MORPHINE MILLLIGRAM EQUIVALENTS (MME)/DAY:

- 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300)
- 33 mg of oxycodone (~2 tablets of oxycodone sustained-release 15mg)

90 MORPHINE MILLLIGRAM EQUIVALENTS (MME)/DAY:

- 90 mg of hydrocodone (18 tablets of hydrocodone/acetaminophen 5/300)
- 60 mg of oxycodone (4 tablets of oxycodone sustained-release 15mg)

AFTER INITIATION OF OPIOID THERAPY

ASSESS, TAILOR & TAPER

- Reassess benefits/risks within 1-4 weeks after initial assessment.
- Assess pain and function and compare results to baseline. Schedule reassessment at regular intervals (≤ 3 months).
- Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.
- If over-sedation or overdose risk, then taper. Example taper plan: 10% decrease in original dose per week or month. Consider psychosocial support.
- Tailor taper rates individually to patients and monitor for withdrawal symptoms.

TREATING OVERDOSE & ADDICTION

- Screen for opioid use disorder (e.g., difficulty controlling use; see DSM-5 criteria). If yes, treat with medication-assisted treatment (MAT). MAT combines behavioral therapy with medications like methadone, buprenorphine, and naltrexone. Refer to findtreatment.samhsa.gov. Additional resources at <u>TurnTheTideRx.org/</u> treatment and <u>www.hhs.gov/opioids</u>.
- Learn about medication-assisted treatment (MAT) and apply to be a MAT provider at <u>www.samhsa.gov/</u> medication-assisted-treatment.
- Consider offering naloxone if high risk for overdose: history of overdose or substance use disorder, higher opioid dosage (≥ 50 MME/day), concurrent benzodiazepine use.

ADDITIONAL RESOURCES

CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN: www.cdc.gov/drugoverdose/prescribing/guideline.html

SAMHSA POCKET GUIDE FOR MEDICATION-ASSISTED TREATMENT (MAT): store.samhsa.qov/MATquide

NIDAMED: www.drugabuse.gov/nidamed-medical-health-professionals

ENROLL IN MEDICARE: go.cms.gov/pecos

Most prescribers will be required to enroll or validly opt out of Medicare for their prescriptions for Medicare patients to be covered. Delay may prevent patient access to medications

JOIN THE MOVEMENT

of health care practitioners committed to ending the opioid crisis at TurnTheTideRx.org.

TURN THE TIDE





The Office of the Surgeon General



Appendix E

CITI Training on Human Subjects' Research



Appendix F

CITI Training on Data Security



Verify at www.citiprogram.org/verify/?wa41c582d-ee1a-4fcc-96c8-67c0aa64f125-35211325

Appendix G

"QI at Atrium Health" module



Atrium Health Nursing Professional Development 5039 Airport Center Parkway Charlotte, NC 28208 Activity: AP140-961

CERTIFICATE OF COMPLETION

This is to certify that

Kimberly Buckner

has completed

Quality Improvement at Atrium Health

Date 0.50

Contact Hours Awarded for Annual AP140 Quality Improvement at Atrium Health

Atrium Health Nursing Professional Development is an approved provider of continuing nursing education by the North Carolina Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

Appendix H

Atrium Health Quality Improvement Project Summary Template

This QI Project Summary guide is designed for projects involving the translation of existing knowledge into clinical practice. Evaluating the effectiveness of knowledge implementation in creating clinical practice change is measured by the QI project outcomes. For such QI projects, privacy and confidentiality regulations (HIPAA) must still be followed. The IRB will review and provide a formal determination; however, the Project Lead is responsible for implementing measures to maintain privacy, data storage and confidentiality in the quality improvement project.

The project summary for the IRB should be no more than 3 pages. Student learners must first gain approval from the appropriate pre-review committee (DNP Council, NSAC, departmental review) before submission to the IRB.

Project Title

"Do acute care providers who participate in opioid prescribing education, compared to providers without additional education, demonstrate a difference in opioid prescribing practices among patients who have chronic non-cancer pain?"

Clinical Site

Atrium Health Carolinas Medical Center: Carolinas Hospitalist Group

Statement of the Problem

In an attempt to follow the Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain, the purpose of this scholarly project is to evaluate acute care providers' opioid prescribing practices in chronic non-cancer pain. Acute care providers consist of medical doctors and advanced practice providers in the hospitalist population. Hospital-based physicians, described as hospitalists, are physicians who work exclusively in the hospital and care for the majority of hospitalized patients (Calcaterra et al., 2017) The CDC (2018a) urges clinicians to prevent opioid overdoses by following best prescribing practices. Calcaterra et al. (2015) states, "these guidelines are not easily integrated into current hospital practice due to a focus on pain control and the acute problem, rather than high-risk patient characteristics for opioid abuse or chronic use" (p. 483).

Evidence-Based Literature Review and Synthesis

In the United States' (US) opioid epidemic is continuing, and drug dose deaths tripled between 1999 and 2016 (Manchikanti et al., 2017). In 2016, there were over 63,600 drug overdose deaths, and opioids played a role in 42,249 of these (Ratycz et al., 2018). In North Carolina, where this project will be implemented, the numbers are devastating. More Powerful NC (2019), a campaign dedicated to raising awareness about the opioid epidemic, reported that five people die from opioid overdoses every day in North Carolina. In addition, their figures showed that between 1999 and 2017 more than 13,169 North Carolina residents lost their lives to unintentional opioid overdoses and there was a 32% increase in opioid overdose deaths in 2017 compared to the previous year, with more than 2,000 deaths. Because of the appreciable mortality risk with opioids, there has been a call for increased clinical guidance, training and mandates, aimed at practitioners prescribing opioids for pain (Barth et al., 2016).

Not only is there a profound human toll but there is also an enormous economic impact. The most recent estimate of costs related to opioid abuse comes from the Society of Actuaries, and actuarial consulting firm Milliman. In 2018 alone, the total number came to \$179 billion. Those costs are borne by all of American society, both by governments providing taxpayer-funded services (estimated to be about a third of the cost) and by individuals, families, employers, private insurers and more (Simmons-Duffin, 2019).

Given the current opioid epidemic, it is vital that we have consistent evidence-based practice (EBP) for how we treat chronic non-cancer pain. Acute care settings are a major source of opioid prescriptions, often for minor conditions and chronic non-cancer pain (Del Portal et al., 2016). Opioids are commonly used for the treatment of acute pain in hospitalized patients, often at high potency with long half-lives. Recent reports highlight that hospital use of opioids impacts downstream use (Herzig et al., 2018). Among opioid-naïve patients admitted to the hospital, 15-25% fill an opioid prescription in the week after hospital discharge, 43% of such patients fill another opioid prescription 90 days post-discharge, and 15% meet the criteria for long-term use at one year (Herzig et al., 2018). With about 37 million discharges from US hospitals each year, these estimates suggest that hospitalization contributes to initiation of long-term opioid use in millions of adults each year (Herzig et al., 2018). In a retrospective cohort study by Herzig et al. (2014) there was considerable hospital opioid variation in opioid use and severe opioid-related adverse events occurred more frequently with higher opioid prescribing rates, and the relative risk of a severe adverse event per patient prescribed opioids was also higher in the hospital.

Additionally, opioid prescribing practices vary between hospital providers and hospitals, highlighting the need for prescribing standards and guidance. There are no existing guidelines for improving the safety of opioid use in hospitalized patients outside of the intensive care or immediate peri-operative settings (Herzig et al., 2018). Manchikanti et al. (2012) found a common theme that this crisis is rooted in the lack of education and misinformation, leading to overprescribing. The majority of cases involving injury and death occur in those using opioids as prescribed, not just those misusing or abusing them. Despite adequate relief and improvement in function with modalities other than opioids, patients continue on opioids (Manchikanti et al., 2012).

The prescriber's role in generating and sustaining opioid abuse has been made clear by studies that link a practitioner's prescribing patterns to a patient's likelihood of long-term opioid dependence (Meisenberg et al., 2018). Calcaterra et al. (2015) found that 25% of opioid-naïve patients received an opioid at hospital discharge, were more likely to become chronic opioid users, and had an increased number of opioid refills one-year post-discharge, compared to patients without opioid receipt. This linkage between prescribing patterns and opioid dependency formed the rationale for a targeted initiative to reduce opioid prescribing (Meisenberg et al., 2018).

Project Aims

This project has several related objectives. First, to evaluate acute care providers' baseline prescribing practices of opioids in acutely ill patients admitted to the hospital who suffer from chronic non-cancer pain. Then, to develop and implement an educational and quality improvement course with the goal to improve opioid prescribing practices in line with current EBP opioid prescribing guidelines (specifically the CDC). Finally, to evaluate change in knowledge and practices before and after completing the education, and to identify barriers adhering to the CDC guidelines. A long-term objective would be to reduce the current opioid burden of addiction and overdose, as well as the economic impact, with adherence to CDC opioid prescribing guidelines.

Project Methods

Data collection will begin by measuring the current opioid prescribing practices of the hospitalists, including both medical doctors (MDs) and advanced practice providers (APPs), at Atrium Health Carolinas Medical Center. This consists of 44 providers including 34 MDs and 10 APPs. An Excel spreadsheet will be utilized to list each provider, identified by a number, to identify current opioid prescribing practices pre-intervention. Opioid prescribing practices will be specifically measured by the number of opioid prescriptions written.

The educational component of this Doctor of Nursing Practice (DNP) project will be measured by pre-and post-test scores as well as attendance of the initial training. There will be an Excel spreadsheet that will list each provider, identified by a number, to identify their chart audits to maintain confidentiality. The identity of each provider will be kept separate from the data collected. Retrospective chart audits will be utilized to determine provider compliance with the recommended opioid-prescribing guidelines. Data will be collected from the clinical site, Atrium Health Carolinas Medical Center, to determine whether prescribing practices adhere to the CDCs opioid prescribing guidelines to include the dosage and quantity of opioids that were prescribed to patients. The information will be taken from the Excel spreadsheet and composed for use in the Statistical Package for the Social Sciences (SPSS).

Retrospective chart audits of Cerner will be performed prior to implementation of this project starting in July 2020 to determine if providers adhered to the CDCs current evidence-based opioid prescribing recommendations by identifying opioids prescribed for each patient. A random sample of opioids prescribed from the clinical site will be obtained to determine if opioids were initiated appropriately meaning selection, dosage, duration, and discontinuation.

The sample population will include adult patients with chronic non-cancer pain admitted to the hospitalist group. More specifically, criteria include ages 18-60 years of age; male and female patients; currently with chronic pain attributed to a medical condition, neurological pain, or musculoskeletal pain. The exclusion population will include patients with cancer pain, sickle cell pain, post-surgical or current opioid addiction.

Providers will be given a survey prior to administering evidence-based opioid-prescribing guideline educational material via the KnowPain-12 survey (Appendix A). This is a brief knowledge survey about chronic non-cancer pain that can be used as a reliable and valid measure of a provider's pain management knowledge and attitudes about prescribing (Gordon et al., 2014). The KnowPain-12 is a six-discrete, value Likert-type scoring scale that provides for answering and is sensitive to changes in expertise and confidence. Answers range from strongly agree, agree, neutral and somewhat agree to somewhat disagree, disagree, and strongly disagree. The survey includes eight items with agreement and four with disagreement as correct responses (Gordon et al., 2014). For scoring, items were coded so that the most extreme correct response was assigned 5 points and the most extreme incorrect response 0 points, yielding a possible total scoring of range of 0-60 (Gordon et al., 2014).

An educational session aligned with the Center for Disease Controls (CDC) current evidence-based opioid prescribing practices will be administered via PowerPoint presentation at the clinical site (Appendix C). The PowerPoint presentation will cover the following recommendations: when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; assessing risk and addressing harm (Providers Clinical Support System [PCSS], 2019). A pocket card entitled "Prescribing Opioids for Chronic Pain (CDC, 2016b)" will also be provided to each provider that is directly adapted from the CDC guideline (Appendix D).

Following the presentation, the KnowPain-12 survey will again be administered to reassess pain management knowledge and attitudes. This will be compared to the initial KnowPain-12 survey and data will be analyzed to see if the educational intervention was successful.

Data Collection Plan

Data collected from the pre- and post-tests will be entered into a Microsoft Excel spreadsheet. An Excel spreadsheet will be utilized to list each provider, identified by a number, to identify current opioid prescribing practices pre-intervention. Opioid prescribing practices will be specifically measured by the number of opioid prescriptions written. This information will be obtained by conducting chart audits of patients admitted by CHG in Cerner. This will be compared to the number of opioid prescriptions written pre-intervention.

Timeline

This DNP project will be implemented over an 8-12-week period to begin in August of 2020. This proposal including clinical tools will be submitted to the DNP chair as well as clinical expert for review by mid July 2020 in order to be ready for implementation. By the end of July 2020, approval for implementation will be obtained. Prior to implementation, I will conduct chart audits to determine a baseline of providers' opioid-prescribing practices. This will be used to compare to post-project implementation prescribing practices.

Week 1: I will obtain approval and begin to recruit providers to participate in this DNP project. Recruitment will entail reaching out to each provider via e-mail (Appendix L) with introduction to the project as well as objectives. At this time, I will attach the pre-test questionnaire to be completed. I will provide a 1-week time frame for providers to respond to and complete the questionnaire. I will also include the date and time of the opioid prescribing education to be disseminated.

Week 2: Results will be obtained from the pre-test questionnaire and will be reviewed prior to implementation of the education. This data will be collected and input to an Excel spreadsheet.

- **Week 3:** The evidence-based opioid prescribing guideline educational session will be presented to the providers. This will be followed by a post-presentation test approximately 30 days later with results input into an Excel spreadsheet.
- **Week 4-8:** During this period, pre-test and post-test results will be evaluated and compared to determine the effectiveness of the educational session. This data will be utilized to determine if there are further educational needs. If any are identified, this time period will be utilized to address these.
- **Week 9-10:** Retrospective chart audits will be performed to identify the quantity of opioids prescribed and if prescribed in concordance with the CDC opioid prescribing guidelines. This will be compared to initial data collected regarding the quantity of opioids prescribed prior to implementation of this project.
- **Week 11-12:** I will compare pre-project implementation quantity of opioids prescribed to post-project implementation quantity of opioids prescribed to evaluate effectiveness. This will be directly measured by the number of opioid prescriptions written.

Evaluation Plan

T-test will be conducted to determine if there is any significance in scores pre- and post-educational session. The paired-samples *t* test (dependent *t* test) will compare the means of the pre and post-test scores of the participants. The paired-samples *t* test assumes the test scores are interval or ratio level and are normally distributed. The test scores will be measured with the same scale.

Protected Health Information

Non-applicable. There will be no identifying patient information including name, date of birth, address, social security number, gender or ethnicity.

Privacy, Data Storage & Confidentiality

In order to protect human rights and maintain ethical conduct, mandatory Collaborative Institutional Training Initiative (CITI) training on data security per University of North Carolina at Charlotte (UNCC) and Atrium Health was completed 1/7/2020 and 2/1/2020.

Each patient chart audited will be assigned a number to maintain confidentiality of the patient's information. There will be no identifying patient information including name, date of birth, address, social security number, gender or ethnicity.

All information and data collected will be maintained confidential and protected in a locked filing cabinet as well as on a password protected computer that will be stored in my home office. Individuals with access to this information other than myself will include Dr. Allison Burfield, DNP project chair, and Dr. Erika Myers, DNP clinical expert.

References

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Appendix I

Atrium Health IRB Approval

Confidential

Record ID 773 - Kimberly Beth Buckner (submitted: 04-13-2020)

Page 1

QI vs Research Form

- * All fields on this form are required to be completed before submitting *
- * Do not submit this form for projects already completed. Contact the IRB at IRBInfo@atriumhealth.org *

Response was added on 04/13/2020 2:56pm.

ATRIUM HEALTH Institutional Review Board / Patient Privacy Board IRB Review & Determination of QI vs. Research Projects Submission Date: Project Lead: Kimberly Beth Buckner (Full Name) CHG Department: Phone: (828) 289-4006 E-mail: Kimberly.Buckner@atriumhealth.org Project Title: "Do acute care providers who participate in opioid prescribing education, compared to providers without additional education, demonstrate a difference in opioid prescribing practices among patients who have chronic non-cancer pain?" Is the project supported by funding? \otimes No

Purpose of the project: (Provide a 2-3 sentence description.)

This project has several related objectives. First, to evaluate acute care providers' baseline prescribing practices of opioids in acutely ill patients admitted to the hospital who suffer from chronic non-cancer pain. Then, to develop and implement an educational and quality improvement course with the goal to improve opioid prescribing practices in line with current EBP opioid prescribing guidelines (specifically the CDC). Finally, to evaluate change in knowledge and practices before and after completing the education, and to identify barriers adhering to the CDC guidelines. A long-term objective would be to reduce the current opioid burden of addiction and overdose, as well as the economic impact, with adherence to CDC opioid prescribing guidelines.

Briefly describe project details, including how patients and/or providers will be involved: (Provide a 2-3 sentence description.)

This DNP project will be implemented over an 8-12-week period to begin in August of 2020 at Atrium Health Carolinas Medical Center. This project consists of measuring Carolina's Hospitalist Group (CHG) providers' baseline opioid prescribing knowledge and practices. CHG consists of 44 providers including 34 medical doctors (MDs) and 10 advanced practice providers (APPs).

The sample population will include adult patients with chronic non-cancer pain admitted to the hospitalist group. More specifically, criteria include ages 18-60 years of age; male and female patients; currently with chronic pain attributed to a medical condition, neurological pain, or musculoskeletal pain. The exclusion population will include patients with cancer pain, sickle cell pain, post-surgical or current opioid addiction.

Chart audits of the sample patient population will be performed prior to the educational intervention to a baseline of the number of opioid prescriptions written. CHG providers will be given a survey to determine baseline opioid prescribing knowledge and practices. An educational session aligned with the Center for Disease Controls (CDC) current evidence-based opioid prescribing practices will be administered via PowerPoint presentation at the clinical site. Following the educational session, providers will complete another survey to reassess pain management knowledge and attitudes. This will be compared to the initial survey and data will be analyzed to see if the educational intervention improves opioid-prescribing knowledge. Additional random chart audits will be performed post-educational intervention to determine if there is a change in the number of opioid prescriptions written.

post-educational intervention to determine it there is a change in the number of opiola prescriptions written.
QI Summary Template & Instructions (Please download, complete, and upload back to this form.)
[Attachment: "QI Project Summary Template.doc"]
Attach QI Project Summary:
[document]
Have you completed the Quality Improvement training module?
⊗ Yes
Please upload your (and your team's) completion certificate(s) for the Quality Improvement module:
Certificate #1:
[document]
Certificate #2:
[document]

Is this project Quality Improvement (QI)?			
Quality Improvement includes ac practice to improve the quality of regarding the implementation of purposes. Quality Improvement make universal changes to evidence-based care. See CHS Policy link	of patient care, and (b) collect the practice for clinical, pra projects are limited to a sett	cting patient or provider data actical, or administrative	
See cris i oney link	Yes	No	
Do you consider this project to meet the definition of QI as noted above?	res ⊗	O	
Is the activity primarily designed to: Improve clinical care at CHS?	\otimes	0	
Is the activity primarily designed to: Apply to patients or populations beyond your specific study population? *	0	\otimes	
* (i.e. apply to only Atrium Health patients) Is this project Research?	ts or possibly to patients outside of	f Atrium Health?)	
Research is "a systematic invest evaluation that is designed to develop or co [45CFR46.102 and 45 CFR 164.50	ontribute to generalizable kn		
See CHS Policy link			
Do you consider this project to meet the definition of research as noted above?	Yes	No ⊗	
Does the project involve a systematic investigation that may include a hypothesis, testing and evaluation?	0	\otimes	

Record ID 773 - Kimberly Beth Buckner (submitted: 04-13-2020)

		Page 4
Is the activity primarily designed to: Develop new knowledge?	0	\otimes
Is the activity primarily designed to: Apply to patients or populations beyond your specific study population? *	0	\otimes
* (i.e. apply to only Atrium Health patients	or possibly to patients outside	of Atrium Health?)
Activity Involves Human Subjects?	?	
	Yes	No
	_	
Does your project involve: Interventions or interactions with patients, including manipulation of a person, or a person's environment through surveys, interviews, tests or observations?	0	⊗
Does your project involve: Obtaining identifiable private information about living people?	0	\otimes
Clinical Investigation?		
	Yes	No
Does your project include testing the safety and efficacy of a drug or device in a human subject, including analysis or comparison of outcome data about a drug or device?	Ö	 ⊗
Does your project include a non-FDA-approved assay or In Vitro Diagnostic device?	0	\otimes
Will any data resulting from this activity be submitted to the FDA?	0	\otimes

Record ID 773 - Kimberly Beth Buckner (submitted: 04-13-2020)

Page 5

Other Considerations				
other considerations	Yes	No		
Does your project involve a vulnerable population, e.g. children, impaired adults with special consent issues, Atrium employees? See link	Ö	⊗		
Are there plans to publish information gained from this project?	8	0		
Will patients be consented for entry into this project?	0	\otimes		
What are the potential risks to participants	s?			
None (Please list, separate by comma (,))				
What are the potential benefits to particip	ants?			
Better patient care, increased knowledge (Please list, separate by comma (,))	of evidence-based practices	s		
Signatures				
CERTIFICATION OF PROJECT LEAD:				
I certify that the information provided in this IRB Review of QI and Research Projects screening form is complete and accurate. The above titled project has been/will be conducted in full compliance with the HHS/FDA Regulations and IRB requirements/policies governing human subject research. IRB review is required for projects meeting the criteria of, "Research" as noted above.				
Signature of Project Lead:				
Kimbuly Buckny	_			
Date:				
04-10-2020 23:08:41				
Are you a resident or student?				
⊗ Yes				
What category?				
⊗ DNP/PhD Nursing				
OFFICIAL OF BEDARENT OUTLE (1/				

CERTIFICATION OF DEPARTMENT CHAIR (If a resident or student):

I certify that I have read the attached IRB Review of QI and Research Projects screening form and the project has been reviewed.

Record ID 773 - Kimberly Beth Buckner (submitted: 04-13-2020)

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alison H. Burfried	
- U	

Date:

04-13-2020 12:02:41

Please note: If the AH IRB determines your project DOES meet the definition of Human Subjects Research, you will be required to submit the Expedited/Exempt Protocol Application, prior to beginning any research activities.

required to submit the Expedited/Exempt Protocol Application, prior to beginning any research activities.				
The application can be found, HERE.				
DNP Use Only				
Reviewed completed?	⊗ Yes			
DNP Signature:	&M~			
Date:	04-14-2020 09:24:51 ((click "Now" if signing now.))			
IRB Use Only				
Staff Section				
Please be sure that the DNP section above is completed.				
Reviewed by:	⊗ Jomani Cheeseman			
Forward to which chair?	⊗ Michael Brennan			
Date:	04-14-2020 11:41:43 ((click "Now" if signing now.))			
Chair Section				
Require edits or changes?	⊗ No			
The IRB has determined this project is:	⊗ Quality Improvement			
Completed By:	Michael Brennan ((Please Print Full Name))			

Appendix J

UNCC IRB Submission

IRB Number: 19-0776 Initial Principal Investigator: Kimberly Buckner

General Information

1. General Information

1. Project Title

Evaluation of Acute Care Providers' Opioid Prescribing Practices in Chronic Non-Cancer Pain

 Brief Summary or Abstract. Provide a brief non-technical description or abstract of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words.

Given the current opioid epidemic, it is vital that we have consistent evidence-based practice for how we treat chronic non-cancer pain. In an attempt to follow the Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain, the purpose of this scholarly project is to evaluate acute care providers' opioid prescribing practices in chronic non-cancer pain. The CDC (2018a) urges clinicians to prevent opioid overdoses by following best prescribing practices. Guidelines are not easily integrated into current hospital practice due to a focus on pain control and the acute problem, rather than high-risk patient characteristics for opioid abuse or chronic use (Calcaterra et al., 2015).

Is this new study similar or related to an application already approved by the UNC Charlotte IRB? Knowing this may help the IRB in reviewing your new study.

No

4. Is there anything else you would like the IRB to know about this study? E.g., has this study been approved by another IRB, will you be asking for an IRB authorization agreement, is there a timeline that may be important to mention, etc.

Approved by Atrium Health IRB as Quality Improvement Project

2. Project Personnel

1. Will this project be led by a STUDENT working in fulfillment of requirements for a University course, program or degree?

Yes

A Responsible Faculty is required and should be added in Project Personnel on this page. This should be the faculty member who will mentor and be responsible for the entire study and all study personnel. NOTE: This may or may not be your academic faculty advisor.

The Responsible Faculty will be required to approve the submission along with the student PI. You should make sure the Responsible Faculty has a chance to review and edit the submission <u>before you submit</u>.

Choose the status of the student/trainee:

graduate or professional

Please choose the type of research the student is proposing.

- X Honors Thesis
- X Masters Thesis
- X Dissertation Research
- X Independent study
- × Pilot study
- Other

General Information

1. General Information

1. Project Title

Evaluation of Acute Care Providers' Opioid Prescribing Practices in Chronic Non-Cancer Pain

 Brief Summary or Abstract. Provide a brief non-technical description or abstract of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words.

Given the current opioid epidemic, it is vital that we have consistent evidence-based practice for how we treat chronic non-cancer pain. In an attempt to follow the Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain, the purpose of this scholarly project is to evaluate acute care providers' opioid prescribing practices in chronic non-cancer pain. The CDC (2018a) urges clinicians to prevent opioid overdoses by following best prescribing practices. Guidelines are not easily integrated into current hospital practice due to a focus on pain control and the acute problem, rather than high-risk patient characteristics for opioid abuse or chronic use (Calcaterra et al., 2015).

Is this new study similar or related to an application already approved by the UNC Charlotte IRB? Knowing this may help the IRB in reviewing your new study.

Nο

4. Is there anything else you would like the IRB to know about this study? E.g., has this study been approved by another IRB, will you be asking for an IRB authorization agreement, is there a timeline that may be important to mention, etc.

Approved by Atrium Health IRB as Quality Improvement Project

2. Project Personnel

1. Will this project be led by a STUDENT working in fulfillment of requirements for a University course, program or degree?

Yes

A Responsible Faculty is required and should be added in Project Personnel on this page. This should be the faculty member who will mentor and be responsible for the entire study and all study personnel. NOTE: This may or may not be your academic faculty advisor.

The Responsible Faculty will be required to approve the submission along with the student PI. You should make sure the Responsible Faculty has a chance to review and edit the submission <u>before you submit</u>.

Choose the status of the student/trainee:

graduate or professional

Please choose the type of research the student is proposing.

- X Honors Thesis
- X Masters Thesis
- X Dissertation Research
- X Independent study
- × Pilot study
- ❤ Other

If Other, please explain

Doctor Of Nursing Practice Scholarly Project (Quality Improvement Project)

view

List all project personnel in the following order: principal investigator, responsible faculty, co-investigators, study coordinators, and anyone obtaining consent, collecting identifiable subject data or doing data analysis.

List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB for this study. I.e., do not list collaborators who will submit their own protocol application to their own IRB.

If you are collaborating with community partners who are not functioning as researchers OR if your extended research team includes multiple individuals with limited roles, ask ORC if these individuals need to be listed as project personnel.

Liaison	Last Name	First Name	Preferred Email	Department Name	Role	Detail
Universi	ty of North (Carolina at C	Charlotte (UNCC)			
*	Buckner	Kimberly	kpayne6@uncc.edu	School of Nursing	Principal Investigator	<u>view</u>
	Burfield	Allison	aburfiel@uncc.edu	School of Nursing	Faculty Advisor	<u>view</u>

Note: If applicable and once the study is certified by the PI, personnel listed (for whom we have email addresses) may receive separate instructions about Conflict of Interest disclosure requirements. If further documentation is required the PI will be notified.

3. At any time, will members of the research team or their immediate family members have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study or otherwise have a potential conflict of interest or have the appearance of compromising a researcher's objectivity in fulfilling research responsibilities related to the conduct of this study? Please explain. If there is no conflict of interest state as such.

There are no conflicts of interest among the team members conducting this quality improvement project.

4. If this research is based in a center, institute, or department other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department N/A

Have all research team members listed above completed human subjects research training? Note: Training must be current (not expired).

If yes, upload the completion certificates for all team members. If no, training may be completed via the <u>CITI online training site.</u>

The IRB approval will not be finalized until completion certificates have been provided for all team members.

Yes

3. Funding Sources

1. Is this project funded or proposed to be funded by a contract or grant from an organization EXTERNAL to UNC Charlotte?

No

Reference ID: 184960 Date Received: Draft Page: 2 of 10

2. Is this study funded by UNC Charlotte? E.g., department funds, internal pilot grants, Faculty Research Grants, trust accounts?

Nο

3. Is this research classified (e.g. requires governmental security clearance)?

No

- 4. Is there a master protocol, grant application, or other proposal documentation associated with this protocol submission (check all that apply)?
- X Grant Application
- X Industry Sponsor or Multi-site study Master Protocol
- X Student Dissertation Proposal or Thesis Proposal
- Investigator Initiated Master Protocol
- ✓ Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval. Please refer to ORC quidance before proceeding.

The first question is whether this is RESEARCH.

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge?

For example, do any of the following apply:

- 1. Is your project or activity a systematic investigation? This would typically mean that the same procedure(s) will be used to gather data about more than one person (systematic), in order to test a hypothesis or answer questions (investigation).
- 2. Do you intend to publish or present results from your study with the intent of drawing scientific conclusions or increasing the body of scientific knowledge?
- 3. Will your study help develop or contribute to generalizable knowledge? This would not typically describe projects that are intended only for internal assessment purposes, such as quality improvement or program evaluations.

Nο

The next questions will determine if there are HUMAN SUBJECTS.

2. Will you be obtaining information or biospecimens through intervention or interaction with the individual, and use, study, or analysis of the information or biospecimens? This would include any communication or interpersonal contact between investigator and subject such as using in-person or online questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer Yes unless the information is also ABOUT them.

Yes

3. Will you be obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).
OR

will you be using human specimens that are not individually identifiable for <u>FDA-regulated in vitro</u> diagnostic (IVD) device investigations?

Reference ID: 184960 Date Received: Draft Page: 3 of 10

Principal Investigator: Kimberly Buckner

Yes

4. Are any personnel, organizations, entities, facilities or locations (including foreign locations) in addition to UNCC involved in this research? For example, answer YES if this is a multi-site study meaning the same protocol will be conducted by collaborating institutions at multiple locations. Answer YES if you will request reliance on an external IRB. Answer YES if you will have external researchers relying on the UNCC IRB.

No Answer Provided

Part A. Questions Common to All Studies

A.9. Identifiers

- A.9.1. Check the identifying information below that you already have, or will collect, and or will receive, even if it is not retained with the research data, Or select *None of the above*. This does not apply to information on consent forms, but it does apply to identifying information to confirm attendance, schedule appointments, and or assign credit or other incentives.
- × Names
- X Telephone numbers
- X Any elements of dates (except for year) for dates directly related to an individual, including birth date, admission/discharge date, date of death and all ages over 89 and all elements of dates (including year) indicative of such age (unless aggregated into one category, such as 90 and older).
- X Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- 💢 Fax numbers
- Electronic mail addresses
- X Social Security numbers
- X Student or Employee ID numbers
- Medical record numbers
- Kealth plan beneficiary numbers
- X Account numbers
- Certificate or license numbers
- X Vehicle identifiers and serial numbers (VIN), including license plate numbers
- X Device identifiers and serial numbers (e.g., implanted medical device)
- Web universal resource locators (URLs)
- X Internet protocol (IP) address numbers
- X Biometric identifiers, including finger and voice prints
- X Full face photographic images and any comparable images
- ✓ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the data provider and not disclosed to the researcher
- X None of the above

Principal Investigator: Kimberly Buckner

A.9.2. For any identifiers checked, how will these identifiers be stored in relationship to the research data? separate from the research data. I.e., coded with a linkage file stored in a different physical location.

Provide details about the option you selected above. If a selection was not needed, indicate not applicable.

I will have access to the Medical Record Numbers in order to extract data pertinent to this project (opioid prescriptions written). Once I extract the data needed, I will not record the actual Medical Record Number. Each audited patient chart will be assigned a number to maintain confidentiality of the patient's information. This will also be the case with the provider e-mail addresses. I will not keep the e-mail addresses provided but will only utilize to send out surveys. Each provider will be assigned a number to maintain anonymity. All information and data collected will be maintained confidentially and protected in a locked filing cabinet as well as on a password protected computer.

A.9.3. Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

Part C. Existing Data, Records, Specimens

C.1. Data Sources

- C.1.1. What <u>existing</u> records, data or human biological specimens will you be using? (Indicate all that apply or select 'None of the above'):
- X Data already collected from another research study

Were the investigators for the current application involved in the original collection?

X Participant specimens (tissues, blood, serum, surgical discards, etc.)

Has the clinical purpose for which they were collected been met before removal of any excess?

- X Data already collected for administrative purposes
- Medical records in any format.
- ➤ Data coming directly from a health plan, health care clearinghouse, or health care provider?
- X Student records (You will need to satisfy FERPA requirements.)
- ➤ Publicly available data. Note: IRB review and approval may not be required for publicly available data. Please refer to ORC Guidance regarding publicly available data.
- Restricted use data (i.e., data that requires a data use agreement, restricted use agreement, data license agreement, and or confidentiality agreement). Note: UNC Charlotte Policy 311.9 and associated requirements may apply.
- × Other
- X None of the above
- Electronic medical records
- × Paper medical records

Provide details about each data source checked above (except for None of the above). E.g., a description of the data, proposed use, how data were collected including research consent procedures, where data currently reside, etc.).

Data will be collected from the clinical site, Atrium Health Carolinas Medical Center, to determine whether prescribing practices adhere to the CDCs opioid prescribing guidelines to include the dosage and quantity of opioids that were prescribed to patients. A random sample will be taken from electronic medical records and coded for anonymity. Information obtained will be put into an Excel spreadsheet and composed for use in the Statistical Package for the Social Sciences (SPSS).

view

C.1.2. Describe your plans for obtaining permission from the custodians of the data, records or specimens (e.g., data provider, school, pathology dept, tissue bank, original researcher):

Permission has been obtained based upon approval from the Atrium Health IRB as a Quality Improvement Project.

C.1.3. Do the custodians of the data, records or specimens require a data use agreement? If so, UNC Charlotte <u>Policy 311.9</u> and associated requirements may apply. If this question is not applicable choose NO.

No

C.2. Identifiers

- C.2.1. Identifiers in EXISTING Data. Do the data you will receive have any of the following identifiers? (check all that apply)
- × Names
- X Telephone numbers
- Any elements of dates (except for year) for dates directly related to an individual, including birth date, admission/discharge date, date of death and all ages over 89 and all elements of dates (including year) indicative of such age (unless aggregated into one category, such as 90 and older).
- ✗ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
- X Fax numbers
- X Electronic mail addresses

 The state of the state
- X Social security numbers
- X Student or Employee ID numbers
- ★ Medical record numbers
- X Health plan beneficiary numbers

 The state of the
- Account numbers
- X Vehicle identifiers and serial numbers (VIN), including license plate numbers
- X Device identifiers and serial numbers (e.g., implanted medical device)
- Web universal resource locators (URLs)

Internet protocol (IP) address numbers

➤ Biometric identifiers, including finger and voice prints

X Full face photographic images and any comparable images

X Any other unique identifying number, characteristic, or code other than dummy identifiers that are not derived from actual identifiers

view

C.3. Coding and Data Use Agreements

C.3.1. When you receive these data, records or human biological specimens will they be coded? Coded means identifying information that would enable the research team to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code). If you will not be using existing materials, check NO.

Yes

Will any of the personnel involved in this study (this includes collaborators providing data or specimens, personnel listed on grants, co-authors, and Responsible Faculty) have access to a key that deciphers the code, enabling linkage of identifying information to private information or samples?

No

Do ALL of these data, records or specimens exist at the time of this application?

No

If no, explain how prospective data collection will occur.

Data collection will begin by measuring the current opioid prescribing practices of the hospitalists, including both medical doctors (MDs) and advanced practice providers (APPs), at Atrium Health Carolinas Medical Center. This consists of 44 providers, including 34 MDs and 10 APPs. An Excel spreadsheet will be utilized to list each provider, identified by a number, to identify current opioid prescribing practices pre-intervention. Opioid prescribing practices will be specifically measured by the number of opioid prescriptions written.

The educational component of this Doctor of Nursing Practice (DNP) project will be measured by pre-and post-test scores as well as attendance of the initial training. There will be an Excel spreadsheet listing each provider, identified by a number, to identify their chart audits to maintain confidentiality. The identity of each provider will be kept separate from the data collected. Retrospective chart audits will be utilized to determine provider compliance with the recommended opioid-prescribing guidelines. Data will be collected from the clinical site, Atrium Health Carolinas Medical Center, to determine whether prescribing practices adhere to the CDCs opioid prescribing guidelines to include the dosage and quantity of opioids that were prescribed to patients. A random sample will be taken from electronic medical records and coded for anonymity. Information obtained will be put into an Excel spreadsheet and composed for use in the Statistical Package for the Social Sciences (SPSS).

NHSR

NHSR Activities

Based on your responses, it appears that you are proposing a project that <u>may not</u> constitute research involving human subjects, and therefore <u>may not</u> require IRB approval. Please select the activities from the following list that best describe your project. ORC will review this submission and you will be notified of the outcome. Please refer to ORC <u>Guidance</u>.

Check all the following that describe your project.

Reference ID: 184960 Date Received: Draft Page: 7 of 10

- X Program Evaluation Note: Program Evaluation may also be for research purposes. Please refer to ORC Guidance.
- Class projects for educational purposes only. Note: Projects that will be used for thesis or dissertations are not considered class projects. Please refer to ORC <u>Guidance</u>.
- ✓ Quality Improvement and or Quality Assurance for internal purposes
- ★ Center or core grants to establish infrastructure.
- X Training grants
- X Demonstration projects
- Case report. Publication of clinical scenario that has already occurred.
- X Secondary analysis of existing deidentified data or specimens. Please refer to ORC Guidance.
- ★ Key informant interviews. E.g., interviewing officials about their organizations or policies, not about themselves.
- Emergency use. Emergency use of investigational test article without prior IRB approval.
- X Deceased. Research involving records or specimens from deceased individuals.
- X Other. Please refer to ORC <u>Guidance</u> regarding activities that may or may not require IRB review and approval.

2. Describe your reasons for checking the box(es) above:

This project has several related objectives. First, to evaluate acute care providers' baseline prescribing practices of opioids in acutely ill patients admitted to the hospital who suffer from chronic non-cancer pain. Second, to develop and implement an educational and quality improvement course with the goal to improve opioid prescribing practices in line with current EBP opioid prescribing guidelines (specifically the CDC). Finally, to evaluate change in knowledge and practices before and after completing the education, and to identify barriers to adhering to the CDC guidelines. A long-term objective would be to reduce the current opioid burden of addiction and overdose, as well as the economic impact, with adherence to CDC opioid prescribing guidelines.

Attachments

This submission requires the following attachments

Document Type

CITI Training Documentation

Other Study Protocol

This submission includes the following attachments

File Name	Document Type
8442_TOPICPROPOSAL_Buckner_V5.docx	Other Study Protocol
8442_Project_Recruitment_Buckner.docx	Letter for Recruitment
8442_Project_CONSENT_Buckner_V3.docx	Consent Form
KnowPain-12_Survey.doc	Electronic Questionnaire Survey
AtriumIRB_Approval_Buckner.pdf	External IRB Approval Letter
Burfield_CITI_Biomedical Certification of Completion_May 2024.pdf	CITI Training Documentation
Burfield_CITI_Social & Behavioral Research_Certification_May 2024.pdf	CITI Training Documentation
Citi_Atrium_DataMgmtIntegritySecurity_Buckner.pdf	CITI Training Documentation
Citi_GoodClinicalPractice_Certficate_Buckner.pdf	CITI Training Documentation

Reference ID: 184960 Date Received: Draft Page: 8 of 10

IRB Number: 19-0776	Initial	Principal Investigator: Kimberly Buckner
Citi_UNCC_HealthInformationPrivacySecurity_Br	uckner.pdf	CITI Training Documentation
Citi_UNCC_SocialBehaviorlResearch_Buckner.p	df	CITI Training Documentation
		view attachment

IRB Number: 19-0776	Initial	Principal Investigator: Kimberly Buckner
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By certifying below, the Principal Investigator affirms the following:

I will notify the IRB if the scope of the activity changes in such a way that the answers on this form are no longer valid. I will ensure that all collaborators, students and employees assisting in this project are informed about these obligations. All information given in this form is accurate and complete.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

I accept ultimate responsibility for ensuring that this project complies with all the obligations listed above for the Applicant.

Date: 5/08/2020 09:34:07 PM
Date:

Appendix K

UNCC IRB Approval

From: IRB <uncc-irb@uncc.edu>

Date: May 20, 2020 at 10:57:46 AM EDT To: Kpayne6@uncc.edu, aburfiel@uncc.edu

Cc: uncc-irbis@uncc.edu Subject: IRB Notice - 19-0776

To: Kimberly Buckner

School of Nursing

From: Office of Research Compliance

Date: 5/20/2020

RE: Determination that Research or Research-Like Activity does not require IRB Approval

Study #: 19-0776

Study Title: Evaluation of Acute Care Providers' Opioid Prescribing Practices in Chronic Non-

Cancer Pain

This submission was reviewed by the Office of Research Compliance, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (e or I) and 21 CFR 56.102(c)(e)(I)] and does not require IRB approval.

UNC Charlotte Mail - Fwd: IRB Notice - 19-0776

Study Description:

Given the current opioid epidemic, it is vital that we have consistent evidence-based practice for how we treat chronic non-cancer pain. In an attempt to follow the Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain, the purpose of this scholarly project is to evaluate acute care providers' opioid prescribing practices in chronic non-cancer pain. The CDC (2018a) urges clinicians to prevent opioid overdoses by following best prescribing practices. Guidelines are not easily integrated into current hospital practice due to a focus on pain control and the acute problem, rather than high-risk patient characteristics for opioid abuse or chronic use (Calcaterra et al., 2015).

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though IRB approval is not required.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

Appendix L

Participant Recruitment Letter & Consent

Dear colleague,

My name is Beth Buckner. I am a doctoral student at the University of North Carolina at Charlotte Doctor of Nursing Practice program. I am kindly requesting your participation in a doctoral quality improvement program that I am conducting entitled: "Evaluation of Acute Care Providers' Opioid Prescribing Practices in Chronic Non-Cancer Pain." In an attempt to follow the Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain, the purpose of this scholarly project is to evaluate acute care providers' opioid prescribing practices in chronic non-cancer pain.

This study involves completing two surveys and an educational session. The KnowPain-12 pain management knowledge survey (Gordon et al., 2014) and a PowerPoint presentation entitled "Prescribing Opioids for Chronic Pain: The CDC Guideline in Practice (PCSS, 2019)."

Participation in this Quality Improvement Project is completely voluntary, and you may withdraw at any time. Information collected will be de-identified and with the conclusion of the study, unidentifiable to individual participants.

Your participation will be greatly appreciated and will offer invaluable information to advance change in ensuring that patients with chronic non-cancer pain will receive evidence-based care by assessing current prescribing practices.

Thank you for your time,

Sincerely,

Kimberly Beth Buckner, AG-ACNP, Doctoral Student, University of North Carolina at Charlotte

Letter of Consent

You are invited to participate in in a quality improvement project about opioid prescribing practices in the acute care setting. The project leader is inviting hospitalist providers currently working in the acute care setting prescribing opioids for chronic non-cancer pain. This is to allow you to understand this project before deciding whether or not to take part. This project is being conducted by Beth Buckner, who is a doctoral student at the University of North Carolina at Charlotte.

Background

The purpose of this scholarly project is to evaluate acute care providers' opioid prescribing practices in chronic non-cancer pain.

Procedures

If you agree to be part of this project you will be asked to complete the following:

- A brief pre-test survey regarding to assess current knowledge of opioid prescribing practices that includes 12 questions (KnowPain-12) that will take approximately 15 minutes to complete.
- Educational session presented via PowerPoint presentation outlining current evidencebased opioid prescribing practices based upon current CDC guidelines.
- A brief post-test survey (KnowPain-12) that will take approximately 15 minutes to complete.

Risks and Benefits

There are no risks in participating in this project. It is completely confidential with no identifying information. There will be no patient interaction.

Benefits of this project could improve patient care, satisfaction, and outcomes.

Compensation

There will be no compensation for time spent engaging in this project. Participants will receive free education and best-practice tools to use in their practice.

Privacy

This project is completely confidential and identifying information will be kept private. Identifying data will not be used outside of this project or for any other purpose. No identifying factors such as your name will be included with collected data. All information will be deidentified for security purposes. Data will be secure by password protection and data encryption.

Contacts and Questions

If you have any questions or concerns, you can contact the project leader, Beth Buckner, at kpayne6@UNCC.edu.

Statement of Consent

I have read the above information with the understanding of this project to make an informed consent about my participation. By signing below, I understand and agree to the terms described above.