Co-Prescribing Naloxone Policy for Chronic Pain Patients on Opioid Therapy

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Dedication

I want to dedicate this DNP project to those who have lost their lives to opioid misuse or overdose, and to the families that have suffered this loss.

Abstract

Opioid misuse and overdose related deaths are an escalating problem in the nation that crosses all gender, age, sociologic, economic, and race barriers. A private practice clinic treating chronic pain with opioid medication was the focus for a co-prescribing naloxone policy implementation. Over half of the patient sample was male, with an average age range of 51 to 60 years old and having obtained some level of college education. The purpose of the policy was to provide patient education regarding the risks of opioid medication, naloxone education, and to improve provider barriers in prescribing naloxone. The policy addressed this by removing the burden of risk stratification and applying the universal precautions model from infectious disease to chronic pain patients receiving opioid medications. Ultimately, the increased patient education did not have a significant impact on the number of patients choosing to fill the naloxone prescription. Future practice may include further examination of the patient barriers to filling the naloxone prescription and or including this in the narcotic contract to receive opioid medications to treat chronic pain.

Keywords: opioid misuse, opioid abuse, opioid-related overdose deaths, naloxone, universal precautions, chronic pain

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Chapter One: Overview of the Problem of Interest

Prescription drug overdose deaths are escalating in the state of North Carolina (NC).

Opioid misuse can be a relatively easy term to define; however, identifying patients at risk for

opioid misuse can be a more difficult task. In the 2016 Center for Disease Control and

Prevention (CDC) Guidelines for Prescribing Opioids to Chronic Pain Patients,

recommendations for assessing risk factors and addressing potential harm are made, including

the consideration of offering naloxone to high-risk patients (Dowell, Haegerich and Chou, 2016).

Although this is only a recommendation, a universal precaution model for co-prescribing

naloxone can have a significant impact on reducing opioid-related deaths and focusing on harm

reduction. A policy for providers to co-prescribe naloxone to any patient receiving chronic

opioid medications is the most consistent way to improve the overdose risk for the chronic pain

population and remove the burden of risk stratification.

Background Information

  Opioid misuse and overdoses affect an alarming number of the population crossing all barriers,

including age, socioeconomic status, and geographical boundaries. In 2010, there were 16,651

reports of overdose deaths, then growing to 65,000 in 2016 (Soelberg, Brown, Vivier, Meyer &

Ramachandran, 2017). That is over a 200% increase in six short years. In 2011, Cheatle (2015)

reported 488,004 emergency room visits related to the nonmedical use of opioid medications.

There is a problem regarding opioid usage in society that includes not only prescribing practices

but also utilizing the medicines appropriately. One way to help reduce harm in the chronic pain

patient population is to increase access to naloxone. Thus far, there are only recommendations to

co-prescribe naloxone for harm reduction, including only prescribing to high-risk patients from

the CDC (Dowel et al., 2016). This recommendation would not benefit the patients who take the

medication for nonmedical reasons, recreational use, or take someone else's prescribed medications. By only co-prescribing naloxone to these identified high-risk patients, the emergency room will continue to have a high number of visits and overdose deaths will continue.

Healthy People 2020 focuses on reducing nonmedical use of pain relievers as one of the objectives due to opioid misuse being a widespread issue in today's society (Healthy People 2020, n.d.). The National Survey on Drug Use and Health reported that 53% of patients misusing opioid medications had obtained the medication from a friend or relative that received the opioid directly from one doctor between 2012 and 2013, meaning obtaining the drugs via doctor shopping was not the case (Takeda et al., 2016). Doctor shopping is defined by the Center for Disease Control and Prevention as "a patient obtaining controlled substances from multiple healthcare practitioners without the prescriber's knowledge of the other prescriptions" (CDC, 2012, p. 1). One may imply that the opioid was obtained legitimately by a patient to treat pain. However, the prescriber was unaware of the patient's intent to misuse the prescription for an opioid.

Opioid misuse goes well beyond the initial patient who may have been receiving the medication for a legitimate purpose and prescribed the drug. The behavior of sharing medications is difficult to screen for or catch in many patients. Random pill counts, urine toxicology screens cannot account for one pill that may have been taken by a visiting friend or relative, for example. Fifty-three percent of the 11.5 million people aged 12 and older misused a prescription pain reliever given by, bought from or took the medication unknowingly from a friend or relative per the National Survey of Drug Use and Health in 2016 (Alder & Mallick-Searle, 2018).

Access to naloxone can positively impact the number of opioid-related deaths with consistent co-prescribing and patient education from providers. Currently, the barriers to co-prescribing naloxone include time limitations within patient visits, lack of knowledge regarding how to prescribe the medication, lack of consistent guidelines for the assessment of and identifying high-risk patients, patient cost, and lack of patient education materials. Past research reveals that providers' logistical and attitudinal barriers were vital to overcoming the lack of co-prescribing naloxone (Mueller, Koester, Glanz, Gardner, & Binswanger, 2016). Providers are not always comfortable discussing risk factors with many of their patients, especially on initial visits before establishing a patient-provider relationship. Education is an essential component of overcoming the patient and provider barriers for naloxone co-prescribing (Mueller et al., 2016).

Provider and nursing education for the risks of opioid medication in pain management can have a significant impact on positive patient outcomes. The limited education currently provided to patients regarding opioid risks and naloxone is a barrier that can be improved by consistency from the provider (Mueller et al., 2016). The universal precautions model used by the University of New Mexico's Pain Center Study for co-prescribing naloxone rescue kits to all patients on opioid therapy for chronic non-cancer pain found no opioid-related deaths after the education of the patient and family (Takeda et al., 2016).   When applied to the pain population, the universal precautions model means that the naloxone is prescribed to each patient receiving a prescription for opioid medication, rather than being based on the risk evaluation.   Therefore, removing the burden of risk stratification for the provider. Gourlay and Heit (2009) state that the universal precautions model is the most accurate way to decrease risk in the chronic pain population receiving opioid medications due to recognizing the impossibility of accurate risk assessment at the initial visit.

"It is important to note that universal precautions are not simply about opioid prescribing, although it does highlight the value inherent in managing risk in all patients" (Gourlay & Heit, 20019, p. S116).   For example, a patient is not likely to be one hundred percent forthcoming or honest at an initial visit regarding complete health history. Therefore, this impacts the ability of the provider to assess any risk factors accurately. The idea of managing risk in all patients, compared to the medication, is a significant finding; adoption of this model in an ambulatory setting is a useful public health intervention in private practice in eastern NC.   Gourlay and Heit also highlight the fact that there is no reliable data to support chronic opioid therapy prescribed for cancer versus non-cancer pain and co-occurring opioid misuse or overdose risk (2009). Patients receiving opioid therapy for cancer pain are not at any less of a risk for opioid overdose in comparison to the non-cancer pain patient population. Using the universal precautions method, this patient population that can be difficult to treat as a provider has the potential for better outcomes and decreases patient harm.

Significance of Clinical Problem

Currently, the CDC Guidelines for Opioid Prescribing for Chronic Pain Patients recommend naloxone prescribing for those who are at high risk for opioid therapy (Dowell et al., 2015). Currently, the Opioid Risk Assessment Tool is the screening tool for high-risk behavior for all patients. However, naloxone co-prescribing is inconsistent with each provider due to a lack of guidelines or policy. Implementing a naloxone co-prescribing policy, including patient and family education, will help create consistency within the provider group, potentially improving patient outcomes, and harm reduction in this patient population. The proposed Doctor of Nursing Practice (DNP) Project is to implement a naloxone co-prescribing policy for the providers using a universal precautions model. Naloxone co-prescribing is a current gap in

practice and is an essential component for treating the pain patient population utilizing chronic

opioid therapy. There is intense scrutiny of pain management practice with the current opioid

crisis from governing bodies, and harm reduction is a critical component. For the patients on

chronic opioid therapy, the risk of overdose is the most significant harm. However, by placing

the focus on individual risk factors, there is an inhibition of naloxone prescribing due to the

target of patient behavior. Removing the focus on individual risk factors reinforces the value of

standardized or universal naloxone prescribing by lessening provider fears of offending a patient

or medical-legal consequences (Binswanger et al., 2015).

Question Guiding Inquiry (PICO)

The importance of naloxone co-prescribing for the organization is to consistently reduce

harm in the chronic pain population receiving chronic opioid medication and potentially reduce

the number of opioid-related deaths in the community. In 2017, the National Institute on Drug

Abuse (n.d.) reported that 1,953 overdose deaths occurred in the state of NC, a rate of 19.8 per

100,000, and higher than the national average of 14.6 per 100,000. North Carolina had a higher

number of opioid prescriptions written by providers than the national average (National Institute

on Drug Abuse, n.d.). These numbers increase the average healthcare cost in NC and illustrate

the need for harm reduction in this patient population.

Population. The target population for this proposed DNP project is the providers and

nursing staff. The providers include five physicians, two nurse practitioners, and five registered

nurses that rotate in the clinic.

Intervention. A universal precautions model will be used to implement a naloxone co-

prescribing policy for providers for each patient receiving opioid medication for chronic pain.

The policy will be a universal approach to harm reduction and include patient education provided

by the nurse the day the provider writes the initial prescription. The providers will receive

education regarding the new policy in a staff meeting.

        Comparison. There will not be a data comparison for the reason that this is a policy

implementation project. The policy outcome measures will depend on the providers and nursing

staff's adherence after implementation and are independent of any information before the policy.

        Outcome(s). The intended outcomes are improved naloxone co-prescribing, improved

patient knowledge regarding when and how to use naloxone, and actual filling of the prescription

by the patient.   The three identified measurable outcomes would determine if providers follow

the co-prescribing policy universally to all chronic pain patients receiving opioid therapy and if

the policy is effective for the chronic pain population to increase access to naloxone.

Summary

        The chronic pain population treated with opioid therapy is at high risk for opioid-related

overdose and death. Unfortunately, it is not always the patient with a valid prescription for an

opioid that misuses the medication with an adverse outcome such as an overdose. Utilizing a

universal precaution model for co-prescribing naloxone is effective in harm reduction in this

patient population (Takeda et al., 2016). "This model can be a simple, streamlined and valuable

addition to most ambulatory settings- especially pain clinics and primary care sites where

chronic opioid therapy is prescribed" (Takeda et al., 2016, p. 9). Barriers to co-prescribing

naloxone may include provider and patient education as well as previous experience. These

barriers can be overcome with a policy in place to ensure consistency between providers in a

healthcare setting and harm reduction.

Chapter Two: Review of the Literature

One of the attributing factors to the opioid epidemic of recent years is the number of opioid medications prescribed in the United States when compared to other countries. The number of prescriptions for opioid medications directly impacts the number of opioid medications that are misused, highlighting the risk factors due to the increased availability of the medicines. The most significant risk of opioid misuse is an overdose. Implementing a universal precautions model for prescribing naloxone to each patient receiving chronic opioid therapy can significantly impact the number of adverse outcomes and overall harm reduction. A literature review for naloxone prescribing in a universal precaution manner finds supportive evidence for harm reduction.

Literature Appraisal Methodology

Sampling strategies. A literature search was conducted on ECU Laupus Library's "one search" bar initially using the search terms naloxone, co-prescribing, and universal precautions. The inclusion of the term provider education and the other terms did not return any articles. Therefore, removing provider education from the initial search. The search then returned 16 items, including databases OVID, PubMed, CINAHL, and MEDLINE. Then, it conducted a second search utilizing the same keywords on Google Scholar returning 53 articles. After review, 37 articles remained, and after removing duplicate results for the same search terms (see appendix A).

Evaluation criteria. The parameters for the search included English as the primary language and articles within the past ten years. Opening the search for the past ten years was beneficial due to the limited information for the universal precautions model and application to pain management. The literature search was limited to articles within the past five years for

research related to policy implementation.   This limitation excluded six of the articles, and 31

remaining to review the full text. Articles included both primary care settings and specialty

clinics; the type of clinic was an excluding factor.

Articles excluded in this process focused on universal precautions not related to

managing the pain patient, naloxone prescribing, and those that did not focus directly on

prescribing an opioid medication. Then applying the exclusion criterion to the search, seven

articles remained for a full review. The seven articles remaining were directly related to

prescribing naloxone, chronic opioid medication prescribing policies and guidelines, and harm

reduction in this patient population. The seven articles vary in level of evidence, including

systematic reviews, expert opinions, and descriptive/qualitative studies as Melnyk defines the

levels of evidence for research in nursing (Melnyk and Fineout-Overholt, 2015) (see Appendix

B). Melnyk and Fineout-Overholt (2015) described seven levels of evidence; systematic review

and meta-analysis of randomized controlled trials resulting in practice guidelines, one or more

randomized controlled trial, controlled trial with no randomization, case-control or cohort study,

systematic review of descriptive and qualitative studies, single descriptive or qualitative study

and finally expert opinion.

Literature Review Findings

Overdose potential is multifaceted and can include behaviors such as overtaking the

prescribed medication or also taking the medication in combination with other prescribed or not

prescribed medications that create a synergistic effect on the central nervous system. Anesthesia

Analgesia published a literature review, The US Opioid Crisis: Current Federal and State Legal

Issues, which reveals staggering numbers in the increasing number of overdose deaths from

prescribed opioids in 2010. The literature review found that 16,651 overdose deaths documented,

growing to 65,000 in 2016, increasing the number of emergency room visits by over 200% in the short period (Soelberg et al., 2017). The staggering numbers prompted many states to invoke easy access to naloxone in pharmacies without requiring a prescription from a provider. Multiple studies demonstrate a direct correlation between opioid dose and the risk of overdose, reinforcing the importance of appropriate patient selection and risk factor evaluation.

The diversion of prescription drugs, opioids specifically, has had a drastic impact on our society. Data collected from the state and national level reveal that diversion of prescription opioids has been the most significant contributing factor for the increase in the number of overdoses in our country. For an opioid medication to reach the street, for example, it has to start with a prescription rendered to a patient or, in other terms, a patient has to seek care for pain. Often, medications that are not needed or leftover after a surgical procedure end up in a medicine cabinet and forgotten until a child, caretaker, or houseguest finds the remaining pills. The owner of the medication may never know the medication is gone. An opioid medication may have been inadvertently taken from the patient's home and subsequently sold or taken by someone without a prescription for the medication. Taking medications prescribed to others can result in an overdose or other adverse events.

Level one evidence, as defined as clinical guidelines based on a systematic review of literature, was found in the literature review to support the reduction in harm by utilizing universal precautions prescribing model for naloxone, meaning prescribe naloxone to all patients on chronic opioid therapy regardless of risk factor (Melnyk & Fineout-Overholt, 2015). Gourlay, Heit, and Almahrezi (2005) include research from infectious disease and state that a reasonable approach to reducing the risk of transmission of life-threatening diseases to healthcare professionals was to take a basic level of precaution to all patients, including hepatitis B,

hepatitis C, and human immunodeficiency virus. This universal precautions model approach to

the pain population can improve patient outcomes due to the difficulty in accessing risk, and

after the realization that it is impossible to assess risk entirely and accurately (Gourlay, Heit, and

Almahrezi, 2005). Accurately assessing risk in the chronic pain population is nearly impossible.

There is no evidence to support increase harm in prescribing naloxone to any patient, although

there is provider apprehension that naloxone may encourage drug abuse. The most significant

limitations found in the literature review were that of the provider. Limitations including a lack

of knowledge of how or when to prescribe naloxone or the apprehension that the patient may feel

targeted when prescribed the rescue drug, and lastly, the naloxone can facilitate the abuse of an

opioid.

The 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain finds that opioid

therapy significantly increases the risk of an opioid use disorder, overdose, and death with dose-

dependent effects (Dowell et al., 2016). However, after review, Dowell et al. (2016) presented

the data as Type 3 evidence meaning there were notable limitations to the randomized and

observational clinical trials. However, one of the CDC's twelve recommendations is to assess

risk and address harms, which includes prescribing naloxone when indicated to high-risk patients

(Dowell et al., 2016). The CDC identifies patients at high risk as patients at risk for opioid

overdose, including a history of overdose, a history of substance abuse disorder, and high-dose

opioids of morphine equivalents higher than 50 milligrams total daily dose or concurrent

benzodiazepine use (Dowell et al., 2016). The recommendations did not include how to

appropriately assess risk other than an evaluation of the patient history of substance abuse,

history of overdose, high dose narcotics over 50 daily morphine equivalents, or concurrent

benzodiazepine use (Dowell et al., 2016). This information is highly dependent on a reliable

patient interview, which is not always the case in this patient population, especially at an initial visit without the patient-provider relationship yet established. The chronic use of opioid medications significantly increases the risk of overdose potential; this is unequivocal in the literature. However, patient-specific risk is more difficult to access accurately.

The prevalence of opioid misuse is significant in the United States (US), as evidenced by the number of related opioid overdoses that have more than quadrupled over the past five years based on the CDC Statistics and National Drug Abuse Survey (Katzman et al., 2018). The definition of opioid misuse is "defined as the intentional therapeutic use of a drug in an inappropriate way while in contrast abuse was defined as an intentional, nontherapeutic use of a drug or substance for the purpose of achieving a desirable psychological or physiological effect" (Cheatle, 2015, p. S4). The literature supports the co-prescribing of naloxone for any patient receiving chronic opioid therapy.   By prescribing naloxone to every patient, the question of how or when to prescribe naloxone is not part of the decision making process. The universal precautions model also effectively and adequately removes the need for providers to assess risk factors for each patient presenting for evaluation, immediately removing two of the provider barriers to prescribing naloxone.

Each of the studies included in the literature review had a similar intervention by prescribing naloxone to patients receiving chronic opioid therapy. Nursing education was a focus in addition to the prescription of naloxone in the study by Costello and Thompson (2015). This study found that the significant gap in nursing knowledge impacts patient outcomes due to the patient not receiving accurate information. Nursing education regarding opioid medications, including patient risks and benefits, positively impacted patient-related outcomes, specifically focusing on the risk of overdose. The findings include that nursing education significantly

reduces harm in this patient population in combination with naloxone prescribing. For this reason, the nursing education component is essential in the proposed co-prescribing policy proposal.

Limitations of the Literature Review Process

The literature review process highlights some limitations to a universal precautions approach to prescribing naloxone to chronic pain patients. Costello and Thompson (2014) found that a significant limitation to their study was the sample size and the lack of similar studies for comparison when evaluating the nurse's role in patient education for co-prescribing naloxone. Other limitations identified in the literature review include findings that may not be generalizable to other settings, including a community at large as the target population versus the small cohorts used for many studies. Due to the Health Insurance Portability and Accountability Act (HIPAA), direct outcome measures of the community members who received the naloxone are not achievable (Katzman et al., 2018). Tracking the administration of naloxone is difficult and may not correlate with the patient filling the prescription. Another limiting factor includes Katzman et al. (2016) findings that there is a lack of consistency when evaluating the provider's ability to identifying risk factors. Depending upon medical and psychosocial conditions, the risk of a drug overdose death and aberrant behaviors can be fluid and ever-changing. Risk mitigation is ongoing for the chronic pain population. Circumstances change, as do patient intentions with time, and find that evaluation of risk factors cannot merely be accurate with one visit. Providers should be addressing risk factors on every visit. A limitation of the literature review includes that the studies are a snapshot of a moment in time in an evolving problem in this patient population. Risk evaluation is an ongoing process throughout the patient-provider relationship.

Discussion

  Conclusion of findings. The literature review for co-prescribing naloxone for patients receiving chronic pain medications is supportive of the intervention for harm reduction in the patient population. The CDC has put forth guidelines for prescribing opioid medication in 2016 that includes prescribing naloxone for patients receiving opioid medication found to be at risk of overdose. It is not clear how to appropriately assess patient risk.   The literature review does support prescribing naloxone to all patients receiving opioids rather than based on the risk or behavior focus of the individual patient.   The ultimate goal is harm reduction, decreasing the risk of overdose and opioid misuse.

  A key component for a successful policy to be implemented is education for the provider and the patient. The provider education can improve many of the barriers to prescribing naloxone, including knowing when and how to prescribe naloxone and the fear of medical-legal issues and patients feeling targeted receiving a prescription. Patient education is essential regarding the correct use of naloxone and how to identify an opioid overdose. Implementing a universal precautions model to prescribe naloxone to all chronic pain patients with a prescription for an opioid medication removes the barriers to care and improves patient outcomes. The removal of these barriers is beneficial for providers caring for a patient population that can be difficult to care for safely and effectively.

  Advantages and disadvantages of findings. The advantages of the literature search findings include guidance in applying the universal precautions model to a naloxone co-prescribing policy. The literature also highlights the importance of the education component of prescribing naloxone and that it is essential for successful patient recognition of when and how to use the medication.   The patient education component of the policy will significantly improve

patient outcomes as evidence of the previous research. The disadvantages of the proposed

naloxone co-prescribing policy that the literature search reveals did support the apprehension of

providers prescribing the medication for reasons including lack of knowledge and fears; this may

affect provider compliance with the new policy implementation.

  Utilization of findings in practice change. The implementation of The Policy for Co-

prescribing Naloxone for Chronic Pain Patients Receiving Opioid Medications and utilization by

all providers in the clinic will be effective on the implementation date. The targeted environment

will be an interventional pain clinic. Before the implementation date, a clinic meeting will be

held with all the nursing staff to provide staff education for the policy and the nursing education

role that is a vital component for the success of decreasing patient harm with prescribing opioid

medications. A vital component of the nursing education is informing patients of the risks of

opioid medications, identifying an overdose, and when/how to use the naloxone.   A new patient

may choose not to reveal a history of substance abuse for many reasons on an initial visit. It will

be essential to clarify the universal precautions model of the co-prescribing naloxone policy for

the staff. The literature supports that the nursing education component is essential for patients to

know how and when to use the naloxone potentially. Once the nursing staff education is

complete, a provider meeting will be the next step to review the policy and answer any questions

or concerns. The objective will be a policy applied to all patients receiving an opioid

medication. Beyond the education component, the literature does not support a specific

implementation of a universal precaution model for new policies.

Summary

  The proposed Co-Prescribing Naloxone Policy planning and implementation as a clinic

policy can occur after completing nursing and provider education. The universal precautions

model will be used to implement the policy in the interventional pain clinic. Prescribing

naloxone based on patient-specific risk factors will no longer be current practice; instead,

prescribing naloxone due to the focus on the risk factor than an opioid medication prescribed.

One of the objectives for Healthy People 2020 is to reduce the number of opioid-related

overdose deaths; this number has been steadily increasing over the past ten years. North

Carolina has 25.1 deaths per 100,000 and is higher than the United States, with 22.8 deaths per

100,000 (Healthy People 2020, n. d.). The universal precautions approach to applying the co-

prescribing naloxone policy will impact a higher number of people our population beyond the

pain population. With consistency, the policy will improve patient outcomes and harm reduction

with nursing education. Policy compliance will improve the overall patient experience removing

the stigma of a naloxone prescription and improving understanding of the risks of opioid

medications. The policy will also achieve harm reduction in the patient's pain population by

decreasing the risk of overdose deaths. There potentially should be a decrease in healthcare costs

with a decrease in emergency room visits due to opioid misuse.   The aspects of co-prescribing

naloxone to chronic pain patients receiving opioid medications accomplishes all three goals of

the Triple Aim outlined by the Institute for Healthcare Improvement.

Chapter Three: Theory and Concept Model for Evidence-based Practice

Health care change is grounded in a theoretical framework. Nola Pender is a nursing

theorist that first appeared in nursing literature in 1982, and has been utilized in healthcare

studies for over 27 years. The primary focus of Pender's health promotion model is to identify

the behavioral factors influencing health behavior and pursuing a change in behavior to achieve a

healthy lifestyle (Pender, 2011). The application of health promotion nursing theory to the

PRECEDE-PROCEED model to implement health care policy as a planning tool to guide the

Naloxone Co-Prescribing Policy implementation and evaluation for this policy. The PRECEDE-

PROCEED Model is used to design health programs efficiently, including program planners,

policymakers, and analyze situations to improve health care outcomes. The model includes eight

phases for identifying, planning policy implementation, and review.

Concept Analysis

The literature review identified key terms and concepts throughout the DNP project.

The terms include universal prescribing, co-prescribing, opioid misuse, opioid abuse, overdose,

and substance abuse. The idea of universal prescribing for naloxone models the universal

precautions from infectious disease and patient care. Infectious disease was the first specialty to

apply the same precautions to each patient regardless of a known diagnosis of transmittable

infection to the provider or others, meaning the treatment of each patient with the same

precautions regardless of diagnosis known or unknown. An example of this is wearing gloves

for each patient with a blood draw. The idea of universal precautions not only improves patient

care but also takes away the task of the provider assessing risk for each patient. The application

of the universal precautions model for patients on opioid therapy is to prescribe naloxone to each

patient receiving an opioid, removing the task of assessing risk for the provider, therefor the

patient does not feel targeted. The universal prescribing model leads to the concept of co-prescribing, simply meaning prescribing an opioid and naloxone together each time.

In clinical practice, the concept of opioid misuse applies when evaluating the patient for addiction, overdose risk, side effects, attributing social factors, quality of life measures, opioid risk tools, and barriers to care. For a provider to safely and adequately treat a patient with chronic pain, a thorough evaluation of patient risk must include opioid misuse potential.   The concept does not exist without each application or component.

Each of the articles stresses the importance of appropriate definitions regarding the terms associated with opioid misuse to understand the concept fully.   Many of the terms defined also are identifying the uses of the concept of opioid misuse. As described in the comprehensive review published by Kaye, et al., misuse is defined as the "use of a medication for nonmedical use, or for reasons other than prescribed (2017). Misuse can be willful or unintentional use of a substance in a manner not consistent with legal or medical guidelines, such as altering dosing or sharing medicines, which has harmful or potentially harmful consequences. It does not refer to use for mind-altering purposes" (Kaye et al., 2017, p. S95).   This concept can be used to evaluate further multiple issues with prescribing opioids, including substance abuse disorder, tolerance, physical dependence, addiction, aberrant drug-related behavior, abuse, diversion, and withdrawal.

The literature review consistently identifies the many contributing attributes to the concept of opioid misuse.   First and foremost, the purpose of prescribing an opioid is to treat the patient's pain utilizing evidence-based guidelines. However, beyond the use of treating pain, other things must be considered, including addiction, quality of life, overdose potential,

diversion, side effects, social impact, and barriers to care. Clarification of the identified terms

defines many of the risk factors for chronic pain patients receiving opioid medications.

Addiction is a component of opioid misuse that is misunderstood with other common terms such

as tolerance and physical dependence. For many providers, addiction is a significant concern for

their patients. Kaye, et al. define addiction as,

> A primary, chronic, neuro-biologic disease with genetic, psychosocial, and environmental
>
> factors influencing its development and manifestations. It is characterized by behaviors
>
> that include one or more of the following; impaired control over drug use, compulsive
>
> use, continued use despite harm, and craving (2017, p. S95).

The term addiction is commonly confused with physical dependence. In general, physical

dependence differs from addiction in that abrupt cessation of the drug may produce withdrawal

syndrome (Kaye, et al., 2017). Physical dependence occurs naturally and is not dependent on

patient compliance of the medication rather consistent use of an opioid.

The definition of physical dependence is similar to the tolerance of an opioid that Kaye,

et al. defines as, "a state of adaption in which markedly increased drug doses are required to

achieve the desired effect or exposure results in diminution of one or more opioid effects over

time" (2017, p. S95). Clinically, when treating a patient with chronic opioid therapy, physical

dependence and tolerance will naturally occur. However, addiction is a characterized behavior

that does not routinely happen in patients prescribed opioid medications. As a provider, it is

essential to know the difference between the terms of physical dependence, tolerance, and

addiction. A clear understanding decreases the fear or concern of addiction does not create a

barrier to caring for a patient that may be showing signs of tolerance to a medication that has

been prescribed over the past two years for example. Clinically the patient may present with

increased pain, seeking or asking for medication and can easily be labeled as a drug seeker.

However, in reality, that patient is tolerant of the current dose of medication, and it may no

longer provide a therapeutic effect.

Theoretical Framework

      Naming the Theory. Nola Pender's health promotion model is grounded in

understanding the determinants of health behaviors to promote a healthy lifestyle in the focus

population.   Pender identifies eight significant factors that influence health behavior that nursing

can identify, providing eight opportunities for nursing interventions (Pender, 2011). Pender

explains that the person and environment are heavily intertwined; however, manipulation of the

environment for health-enhancing behavior influences outcomes, including social and cultural

guidance and cues (Pender, 2011).   Pender states that the relationship between the person and

the environment is reciprocal, further saying that characteristics and life experiences shape all

behaviors, including those that involve health (Pender, 2011). Pender defines health as "the

actualization of inherent and acquired human potential through goal-directed behavior,

competent self-care, and satisfying relationships with others, while adjustments are made as

needed to maintain structural integrity and harmony with relevant environments" (Pender, 2011,

p. 3).   Nursing can create a favorable condition for optimal health for the individual by

collaborating with the individual, families, and community, as stated by Pender (2011).

However, there is also an awareness that situational and interpersonal influences can impact

health in a positive or negative outcome regarding health behavior (2011).

 The health promotion model applies to many obesity studies and nutritional behavior in the

literature. It has not been used in research for naloxone co-prescribing based on the research.

However, there are many components to the health promotion model that make it applicable to

this patient population. One of the assumptions of the health promotion model is that individuals

seek to regulate their behavior (Pender, 2011). There is a portion of the opioid crisis that is due

to social determinants, such as coping mechanisms for other health issues such as untreated

mental health or cancer diagnosis.   The policy for co-prescribing naloxone to all patient patients

promotes the goal-directed behavior of harm reduction and self-care. The policy promotes

healthy behavior with the desired end-point of health decision making and preparation for action

resulting in harm reduction and improved health.

     Application to practice change. The application of the health promotion model to the

co-prescribing naloxone policy applies by targeting a specific risk/behavior to improve health

outcomes in the chronic pain population. The policy addresses specific benefits and potential

barriers incorporating many aspects of patient care, including the provider, family, peers, and the

community to commit to a plan of action and decrease the risk of harm for potential opioid

overdose addressing many components of the model. One of Pender's theoretical statements

supports decreasing barriers and improving family involvement.   "Families, peers, and health

care providers are important sources of interpersonal influence that can increase or decrease

commitment to and engagement in health-promoting behavior" (Pender, 2011, p 5).   The

literature review for naloxone co-prescribing does consistently identify the importance of patient

education and family education for the use of naloxone. The education for chronic opioid

therapy for patients also implies a requirement for patients to thoroughly understand the risk of

taking opioid medications, and the potential for an adverse outcome such as an overdose for

health promotion behavior to exist. Provider education is also identified as an essential part of

co-prescribing naloxone to help mitigate medical-legal fears of prescribing the medication, how

to prescribe the medication, and risk assessment of the pain patient.
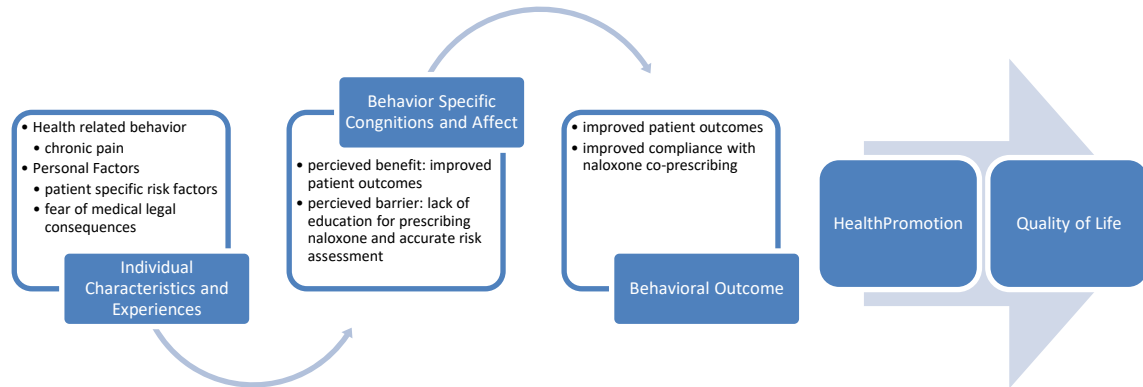
Figure 3.1: This figure outlines Pender's Health Promotion Model as it applies to The Policy for Co-Prescribing Naloxone with Opioid Medications.

EBP Change Theory

    Naming the Change Model. The PRECEDE-PROCEED Model is utilized to create a cost-benefit evaluation framework in health care to design effective programs and policies by guiding initial attention to outcomes rather than the input and using the theoretical framework from the health promotion model from Nola Pender. The PRECEDE-PROCEED model has eight phases that are influenced by the individual and environmental factors, and, has been used as a planning tool with predictive validity (Green, n. d.).

    PRECEDE is an acronym for *P*redisposing, *R*einforcing, and *E*nabling *C*onstructs in *E*ducational *D*iagnosis and *E*valuation (Green, n.d.). This is broken down into the first three phases of the model including diagnosis of the social problem that is affecting the quality of life of the population of interest, the epidemiological diagnosis that determines the specific health issues of the community followed by the education diagnosis that identifies interventions that applies to the patient population selected (Green, n.d.). PROCEED is the second acronym that stands for *P*olicy, *R*egulatory, and *O*rganizational *C*onstructs in *E*ducational and *E*nvironmental *Development* (Green, n. d.). The remaining five phases, including organizational policy

development, implementation of the program, process evaluation, impact evaluation, and finally,

outcome evaluation for the implemented policy to address the identified concern, make this

model applicable to the DNP project to implement a new policy.

The PRECEDE-PROCEED model application to the community health setting, followed

by public health interventions focus on interventions to improve overall health. As it applies to

the co-prescribing naloxone policy, it will be used to reduce harm in the community.

Application to practice change. The PRECEDE-PROCEED Model is an evidence-

based model that will help guide the implementation of the policy to co-prescribe naloxone for

the chronic pain population receiving opioid therapy. There are nine stages to the PRECEDE-

PROCEED Model for healthcare policy implementation. The opioid epidemic and high rate of

overdoses are a community-wide issue; identifying the social diagnosis is stage one of the model.

The desired outcome is identified to reduce the amount of opioid-related overdose deaths. This

goal identified in Healthy People 2020 and harm reduction in the patient population under the

care of a provider for pain with opioid medications.

The second stage of the model is the epidemiological diagnosis, identifying the people at

risk for opioid overdose and whom it effects. The chronic pain patient population that is treated

with opioid medication is at risk for opioid overdose or death by taking a high-risk medication to

treat chronic pain. The third phase is the behavioral diagnosis, patients on chronic opioid

therapy once again are the targets for an improvement in patient outcomes, and chronic opioid

medication use predisposes patients to an opioid-related overdose. It essentially enables family

and friends access to opioid medications.

The fourth and fifth phases of the PRECEDE-PROCEED Model are the developing and

implementation of a healthcare policy to address the healthcare need and improve the quality of

life for this patient population identified.   The educational component of a healthcare policy is evaluated in this phase. For this DNP project, there was a specific lack of provider education regarding the prescribing of naloxone that has been identified. A second educational opportunity is the patient education for when the appropriate administration of the naloxone should be done. Therefore, the co-prescribing naloxone policy addresses both of the education opportunities and was an essential component of the healthcare policy for co-prescribing naloxone.

The sixth phase of the model is the actual implementation of the policy to the specific patient population identified; chronic pain patients treated with opioid medications. After implementation of the policy, phases seven and eight address progress assessment and impact assessment. The nursing staff will address progress assessment with a patient survey at the end of each patient visit, just prior to discharge once the policy is in place. The survey questions will specifically address any lack of adherence for the providers and nursing staff throughout the project on a weekly basis. This will guide the DNP project manager in any changes that need to be made in the implementation process or if further guidance is needed. The impact assessment, phase 8, will also utilize the same patient survey information and data collected throughout the implementation process. The overall impact of the policy for co-prescribing naloxone will be a collection of this same information over a longer period of time.

The final phase of the model is the results of the policy implementation. At this point the final phase and evaluation will reveal if the policy improved patient outcomes by decreasing risk factors for patients treated with opioid medications for chronic pain.   The PRECEDE-PROCEED model is logical to follow for policy implementation and evaluation to improve patient outcomes in this patient population (see Appendix I).

Summary

Pender's health promotion model is grounded in identifying the significant factors influencing health behavior and health promotion. This model also identifies a component in health promotion that is influenced by the social and cultural environment for a patient that impacts health. The health promotion model is essential to understand that the opioid crisis is a community-wide problem and the importance of co-prescribing naloxone to patients in the chronic pain population. Improving and influencing health-promoting behavior can be done by family, peers, and health care providers, and for this reason, Pender's theory applies to this DNP project.

To implement the naloxone co-prescribing policy, the PRECEDE-PROCEED model outlines a model that will encourage the success of the policy by identifying the problem and essentially working backward to finding a solution. The number of opioid-related overdose deaths is the problem identified for health promotion in the chronic pain population. All phases of the model enables identification, implementation, and evaluation in an organized manner.

Chapter Four: Pre-implementation Plan

Policy implementation takes planning, and a good implementation plan has the potential to improve outcome measures for a DNP project. The opioid crisis has shed light on the increasing number of opioid-related overdose deaths.   A policy applying the universal precautions model to co-prescribe naloxone to all patients receiving an opioid medication can decrease the chances of an opioid-related death for this patient population and remove the stress of risk stratification for providers. The organization did not have a policy previously in place to address prescribing naloxone to patients who may or may not display risk factors for opioid-related overdose. The implementation of a successful policy will take collaboration with the providers and nursing staff to ensure policy compliance. The private practice and site for this quality improvement DNP project is willing for this policy implementation and tracking the improvement in patient outcomes and in community health.

Project Purpose

The purpose of the DNP project is to decrease opioid-related overdose deaths in the chronic pain population receiving a prescription for an opioid medication. Healthy People 2020 identifies opioid-related overdose deaths as a focused objective related to substance abuse. Decreasing opioid-related over-dose deaths will address the Triple Aim in healthcare by improving patient care health by decreasing the risk of an adverse outcome with an opioid medication, reducing cost in emergency room visits. Therefore, reduction of overall cost of care, and improving patient education regarding medications.   Partnering with a pain clinic to implement a clinic policy to co-prescribe naloxone to each patient receiving an opioid prescription can impact this patient population by increasing patient safety and decreasing adverse outcomes (see Appendix H).

Project Management

   Organizational readiness for change. The organization, a private pain clinic in Eastern NC, does not currently have a policy regarding naloxone in place to address this critical component of taking care of chronic pain patients maintained on opioid medications. Prescribing naloxone to all patients receiving opioids as a treatment for chronic pain is the missing component. Currently, a naloxone prescription is not consistent practice, and for the most part, is based only on the individual patient risk factors. At previous staff meetings, the nurses have expressed concern for the lack of consistency with the prescribing of naloxone between providers. The most significant barrier, as with any new policy, can be adherence by the providers and nursing staff. Potentially, the time constraints for patient education regarding the naloxone can impact policy implementation. However, as a project leader, it is essential to address this potential barrier by streamlining patient education in a pre-made packet to be as efficient as possible. Optimizing education has the potential to improve adherence to the policy for the nurses providing naloxone education to the patients and is a critical component to the policy's success. Although patient education is an additional task for the nursing staff, there is significant interest in improving the consistency of prescribing naloxone to all patients.

   Interprofessional collaboration. For the policy implementation to be successful, it will take the cooperation of the project site champion, DNP project lead, the office manager, the providers, and the nursing staff of the pain clinic. As the DNP project lead, it will be essential to coordinate meetings for staff education and set forth a clear implementation timeline with the office manager. The site champion will be instrumental in supporting the implementation of the policy with the provider adherence. It will also be beneficial in reviewing the process throughout the implementation to determine if additional education is required for the providers or nursing

staff. The nursing staff will be instrumental in the patient education component of policy

implementation. The perception is that the DNP project lead is the top of the hierarchy;

however, collaboration is more critical to accomplishing successful policy implementation.

Risk management assessment. The strengths, weaknesses, opportunities, and threats of

a project, known as SWOT analysis, can evaluate a project for potential issues during the

implementation process. The *strengths* of this project include the implementation of a policy to

the clinic where one does not currently exist.   The policy implementation can be done once the

provider and nursing education is complete.   Provider and nursing education that takes place

before implementation can make this a smooth transition into a practice change for the providers

and solve questions, concerns, and provide clarification for the staff prior to implementation.

The policy implementation date will be determined and from there, the policy can be expected to

be followed by all of the staff for the clinic site.

Weaknesses for the policy implementation include the time-consuming nature of the

patient education for nursing that is a component of successful policy implementation. Patient

education for the nursing staff to complete at discharge will be a packet of three to four

documents to be reviewed with the patient.   The post-policy implementation survey will be less

time consuming than the primary education, taking five minutes or less.

The clinic site presents an excellent *opportunity* to improve patient outcomes with a

naloxone policy implementation and dissemination in the future to the other clinical sites in

practice throughout NC. Currently, there is not a policy in place for any of the clinical sites of

this practice. The project is an opportunity to address a Healthy People 2020 goal to decrease

opioid-related deaths, improving patient safety, reducing adverse outcomes, and addressing a

community health issue for the patient pain population.

Threats to the co-prescribing naloxone policy include provider compliance. Compliance can be at the provider level or the nursing level, and include the potential of not prescribing the naloxone, incomplete patient education, or lack of follow up survey completion (see figure 4.1).

Strengths

Policy implementation can be a simple change in practice if the provider/nursing education is adequate.

Weaknesses

Time consuming nature of patient education.

Opportunities
The clinic provides an opportunity address a Healthy People 2020 measure, reducing adverse outcomes while addressing a community health issue.

Threats

Provider Compliance

Figure 4.1. SWOT Diagram for Co-Prescribing Naloxone Policy Implementation

Organizational approval process. The organization is an extensive anesthesia practice across NC with a pain management division under the larger entity. The eastern NC pain clinic site is private practice. Concerns presented by the nursing staff have been due to the lack of consistency of prescribing naloxone between the providers.   For this reason, a meeting scheduled with the medical director was an opportunity to present the proposed DNP project. The project approval was seamless after the concern and recognition that a policy was not in place for prescribing naloxone. A presentation of the proposed project then included the site

champion, office manager, and DNP project lead outlining the proposed DNP project process

and potential outcome measures. The literature review was helpful to support the co-prescribing

naloxone policy, and the site approval letter from the practice manager was provided to proceed

with the implementation of the policy. The clearance site letter was completed by the end of the

week to pursue the project at this site. Due to the opioid epidemic, this project is focusing on

harm reduction. The practice agreed to provide this author the pain clinic to pursue the DNP

proposed project (see Appendix C).

   Information technology. The information technology of this project is minimal since it

involves a policy implementation. Information that relates to the policy, including the patient

education, will be a part of the electronic health record (EHR) as a document in the media tab via

scanning into the chart. The EHR will not be used to collect any data for this project. An Excel

spreadsheet will be used to track the data collection from the post-implementation policy survey

that will be administered by the nursing staff; however, it will not include any patient

information. Provider and nursing education will be a presentation in a PowerPoint format with a

printout of the presentation slides.

Cost Analysis of Materials Needed for Project

   The cost burden of opioid-related overdose deaths is an economic burden on health,

substance abuse, and the criminal justice system that totals close to $79 billion, according to the

Center for Disease Control and Prevention (2016). There is an average of $15,000 cost

difference for patients that carry a diagnosis of substance abuse or opioid dependence according

to 2013 data from the National Center for Injury Prevention and Control (Florance, Lu, Xu, &

Zhou, 2016). This is a significant health care cost burden for the nation. The cost associated

with providing a prescription for naloxone and education is minimal in comparison.

The Federal Drug Administration (FDA) reveals that naloxone can cost from $150 to over $4000, depending on the administration route, intravenous, subcutaneous, or intramuscular (Jiang, 2018). In comparison, the wholesale generic cost of naloxone is $20, and in comparison Evzio, the brand name autoinjector is $4000 per dose, a 680 percent increase in cost (Wood, 2018).   In this project, each patient education packet costs less than $10; this includes a magnet for the refrigerator to indicate to emergency services, family, or friends where naloxone is located in the home. The education for the providers and nursing is minimal in cost, other than the cost of their time (see Appendix D).

A prescription for naloxone and patient education can decrease healthcare costs additionally in emergency room visits. It is difficult to evaluate a specific value due to the difficulty of tracking whom the naloxone had been prescribed to, and who administered or received the medication. Regardless of whom the medication is used on, it will decrease healthcare costs and potentially identify those who may need further substance abuse counseling.

Plans for Institutional Review Board Approval

This project site does not have an independent Institutional Review Board (IRB). The practice does not have a formal process for project approval. This will be the first formal quality improvement project performed at this practice site. The process for site approval was a presentation to the medical director, identifying the need for a policy, and the practice benefits regarding patient outcomes accomplished in a 45-minute meeting. The project idea was introduced to the practice manager, and site champion, with a presentation outlining the project and the site clearance approval letter then followed.

For the East Carolina University IRB process, initially, an IRB QI/program evaluation self-certification tool was completed that included eight questions regarding the project, and a

brief description. The DNP faculty, fulfilling the initial stage of the IRB evaluation process,

approved the initial self-evaluation. The second stage of the process was submitted via a

Qualtrics™ survey. Upon submission, the project was deemed quality improvement, and did not

require IRB approval (see Appendix D).

Plan for Project Evaluation

        Demographics. The data collection will be accomplished with a patient survey to be

administered by the nursing staff (see Appendix F). The demographic information collected will

be limited to age, gender, and education level. The demographic variables for age will be

demonstrating ranges in a circle graph. Gender will be reported in percentage distribution.   The

education level and distribution will be presented in a bar graph.

        Outcome measurement. The primary outcome for the project is an increase in co-

prescribing naloxone with any opioid medication to patients in treatment for chronic pain.

Ultimately, the increase in the availability of naloxone will decrease the risk of opioid-related

overdose deaths for the chronic pain patient population. The outcome measures will be derived

from the post-policy implantation survey. The patient survey will include the three questions

addressing naloxone patient education, rendering the naloxone prescription, and filling the

prescription for naloxone (see Appendix F).

        If the naloxone is not co-prescribed by the provider, there may be an indication that more

provider education is needed. Policy adherence is an outcome measure. If the naloxone is

prescribed, and patient education is not provided, the patient may not understand when or how to

administer the life-saving medication. Therefore, it does not matter that the prescription was

provided to the patient. Further education will be needed for the nursing staff regarding the

importance of patient education.

Lack of patient education could result in poor patient outcomes, and the decrease in opioid-related overdose deaths may not improve. This outcome is a process measure that can be impacted by patient education and the overall patient outcome. Tracking distribution of patient education packets will indicate if further nursing education is essential.

Finally, the last question indicates ultimately that the patient understood the prescription for naloxone was rendered, and that patient education was received, including the importance of having this medication available.   Filling the prescription is the final step to impact safety and positively impact patient outcomes when taking opioid medications for chronic pain. The three outcome measures include a process measure, an outcome measure, and lastly, a clinic measure. The overall goal is to improve patient outcomes, and if the naloxone is not filled, this will never improve.

Evaluation tool. The evaluation tool used for this DNP project is a patient survey that the nursing staff administers on a follow-up visit prior to discharge. The survey will consist of six questions, three demographic questions, and three outcome measure questions after the policy implementation. The creation of the patient survey is specific to this DNP project. Therefore, permission to use the tool is not necessary (see Appendix F).

Data analysis. The data from the evaluation tool will track with an Excel spreadsheet. The outcome measures are binary, meaning the outcome measures have been met or not since the project will implement a new prescribing policy. Data will be collected each night from the nursing staff at the clinic to be entered into the spreadsheet three times a week.

The primary outcome measure will determine if the providers are abiding by the policy. As the data is collected, there may be an identified need for an increase in provider or staff education.

The second measure is process measure analyzing if the nursing education is provided; if nursing does not follow this process, the outcomes will not be accomplished. Therefore, as the data is entered, and analysis starts, this can indicate if more nursing education is needed to impact better results.

Finally, the third outcome measure is determining if the patient filled the prescription for the naloxone; this is the ultimate project outcome, and may be impacted by the process. For this reason, it is essential to start data analysis and measures frequently and consistently throughout implementation to make adjustments and potentially improve patient outcome measures. There are currently no benchmarks to use for comparison.

Data management. Project data collection will be each evening after the clinic is complete. On Mondays, Wednesdays, and Fridays, the patient surveys will be coded and entered into the Excel Spreadsheet. Frequent data entry will ensure adequate time to make any adjustments to the policy the next week, including the additional provider or nursing education. The paper surveys will be collected at patient discharge and stored in a locked file cabinet in the office manager's office for the duration of the project. The information is then collated in the Excel data spreadsheet for data analysis on a password-protected computer; however, the hard copy of the survey will be accessible if needed throughout the project duration. Once the project is complete, the patient surveys will be shred, and the Excel spreadsheet will be kept for later dissemination and poster information. There will not be any patient information included in the survey information. The practice administrator, project site champion, office manager, and project leader will have access to the information collected for the project.

Summary

The DNP project site is ready for change and improvement in practice. Although, in this practice, naloxone prescribing is addressed for high-risk patients, there is not currently a policy in place to ensure consistency. Readiness for change will enhance provider compliance, and in combination with nursing education prior to policy implementation, there is an expectation for improving patient outcomes. Data collection with a patient survey will provide outcome measures throughout the implementation process to continuously evaluate provider and nursing compliance. This will allow the project to evolve to accomplish measurable outcomes including prescribing naloxone, patient education for how and when to use the medication, and finally including the patient filling the prescription.

Chapter Five: Implementation Process

Policy implementation takes organization from the project leader and cooperation from a clinical site that is willing to change. A private practice pain clinic that is a part of an extensive anesthesia practice has identified a need for practice change to decrease the risk of opioid-related overdose deaths for patients receiving opioid medications. The project will include all six providers in the practice, and the three nurses in the practice location. The policy will apply to the entire clinic. The PRECEDE-PROCEED model will guide the policy implementation and the potential need to modify the implementation throughout the process.

Setting

The setting for this DNP project is a private practice office-based setting. The private practice is an extensive anesthesia practice located across the state of North Carolina (NC). Within the anesthesia practice, there is a pain management division. The project site is the office in eastern NC that is a part of the pain management division of the larger anesthesia practice. The practice does affiliate with the local medical center regarding anesthesia; however, the pain division is only private practice. The majority of the patient population in the DNP practice site has commercial insurance.

Participants

The DNP project participants are the provider and nursing staff for practice location. There are four physicians, two nurse practitioners, and three nurses that will be participating in the policy implementation. Three of the four physicians are anesthesiologists and board-certified in pain management. The remaining physician is specialized in physical medicine and rehabilitation and is also board certified in pain management. The physical medicine and rehabilitation physician is the site champion for the DNP project.

In addition to the providers and nursing staff, the office manager will also be helpful in the policy implementation in staff education and day-to-day evaluation to ensure the implementation is progressing smoothly. The practice office manager will be essential in helping identify any issues or changes that need to be addressed during the implementation process to ensure the success of the policy. All of the participants are employees of the more extensive anesthesia practice, the nursing staff have been working full time in this location, and the providers rotate to three of the other pain management clinics in practice.

Recruitment

The participants of this DNP project came to be as an employee of the practice at the specific clinical site on a regular basis. Those providers and nurses not employed at the project site are not to be included in the co-prescribing naloxone policy implementation. Before the policy implementation, the providers will participate in a staff meeting to include policy education and the implementation process for the clinic location.   Each provider and nurse will be made aware of the specific implementation date for the policy, and after that, assume to abide by the co-prescribing naloxone policy. This education will also include a PowerPoint for the policy and additional information.

The participants are a convenience sample based on the assumption that they are required to participate as employees of the practice. The option to not participate has been given to the employees. The participant groups are providers, nursing staff, and ancillary staff. The job roles identify the subgroups, and each will be engaging in a different aspect of the project implementation. The provider group has an interest in engaging in the project to provide consistency in care to the patients that are on chronic opioid therapy. The nursing staff has a

desire to create a standard of care for the clinic for all patients that receive opioid medication to

chronic pain patients.

Prior to the policy implementation, a staff meeting addressed the provider and nursing

education; there was a sense of excitement and relief with the staff to create a new standard of

care. The consistency with a new policy in the clinic has the potential to improve patient

outcomes and decreases the risk of adverse patient outcomes for the chronic pain population.

The chronic pain population is a high-risk patient population for opioid-related overdose deaths.

The providers and nursing staff are receptive to any change to improve patient outcomes. The

most prominent concern after the provider education time was the patient cost of the naloxone.

The cost of the medication is dependent on insurance coverage, although NC does allow patients

to pay for naloxone over the counter without the use of insurance.

Implementation Process

The PRECEDE-PROCEED model will guide the policy implementation process (see

Appendix I). The initial stage, known as social diagnosis, begins with the identification of the

opioid-related death risk factor for patients on chronic opioid therapy. Although the DNP project

site providers do prescribe naloxone, it is not consistent among the providers, and therefore

identified a need for a policy.. The creation of the policy is the second and third stages of the

PRECEDE-PROCEED model. The co-prescribing naloxone policy need was identified based on

the opioid epidemic that has been identified by the CDC.

The fourth stage of the PRECEDE-PROCEED model is the educational component of

policy implementation. The next step was to identify the materials for the patient population

regarding naloxone education and use. A patient information packet was created, including

information about naloxone, when and how to use opioid medication safety, where to keep

opioid medications, and the risk factors when taking opioid medications. The patient education

packet includes a magnet for the patient to place on the refrigerator to identify the naloxone

location in an emergency.   The magnet potentially would be for any family member or first

responder that enters the home in an emergent situation to be able to locate the naloxone.

The policy is the fifth stage of the PRECEDE-PROCEED model.   The fifth stage is

developing a policy to address the community health assessment issue. A policy can then

address the identified social and environmental factors in the community. The need for patient

education materials is identified as specific to the opioid-related overdose risks. At that time, a

policy is written for the practice location utilizing the universal precautions model from

infectious disease and Pender's health promotion model. The goal is to prescribe naloxone to

every patient receiving opioid medication for chronic pain regardless of individual risk factors

(see Appendix C).

The implementation of the policy is the next step, and also stage six of the model. Before

the implementation of the policy, provider education regarding the policy is accomplished in a

staff meeting utilizing a PowerPoint presentation. The PowerPoint includes the actual policy,

why the policy is essential with supporting evidence, the overall goal of implementation, and

how to accomplish the policy change within the clinic site. The nurses will be included in

education due to the essential role they will play in patient education. After the instruction is

complete, a policy implementation date of January 13, 2020, is set.

The evaluation of the project during the implementation process is known as progress

assessment, or stage seven of the PRECEDE-PROCEED model. Once the policy is in place, the

nursing staff will identify any patient receiving an opioid medication before discharge. The nurse

will present the education packet to the patient, and record the packet number, and if the nurse

provides the naloxone education. If the education was not provided, documentation would be

recorded in the log. This log will be later recorded into an Excel spreadsheet at the end of each

day.

Stage seven of the PRECEDE-PROCEED model is defined as impact assessment. One

month after the policy implementation, the nursing staff administered a post-implementation

survey to all patients receiving an opioid medication. The post-policy implementation survey

consists of six questions for every patient, including if naloxone education was completed, if a

prescription for naloxone was rendered, and if the medication was filled. There are additional

three demographic questions that will be included. The administration of the survey will be in

addition to continuing to identify patients needing a naloxone education packet.

This final data collection is the eighth and final stage of the PRECEDE-PROCEED

model known as results assessment. Once the nurse completes the short questionnaire, it will be

placed in a locked cabinet and recorded in the Excel spreadsheet each week. The data will be

kept weekly in the spreadsheet, as well as the totals for all of the data collected. The hard copies

of the survey will be kept for the duration of the project and then destroyed. The data collection

will take place for approximately 90 days.

Plan Variation The PRECEDE-PROCEED model is a guide for healthcare policy

implementation and revision during the implementation process. Throughout implementation,

the project was able to continue. However, the data collection at the clinic site was impacted by

the COVID 19 health pandemic that was named by the CDC on March 10, 2020. Many of the

patients face to face clinic visits were transitioned to a telehealth visit utilizing a platform called

Doxy.me. The patients presented virtually, therefore, were not physically present in the clinic to collect the post-implementation survey information. At this time, a decision was made with the site champion to continue data collection over the phone when appropriate by the provider or nursing staff. At this time, a practice decision was made not to initiate any opioid medications without a face to face visit. Therefore, the number of opioid packets dispensed to patients significantly decreased since March.

Summary

For policy implementation to be successful, an organized implementation plan is a necessity. The PRECEDE-PROCEED model is a guide for policy implementation that is beneficial for the process, including process evaluation throughout the implementation before the final stages of impact and results assessment. The goal of policy implementation is to improve an identified community or environment that describes a social diagnosis to improve a specific patient population risk factor, and the PRECEDE-PROCEED model can be a guide for success.

Chapter Six: Evaluation of the Practice Change Initiative

The co-prescribing Naloxone to Chronic Pain Patients receiving Opioid Therapy Policy implementation revealed short and long-term goals that can be objectively measured with the results of a patient survey administered by the nursing staff at the DNP project site. The data gathered was straight forward, and due to the project being a policy implementation, the results included are throughout the implementation time frame. There is no data to compare from before the policy implementation. The project did reveal intended and unintended outcomes that had not been identified before implementation, affecting the number of surveys administered in the implementation process and an unexpected health pandemic.

Participant Demographics

There was a total of 48 total DNP Project participants in the post-policy implementation survey data collected by nursing staff (see Appendix G). The participants were comprised of 52% males and 46% females, leaving 1% of the participants who preferred not to answer the question.   Forty-six percent of the patients were of the ages 51-60 (see figure 6.1).
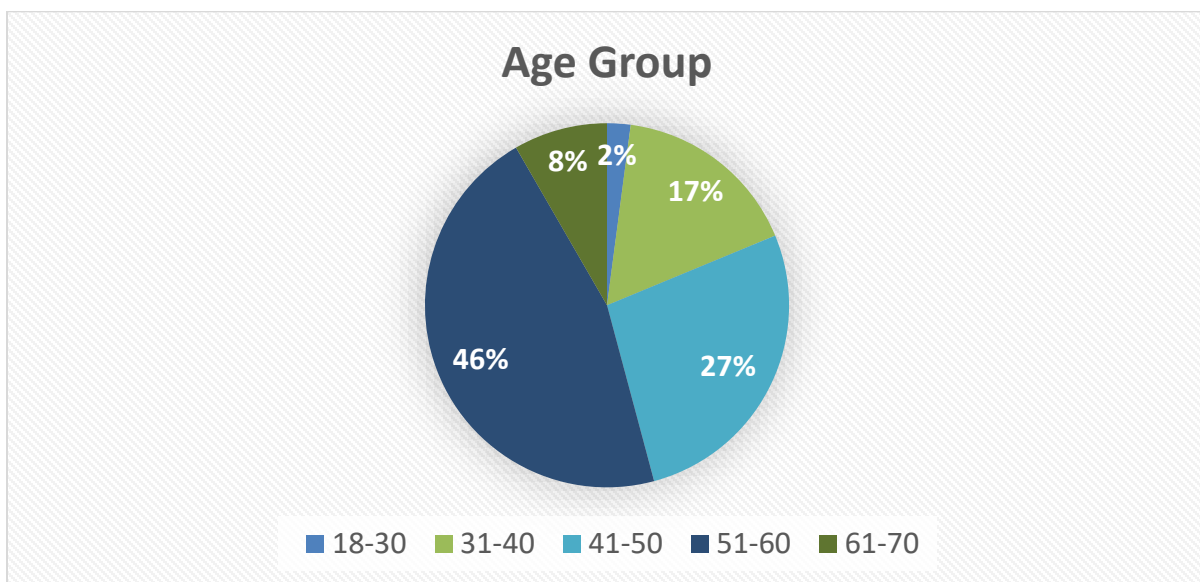

Figure 6.1. Distribution of ages of the project participants.

The education level of the DNP project participants varied from some high school to graduate degree. However, 46% of the participants had completed some college. Thirty-one percent of the remaining patients had completed a college or graduate degree, while 17% of the participants graduated from high school. Six percent of the participants had not completed a high school degree (see Figure 6.2).
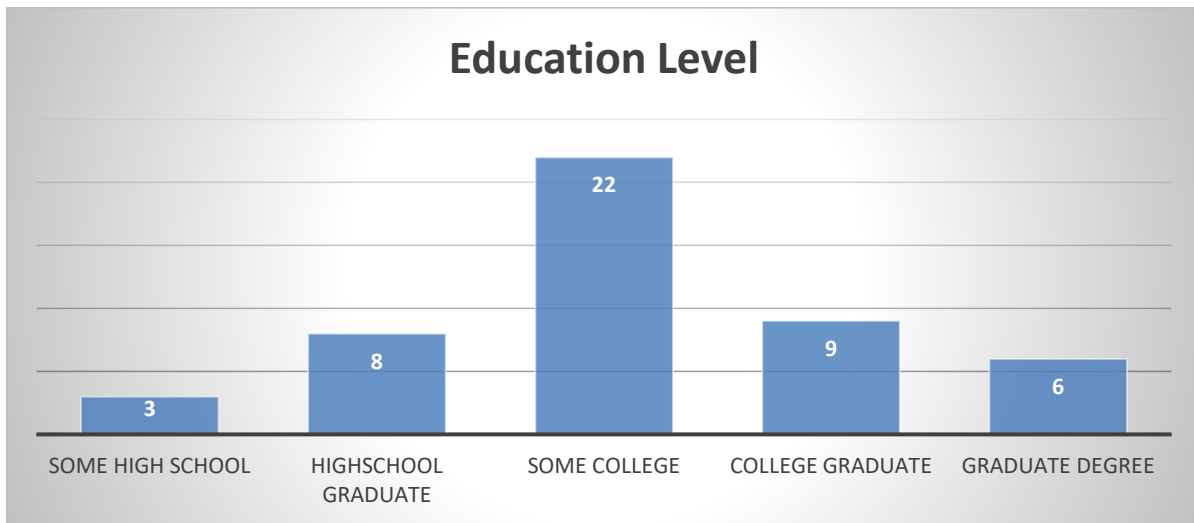

Figure 6.2. Education level of the project participants.

Intended Outcome(s)

Short-term outcomes. The short-term outcomes of this DNP project include the implementation of the co-prescribing naloxone policy. A component of the policy implementation was to provide each patient with an opioid packet that is receiving an opioid medication. This opioid packet includes education materials for opioid medications, naloxone education, instructions for the use of the rescue medication, a prescription for naloxone, as well as a magnet to be placed on the refrigerator for emergency responders or family. Seventy-seven

percent of the patients at the project site have been provided an opioid packet and education when prescribed medication for chronic pain.

Intermediate Outcome. An intermediate outcome in this DNP Project was to determine if a prescription for naloxone was provided to every patient receiving an opioid medication for chronic pain. Fifty-eight percent of the patients at the DNP project site have been provided a prescription for naloxone.

Long-term outcomes. Long term outcomes include increasing the consistency of the providers prescribing naloxone to chronic pain patients on opioid therapy. A second long term outcome evaluated in this DNP project policy implementation included filling the naloxone prescription that was rendered to the patient after the policy implementation.

Findings. The post-policy implementation survey revealed that 77% of the patients received an opioid packet. Fifty-eight percent of the patient population revealed in the survey that a prescription was rendered at the time of the visit. In contrast, the remaining 33% of the patients did not receive an opioid packet with education, and 42% did not receive a naloxone prescription at the time of their visit. Provider and staff education potentially could improve this finding to the goal of 100% adherence to the policy (see Figure 6.3).
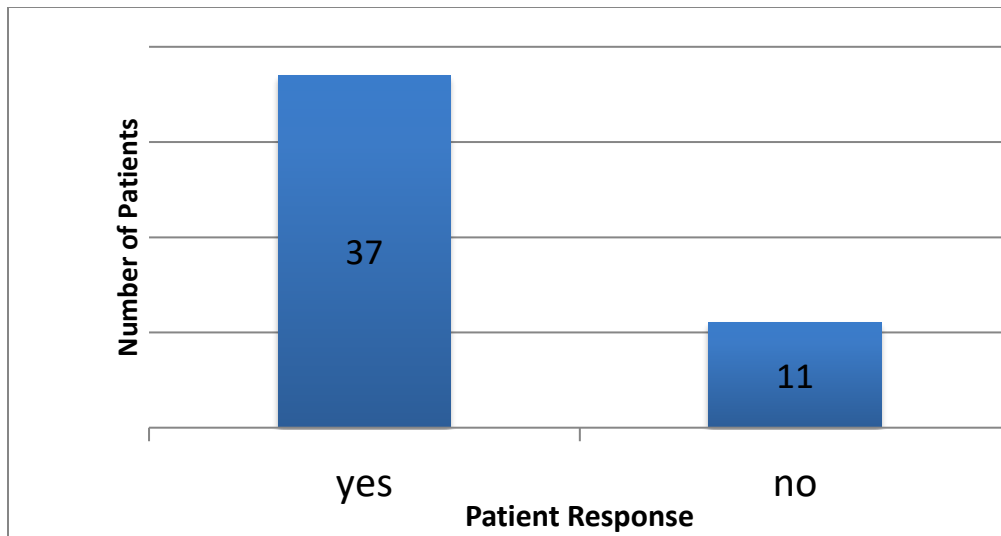
Figure 6.3. Percentage of patients that received an opioid packet and naloxone education.

Although the patients were educated about the risks of chronic opioid therapy, only 33% of the patients filled the naloxone prescription, and 54 % chose not to fill the prescription. Thirteen percent of the patients stated that the prescription for naloxone remained at the pharmacy, and had not picked up at the time of the survey, although it does not identify why the prescription was not filled (see Figure 6.4).

Figure 6.4. Number of project participants that filled the naloxone prescription that rendered at the time of the visit.

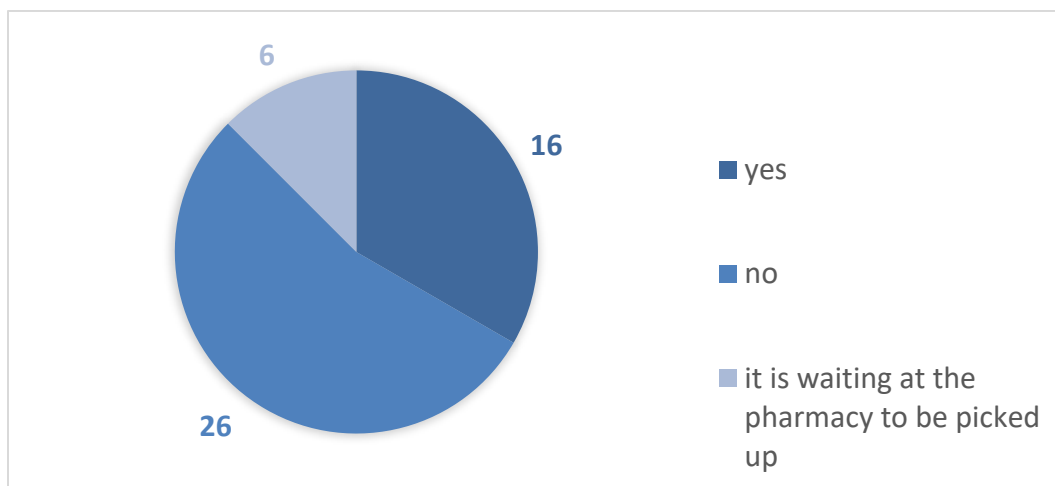An unintended consequence of this DNP project was the actual number of patients prescribed schedule II narcotics at this practice site was lower than expected. The Drug Enforcement Agency (DEA) schedules medications into five categories depending upon the acceptable medical use of the medication as well as the abuse and dependency potential (United States Department of Justice [USDJ], n. d.). Schedule I medications have a high level of abuse potential and physical dependence, as the schedules decrease, so does the abuse and dependence risk for the medications, some examples include buprenorphine products or tramadol (USDJ, n. d.). Schedule III medications contain less than 90 milligrams of codeine per unit or dose per the DEA (n.d.). In comparison, schedule II medications are the more potent opioid medications including medications such as hydrocodone, oxycodone morphine, etc. with higher abuse potential and physical dependence (USDJ, n. d.). The number of surveys collected was lower than expected. The project site does have a significantly higher proportion of patients taking schedule III medications with opioid properties, including tramadol and buprenorphine products. If patients receiving schedule III drugs were included in the data collection, the findings would include a larger sample size.

A second unintended consequence of the DNP project was the public health pandemic that occurred during policy implementation.   On March 10, 2020, the World Health Organization declared the COVID-19 viral disease to be a pandemic. As a result of this emergency, practice patterns were shifting to accommodate the need to treat with unprecedented guidance from federal, state, and local authorities. Some of the advice included, however, was not limited to self-quarantine and limiting physical proximity to others. Patient care continued with the utilization of "telehealth" visits rather than a face to face visits. For this reason, during the implementation, adjustments were made in how the survey was administered. Initially, the

nursing staff administered the survey prior to the patient's discharge. During the health pandemic, telephone surveying was used to administer the remaining surveys for the implementation period.

Summary

The DNP project policy implementation and data did reveal a discrepancy when comparing the number of opioid packets provided to patients and the number of naloxone prescriptions rendered. If providers had followed the policy, 100% of the patients should have received an opioid education packet and a naloxone prescription. However, in comparison, only 77% of the patient received an education packet and subsequently, 58% of the patients received a prescription for naloxone. Provider adherence to the policy was a significant factor in the discrepancy.

After the policy implementation, only 33% of the patients filled the naloxone prescription. Risk mitigation for the chronic opioid patient was removed using the universal precautions model; however, patients still did not recognize the importance of filling the naloxone prescription and the risk of chronic opioid medication usage. A consideration in the future to combat the patient lack of adherence to medical advice will be to discontinue the use of an opioid medication if the prescription is not filled to guarantee the availability of naloxone to this high-risk patient population.

The unintended consequences did affect the number of surveys collected for the implementation period and an unexpected health pandemic. Change in practice did affect survey collection and the number of patients available for this DNP project. Although only 33% of the patients included in the survey filled the naloxone prescription, there will still be a positive impact on harm reduction in the chronic pain patient population.

Chapter Seven: Implications for Nursing Practice

The eight *DNP essentials* create the foundation of the doctorate of nursing practice

degree. This DNP project is a quality improvement (QI) project using a policy implementation

to fulfill all eight of the essentials to advance nursing practice. Advancing nursing practice in the

future with the dissemination of the data collected to improve patient outcomes and harm

reduction to a broader patient population is the ultimate goal. Dissemination of the data includes

potentially applying the policy to future nursing and standard of care practice.

Practice Implications

Essential I: Scientific underpinnings for practice. The scientific underpinnings for

practice are grounded in evidence-based research and the practice of nursing, specifically chronic

pain management. The CDC has outlined guidelines and recommendations for prescribing

opioid medications due to the opioid crisis in the community. The literature review reveals

evidence to support the prescribing of naloxone for harm reduction in this patient population.

The literature review indicates that risk analysis is a difficult task for providers in the chronic

pain population and has been a barrier to prescribing in the past. In this DNP project and policy

implementation, practice guidelines have the potential to impact harm reduction by removing the

task of risk assessment and prescribing naloxone to each patient receiving a prescription for a

schedule II opioid to treat chronic pain utilizing the universal precautions model from infectious

disease, and Pender's health promotion model.

Essential II: Organization and systems leadership for quality improvement and

systems thinking. There is an opportunity for quality improvement when there is an identified

community health crisis. For this DNP project, the opioid crisis provides an opportunity for

harm reduction and quality improvement. As an advanced practice nurse, this crisis provides an

opportunity to implement a quality improvement project to fulfill *Essential II*. The co-prescribing Naloxone policy in this DNP project is an example of identifying a health crisis, and attempting to improve harm reduction and patient outcomes through prescribing naloxone to all patients receiving a schedule II opioid prescription independent of risk factors. Accomplishing harm reduction for a specific patient population helps advance the practice of nursing for current and future nurses.

This DNP QI project policy will be utilized initially in one practice site. The intention is to disseminate the information throughout the practice to all clinic sites managing patients with chronic pain, and further dissemination potentially to all the clinical sites across the state of NC.

Essential III: Clinical Scholarship and analytical methods for EBP. A literature review provided the foundation for this DNP project policy development. Evidence-based practice literature for the chronic pain population includes retrospective studies on the chronic pain population and data for naloxone prescriptions rendered by the provider in the current health care setting. The literature review also revealed the barriers to prescribing that included the provider burden of risk evaluation. Risk evaluation is difficult to access for many reasons, including provider apprehension, lack of time, and the honesty of the patient on the first visit without a patient-provider relationship established. These examples demonstrate the benefit of omitting risk evaluation in many clinical settings. Application of the universal precautions model to the chronic pain patient population on opioid therapy removes the stress of risk evaluation for providers. The knowledge gained through the literature review is beneficial to develop the Co-prescribing Naloxone Policy for implementation in the chronic pain population for harm reduction. A PowerPoint presentation accomplished the nursing staff, and provider education for policy implementation in a clinical meeting setting. Throughout implementation,

the nurses collected data that is presented in an Excel spreadsheet that reflects total data collected and then broken down into weekly data collection segments. Throughout the project implementation, other platforms including electronic mail, telephone calls, and face to face visits for communication.

Essential IV: Information systems/technology and patient care technology for the improvement and transformation of healthcare. Information systems that including the Laupus Library one bar search engine were used for the literature search, providing access to many resources through technology. During project implementation, and data collection, Excel spreadsheets are beneficial to organize and keep track of the data collected. The Excel spreadsheet will allow data collection presentation in the future, including graphs, charts, and create visuals for a PowerPoint poster presentation. This technology will facilitate the dissemination of the data for future improvement in health care policy for naloxone, and continue harm reduction.

Essential V: Healthcare policy for advocacy in healthcare. Healthcare policy is a strategy to advocate safer practice and improve patient outcomes in healthcare based on literature review and research. This DNP project is a policy implementation that advocates for harm reduction in the chronic pain patient population. The foundation for the policy is grounded in the *Essentials I and III* through research and evidence-based practice. Literature supports that patients provided with chronic opioid therapy are at increased risk for overdose. One of the only ways to accomplish harm reduction in the chronic pain patient population is to provide patients with a prescription for naloxone, and education on how or when to utilize the medication.

Essential VI: Interprofessional collaboration for improving patient and population health outcomes. Interprofessional collaboration is essential for improving patient and

population health outcomes. Collaboration with physicians, nursing staff, and pharmacies, to

name a few are essential to improve patient outcomes. For example, the knowledge of the site

champion, the ability of the nursing staff to provide patient education, and the pharmacy helping

the patient being able to fill the naloxone prescription written by the provider are all essential for

the policy to be successful. The interprofessional collaboration will support successful policy

implementation.   The interprofessional collaboration will potentially enhance future

collaboration with other practice sites as well.

Essential VII: Clinical prevention and population health for improving the nation's

health. The opioid crisis has highlighted the risk of overdose death in the US. This DNP project

policy potentially will prevent or decrease the number of opioid-related overdose deaths, and

reduce harm in this patient population. The data collected has the potential to support this DNP

project policy to be utilized in many health care settings, including specialty, and primary care

clinics.

Essential VIII: Advanced nursing practice. Advanced nursing practice is using

underlying knowledge and scientific underpinnings to apply to a current health crisis or problem

to improve patient outcomes and the population.   This DNP policy implementation project is

grounded in the literature review, scholarship, collaboration, data collection, and presentation to

advance nursing practice. The first seven *Essentials* culminate to fulfill the eighth *Essential* and

advance the practice of nursing through quality improvement to disseminate to a broader patient

population.

Summary

The eight *DNP Essentials* are the building block for the Doctoral Education for Advanced

Nursing Practice. Each *Essential* provides a greater depth of knowledge to pursue a successful

project, collaboration, and dissemination to complete the requirements for the DNP degree to be

completed and, ultimately, advanced nursing practice. The eight *DNP Essentials* have been met

throughout this quality improvement DNP project and policy implementation.

Chapter Eight: Final Conclusions

Quality improvement projects are essential to improve patient care and outcomes, and policy implementation is a way to accomplish a specific patient population. This DNP quality improvement project addresses potential patient harm for the chronic pain population on opioid therapy.

Significance of Findings

The post-policy implementation survey found that 77% of the patients received an opioid packet and naloxone education; the goal or intention of the policy was 100%. The same patient population participating in the survey revealed that only 58% of the patients received a naloxone prescription at the time of the visit. Provider adherence to the policy had a significant impact on the findings. The outcomes of the project intended to improve the consistency of co-prescribing naloxone with opioid medications, increase patient knowledge and naloxone prescription filled by the patient. One third of the patients that did fill the prescription have the potential to decrease harm. However, moving forward provider and staff education for the policy will need to be reinforced for improved adherence. Before the organization policy implementation in the other clinic locations, staff education needs to be more intensive and consistent for better adherence. Information that would be beneficial regarding the next step would include identifying the barriers to filling the naloxone prescription. An example may be the cost of the naloxone that may be a barrier for patients. Out of pocket cost for the naloxone or lack of understanding of the purpose of the naloxone are examples of barriers for the patient filling the naloxone. The over-the-counter cost for naloxone is $40.

Project Strengths and Weaknesses

Strengths. The strengths of the project include the simplicity of policy implementation and the minimal cost to the organization. The PRECEDE-PROCEED model outlines an organized process for the implementation of a health care policy and periodic review to ensure success. The education material is reproduced at a low cost per patient and can be adjusted depending on the organization's needs. A regular presence by this author at the project site was also found to be a strength of the policy implementation.

Weaknesses. Provider adherence to the policy was a weakness found in the implementation process. The patient education was time consuming for the staff. This may be a component of the 77% of the patients receiving the education compared to the goal of 100% adherence.

Project Limitations

One of the project limitations includes provider adherence to the policy. One provider in the practice was not in agreement with the risk assessment of patients on opioid medication with the use of the universal precautions model.   The belief of the provider was that the risk is not present for patients on low-dose opioids. Low dose opioid medications are those with less than the equivalent of forty milligrams of morphine for the DNP project site.

A second limitation for the DNP project was the number of schedule II versus schedule III medications prescribed at the project site. This number does vary dependent on the provider in the clinic. For risk reduction and decrease patient harm, schedule III prescriptions should be included in the future in the policy for this patient population due to the opioid properties present in these medications.

An unexpected limitation for the DNP project was the COVID-19 health pandemic occurred in the midst of project implementation. The health pandemic changed how patient care was provided, including telehealth visits rather than face-to-face visits impacting the data collection and the number of patients seen in the DNP project site clinic.

Project Benefits

The benefit of this DNP project includes harm reduction in the chronic pain patient population. The cost of the project is minimal to implement the policy and is dependent on the amount of education material in the opioid packet. The magnet in the education packet used in this project was the costliest component, however, can be omitted if the cost is too significant without changing the project outcomes. The overall project benefits to the site include harm reduction in the chronic pain patient population and quality of care improvement. The use of the universal precautions model from infectious disease removes the provider barriers, including time constraints for risk assessment in a patient visit.

Practice Recommendations

To facilitate change for the project site and organization recommendations to improve provider and staff education before and during the policy implementation are essential for adherence to achieve the goal of 100% of the patient population receiving the opioid packet and naloxone education. Beyond the time commitment for increased education, the cost remains low for policy implementation.

The policy can be improved before dissemination into the other clinical practice sites to include schedule II and schedule III medications. This inclusion of both schedule II and III medications enables the policy to capture a greater portion of the chronic pain population at risk

for increased harm. Ultimately, the goal is for all patients with an opioid prescription to have naloxone available for emergencies.

Future policy implementation may benefit from additional information, including the barriers for the patients filling the prescription for naloxone.   The medication may be costly or not covered by insurance. An addition to the policy may include filling the provided naloxone prescription as part of the care plan as a requirement when treating chronic pain with opioid medication.   The patient potentially could be required to bring the naloxone to each visit as documentation, similar to what is done with the opioid medication for pill counts.

Final Summary

Opioid overdose and misuse have been identified by Healthy People 2020 as one of the goals for harm reduction in the chronic pain patient population to decrease the number of opioid-related overdose deaths. This DNP project addresses harm reduction for the chronic pain population maintained on opioid medications through a quality improvement project policy implementation. The concept of applying the universal precautions model to co-prescribe naloxone to each patient that receives an opioid prescription has the potential for harm reduction. It removes the barrier of providers assessing risk potential for an individual patient. The post policy implementation survey reveals that although 77% of the patients received education regarding the risks of opioid medication and naloxone, only 33% of the patients filled the naloxone prescription.   Prior to further dissemination, identifying the patient barriers to filling the naloxone may be beneficial in addition to further education for providers and nursing staff. Although the goal of 100% was not achieved, significant harm reduction was accomplished for the chronic pain population.

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opioid-overdose-numbers-rise-so-does-the-cost-of-naloxone/

Appendix A: PRISMA Flow Diagram

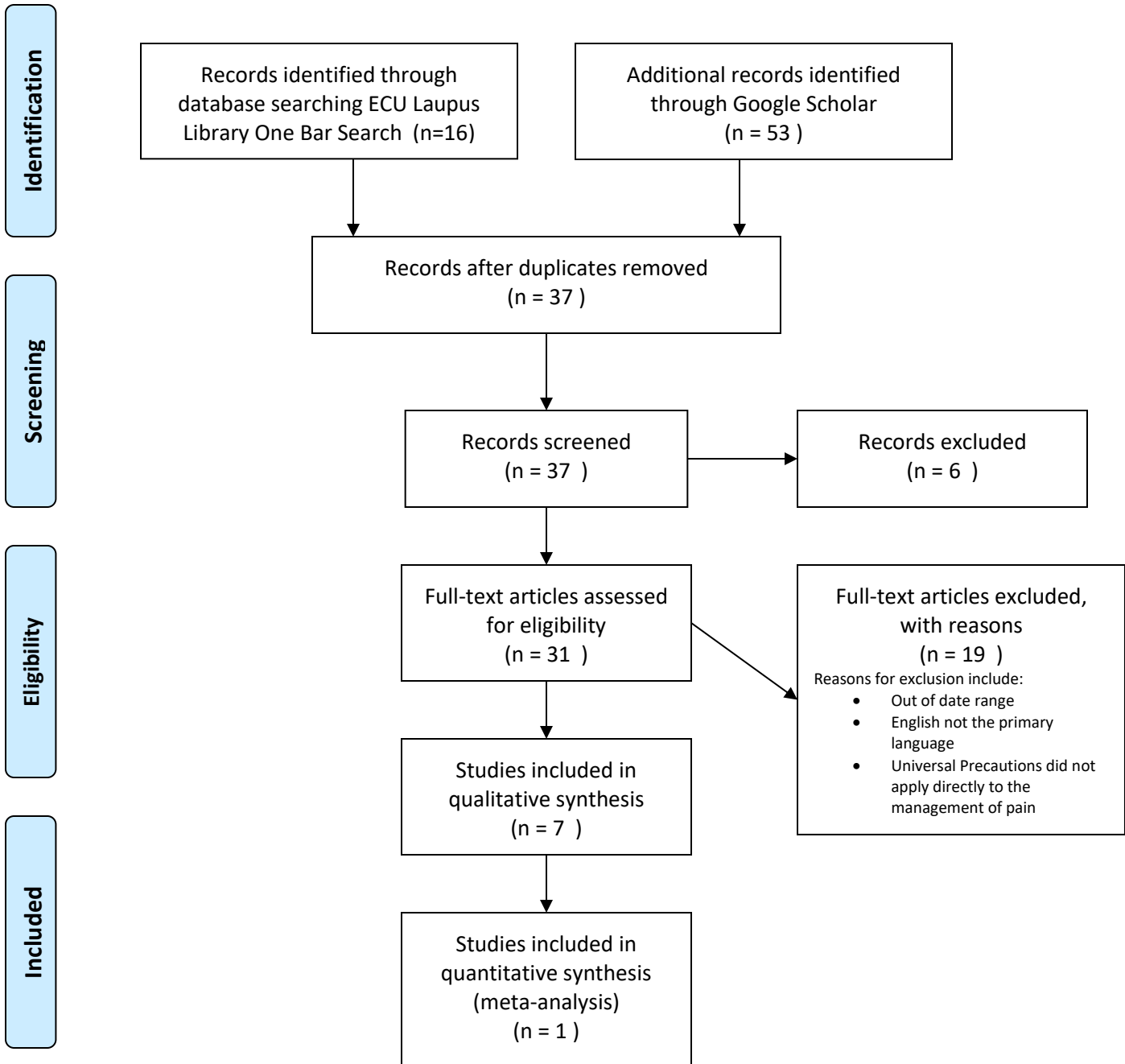Figure 1. PRISMA Flow Diagram for Literature Review

Figure 1. PRISMA Flow Diagram shows the process of the literature search accomplished for the literature review for co-prescribing naloxone to chronic pain patients on opioid therapy (Moher, Liberati, Tetzlaff & Altman, 2009).

Appendix B: Literature Matrix

Figure 2. Literature Review Matrix

Literature Review Matrix				
Student: Margaret Dillon			**Date of Submission: September 25, 2018**	
Faculty: Dr. Reilly				
Co-Prescribing Naloxone Policy for Chronic Pain Patients on Opioid Therapy				
Article (APA Citation)	**Level of Evidence** (I to VII)	**Data/Evidence Findings**	**Conclusion or Summary**	**Use of Evidence in EBP Project Plan** *(Include your evaluation, strengths/limitations, and relevance to your project and other information that you would like to make note of)*
Adler, J. A. and Mallick-Searle, T. (2018). An overview of abuse-deterrent opioids and recommendation for practical patient care. Journal of Multidisciplinary Healthcare, 11, 323-332.	Level I	Outlines best practice guidelines for prescribing abuse deterrent opioids including evaluating risk factors and co-prescribing naloxone based on risk evaluation.	Risk is difficult to assess, and over 53% of the pain relievers misused were given to, bought from or took from a friend to relative, highlighting the importance of opioid medications are not always misused by the patients that are prescribed the meds.	Comprehensive risk management of patients that are prescribed opioid medication needs to be recognized by all providers and the lack of prescriber training on critical issues is a barrier to this patient population.

Binswanger, I. A., Koester, S., Mueller, S. R., Gardner, E. M., Goddard, K. and Glanz, J. M. (2015). Overdose Education and Naloxone for Patients Prescribed in Primary Care: A Qualitative Study of Primary Care Staff. Journal of General Internal Medicine, 30, 1837-1844. Doi: 10.1007/s11606-015-3394-3	Level VI	Focusing on individual risk factors potentially inhibit the naloxone prescription by targeting patient behavior.	Universal prescribing of naloxone to all patients would standardize care between providers and lessen provider fears of offending patients and medico-legal consequences.	Strong evidence that universal precautions prescribing will mitigate some of the barriers to prescribing naloxone for chronic pain patients. Focusing and specific patient behaviors did not improve outcomes. The most significant barriers identified were knowledge, attitude, and contextual barriers.
Cheatle, M. D. (2015). Prescription Opioid Misuse, Abuse, Morbidity, and Mortality: Balancing Effective Pain Management and Safety. Pain Medicine, 16, S3-S8. Retrieved from https://academic.oup.com/painmedicine/article-abstract/16/suppl_1/S3/2472480	Level V	Effective risk assessment and mitigation strategies should include screening for all potential medical and illicit drugs due to the high risk of overdose with opioid medications and concomitant use of substance abuse disorder and psychiatric disorders.	Adequate pain relief should be balanced with risks associated with therapeutic agents used for both the individual and the society.	Many overdoses with opioid medication include the concomitant use of other medications increasing risk factors, and this should be thoroughly evaluated before initiating therapy, this also supports universal prescribing of naloxone.

Costello, M. and Thompson, S. (2015). Preventing Opioid Misuse and Potential Abuse: The Nurse's Role in Patient Education. Pain Management Nursing, 16 (4), 515-519.	Level VI	The lack of knowledge from nursing and lack of sufficient information affect the ability to provide useful medication instructions to patients receiving opioid medications.	The lack of knowledge does not provide that patient with adequate knowledge about the risks of this class of medication and overdose potential.	Although naloxone in this small study, it does reinforce that improved patient education can produce positive outcomes related to the knowledge of opioid medication use.
Dowell, D., Haegerich, T. M., Chou, R. (2016). CDC Guidelines for Prescribing Opioids for Chronic Pain- United States, 2016. Journal of the American Medical Association, 315(15), 1624-1645. Clinical Review and Education Special Communication. Doi:10.1001/jama.2016.1464.	Level I	Evidence-based guidelines for prescribing opioids to the chronic pain patient.	The guidelines include evaluating the patient for risk factors and prescribing naloxone when appropriate or when risk factors are present.	The evidence-based guidelines do recommend prescribing naloxone for patients with identified risk factors; however, it does not identify the best way to evaluate risks; this is a significantly limiting factor.
Gourlay, D. L. and Heit, H. A. (2009). Universal Precautions Revisited: Managing the Inherited Pain Patient. American Academy of Pain Medicine, 10, S115-S123. Doi: 10.1111/j.1526-4637.2009.00671.x	Level VII	This article is an expert opinion and proposed clinical guidelines to manage an inherited pain patient	A universal precautions model to prescribe naloxone to all patients receiving chronic opioid therapy is affectively managing risk in all patients.	This article specifically addresses the importance of using universal precautions model for naloxone prescribing to all patients receiving opioid therapy, highlighting the difficulty of assessing the patient for risk factors on an initial visit. There are limiting factors for accessing risk, including patient reliability, co-morbid conditions, psychiatric disorders, and other medications.

Citation	Level	Finding 1	Finding 2	Relevance
Gourlay, D. L., Heit, H. A., and Almahrezi, A. (2005). Universal Precautions in Pain Medicine: A Rational Approach to the Treatment of Chronic Pain. American Academy of Pain Medicine, 6, 107-112	Level I	The Ten Steps of Universal Precautions in Pain Medicine	The universal precautions model applied to pain management includes prescribing naloxone to each and every patient receiving opioid medication.	The universal precautions model for naloxone prescribing removes potential barriers to prescribing naloxone for chronic pain patients, including provider bias and stigma. It improves patient care, and risk is contained.
Katzman, J. G., Takeda, M. Y., Bhatt, S. R., Balasch, M. M., Greenberg, N., and Yonas, H. (2018). An Innovative Model for Naloxone Use Within an OTP Setting: A Prospective Cohort Study. Journal of Addiction Medicine, 12 (2), 113-118. Doi: 10.1097/ADM.0000000000000374.	Level IV	87% of the community members that received naloxone in this study were friends or relatives of the study participants.	Naloxone is not always used on the prescribed patient but often used on friends or family members that abuse medications.	This article addresses the drug misuse and abuse explicitly, highlighting that the naloxone may not be used on the patient in whom it is prescribed, and this reinforced the importance of not treating the individual's behavior as risk factors rather the medication itself is the risk factor.
Mueller, S. R., Koester, S., Glanz, J. M., Gardner, E. M., Binswanger, I. A. (2016). Attitudes Toward Naloxone Prescribing in Clinical Settings: A Qualitative Study of Patients Prescribed High Dose Opioids for Chronic Non-Cancer Pain. Journal of General Internal Medicine, 32(3), 277-283. Doi: 10.1007/s11606-016-3895-8.	Level VI	With education and a description of naloxone, the patient was able to recognize the ability to reverse overdoses; however, barriers were identified as acceptance of naloxone prescribing.	Barriers to naloxone prescribing include cost, expiration, lack of presence of someone to administer the naloxone, ability to identify an overdose, ability to administer the medication, fear of inducing pain, fear of withdrawal, fear of drug interactions or an adverse event.	This article identifies the barriers and limitations currently with prescribing naloxone to chronic pain patients. The education of patients and providers is the key to overcoming the barriers in this study.

Mueller, S. R., Walley, A. Y., Calcaterra, S. L., Glanz, J. M., and Binswanger, I. A. (2015). A Review of Opioid Overdose Prevention and Naloxone Prescribing: Implications for Translating Community Programming into Clinical Practice. Substance Abuse, 36, 240- 253. Doi: 10.1080/08897077.2015.1010032	Level I	People at risk for overdose and other bystanders are willing and able to be trained on how to administer naloxone to prevent overdoses.	Counseling patients on the risks of opioid overdose and prescribing naloxone has the potential to reduce fatalities and enhance safe opioid prescribing.	This article strengthens the needs for naloxone prescribing policy for all patients receiving chronic opioid medications, highlighting that patient education is an essential component. This needs to be addressed in my DNP project with policy implementation.
Takeda, M. Y., Katzman, J. G., Dole, E., Bennett, M. H., Alchbli, A., Duhigg, D., and Yonas, H. (2016). Co-Prescription of naloxone as a Universal Precautions Model for patients on chronic opioid therapy- Observational study. Substance Abuse, 37(4), 591-596. Retrieved from https://doi-org.jproxy.lib.edu.edu/10.1080/08897077.2016.1179704	Level VI	A universal precautions model was used to prescribe naloxone in a specialty clinic, and after the naloxone rescue kits were dispensed at the seven months follow up, no overdoses had occurred.	Universal prescribing for naloxone to all patients of chronic opioid therapy had a significant impact on harm reduction and decrease in overdose deaths.	This article strongly supports the universal precautions prescribing model for naloxone in harm reduction in this patient population.

Figure 2. Literature Review Matrix for the literature search for DNP Proposed Project- Co-Prescribing Naloxone to Patients Receiving Opioid Therapy.

Appendix C: Policy

Co-Prescribing Naloxone Policy for Chronic Pain Patients on Opioid Medication

Co-Prescribing Naloxone Policy

The recent opioid epidemic has led to an increase in opioid related overdoses. Research has shown that co-prescribing naloxone to patients receiving opioid medication has decreased the amount of opioid related deaths. Therefore, this policy is to address the need for prescribing naloxone to each of our patients receiving and opioid medication by utilizing the universal precautions model from infectious disease. This ensures that each patient receives the education and the prescription regardless of risk assessment, provider knowledge of naloxone or targeting specific patients.

Policy Implementation Date: January 23, 2020

Date of Policy: September 21, 2019

POLICY: Each of these patients identified by the nursing staff as receiving an opioid medication will then receive an opioid packet prior to discharge. Within the opioid packet will be the prescription for naloxone from the provider, naloxone education and instruction, and SAMSHA information for patients and family members on opioid medication. Nursing staff will review with the patient the information and answer any questions or concerns of the patient.

Universal Precautions Model: The application to each patient of the same level of precaution regardless of risk or knowledge of patient specific information.

Appendix D: Site Approval Letter
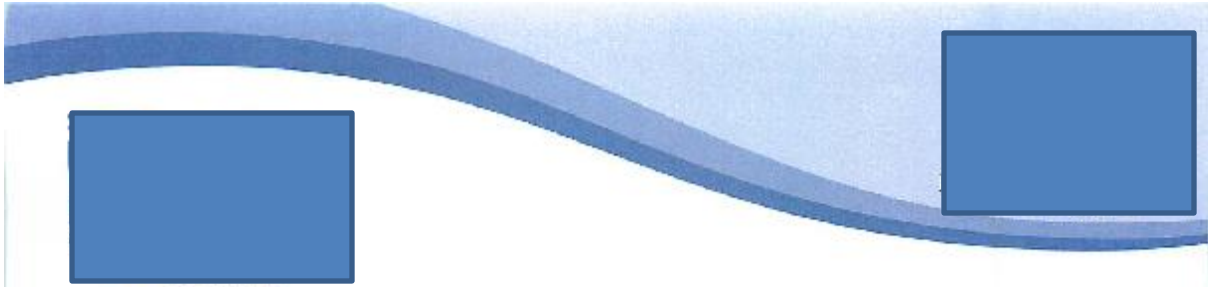
July 8, 2019

To East Carolina University College of Nursing:

[   ] have reviewed
[   ] Project Proposal *"Co-Prescribing Naloxone Policy for Chronic Pain Patients on Opioid Therapy"*. Ms Dillon has organizational support and approval to conduct their Doctor of Nursing Practice student project within our institution [   ] Our organization's liaison, or project champion, for the project is [   ]

We understand that the timeframe for this project is from the date of this letter through August 1, 2020. Implementation at the project site will occur January 2020 through April 2020, unless otherwise negotiated. We understand that for Ms Dillon to achieve completion of the DNP program, dissemination of the project is required by the University and will include a public presentation related to the project and submission to the ECU digital repository, The ScholarShip. In addition, we understand that ECU College of Nursing encourages students completing exemplary scholarship to develop a manuscript for publication, but that is not a requirement. Our organization understands and agrees that the student will not use our organization's name in the formal project paper or any subsequent posters, presentations, or publications.

Our organization has deemed this project as a policy development initiative. Our organization is aware that this project will be processed first through our organizational approval process and then through the ECU College of Nursing process, which may include a formal review through University and Medical Center Institutional Review Board of East Carolina University (UMCIRB), if needed. Our organization does not have an Institutional Review Board (IRB). We are aware that in the absence of an organizational IRB, the project will be submitted through the ECU College of Nursing review process which may include UMCIRB review if needed.

Thank you,
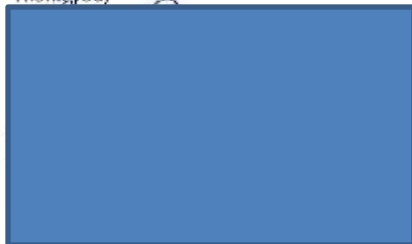
Appendix E: Project Budget

DNP PROJECT BUDGET			
Item	Units	Unit Cost	Total
Patient Education Packet			
Two pocket folder	250	$0.49	$122.50
Naloxone instruction document- 2 pages	500	$0.10/page	$50.00
Opioid safety document- 6 pages	250	$0.10/page	$150.00
Magnet	250	$0.57	$142.50
Business card	250	$0.15	$37.50
Policy Provider Education Meeting			
Policy documents- 2 pages	20	$0.10	$2
Staff coffee & donuts- two dozen and one coffee carafe from dunkin donuts	1		$40
Nursing staff hourly wage	4	$24	$96
TOTAL COST			**$640.50**

Appendix F: IRB Waiver

Quality Improvement/Program Evaluation Self-Certification Tool

Purpose:
Projects that do not meet the federal definition of human research pursuant to 45 CFR 46 do not require IRB review. This tool was developed to assist in the determination of when a project falls outside of the IRB's purview.

Instructions:
Please complete the requested project information, as this document may be used for documentation that IRB review is not required. Select the appropriate answers to each question in the order they appear below. Additional questions may appear based on your answers. If you do not receive a STOP HERE message, the form may be printed as certification that the project is "not research", and does not require IRB review. The IRB will not review your responses as part of the self-certification process.

Name of Project Leader: Margaret Dillon

Project Title: Co-Prescribing Naloxone Policy for Chronic Pain Patients on Opioid Therapy

Brief description of Project/Goals:
The proposed DNP project is to implement a policy for providers to prescribe naloxone to chronic pain patients receiving opioid therapy utilizing the universal precautions model. The goal is to decrease the risk of potential overdose and adverse outcomes for patients on opioids and in the community. By using a universal precautions model for this policy, the difficulty of accessing accurate patient risk factors is removed, the provider education for naloxone prescribing is improved and this model will remove the possibility of a patient interpreting the naloxone as a negative or personal risk factor. The providers will participate in an education session for the policy and naloxone. Once the policy is then implemented data will be collected to determine if the policy is being followed and each patient is prescribed the naloxone with education and filling the prescription. The site for the proposed DNP project is a pain clinic in Greenville, North Carolina, East Carolina Pain Consultants.

Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?
no
Has the project received funding (e.g. federal, industry) to be conducted as a human subject research study?
no
Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?
no

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?
no
Will the results of the project be published, presented or disseminated outside of the institution or program conducting it?
yes
Would the project occur regardless of whether individuals conducting it may benefit professionally from it?
yes
Does the project involve "no more than minimal risk" procedures (meaning the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)?
yes
Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program, and falls under well-accepted care practices/guidelines?
yes

Based on your responses, the project appears to constitute QI and/or Program Evaluation and IRB review is not required because, in accordance with federal regulations, your project does not constitute research as defined under 45 CFR 46.102(d). If the project results are disseminated, they should be characterized as QI and/or Program Evaluation findings.

Finally, if the project changes in any way that might affect the intent or design, please complete this self-certification again to ensure that IRB review is still not required. Click the button below to view a printable version of this form to save with your files, as it serves as documentation that IRB review is not required for this project. 9/11/2019

Appendix G: Data Collection Tool

Co-Prescribing Naloxone Policy for Chronic Pain Patients

on Opioid Therapy

Please answer the questions to the best of your ability. If you have any questions please ask the Nursing staff.

1. What is your age group?

    a. 18-30

    b. 31-40

    c. 41-50

    d. 51-60

    e. 61-70

    f. 71 and over

2. What is your gender?

    a. male

    b. female

    c. other/prefer not to answer

3. What is your education level?

    a. Some high school

    b. High school graduate

    c. Some college

    d. College graduate

    e. Graduate degree

4. Have you been prescribed naloxone from this clinic?

    a. Yes

        b.   No

5.   Did you receive an opioid packet with patient education materials for opioid medications that included naloxone education, when and how to use it?

        a.   Yes

        b.   No

6.   Did you fill the prescription for naloxone?

        a.   Yes

        b.   No

Appendix H: Excel Spreadsheet for Data Management

Post Policy Implementation Survey	
Demographics	
Age	
	18-30 (1)
	31-40 (2)
	41-50 (3)
	51-60 (4)
	61-70 (5)
	70 and over (6)
Gender	
	Male (1)
	Female (2)
	Other (3)
Education	
	some high school (1)
	high school graduate (2)
	some college (3)
	college graduate (4)
	graduate degree (5)
Project Specific Questions	
Have you been prescribed naloxone from this clinic?	
	Yes (1)
	No (2)
Did you receive an opioid packet with patient education regarding opioids that included education of how and when to use naloxone?	
	Yes (1)
	No (2)
Did you fill the prescription for naloxone?	
	Yes (1)
	No (2)

Appendix I: PRECEDE-PROCEED Model