

**Naloxone Nasal Spray Co-Prescription for the Prevention of Opioid Overdose
Complications**

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Dedication

It is with deepest gratitude and utmost love that I dedicate this project to my family. I give special thanks to my husband Raju Pappachan, who accepted my frustrations and celebrations equally, calmly and encouraged me constantly. My family far and near, played a significant role in my success with prayers, love, and support. This DNP project took a great amount of time and energy, which otherwise I could have spent with my children. I thank my children for the unconditional love and understanding they provided me throughout the course. My accomplishment today, the dream of my life, got realistic because of you all.

Abstract

Background: Opioid overdose is becoming a global epidemic. According to Centers for Disease Control and Prevention (CDC), 67,367 drug overdose deaths occurred in the United States (US) in 2018. The US Food and Drug Administration (FDA) approved Naloxone nasal spray as a life saving measure to reverse the effect of narcotic overdose in community settings.

Purpose: The purpose of this Doctor of Nursing Practice (DNP) project was to implement an educational intervention to increase Naloxone spray co-prescription, at least by 5% during a two months period, in a primary care setting.

Methods: An educational intervention was conducted to teach providers and staff regarding the implications of Naloxone nasal sprays in narcotic overdoses and to encourage co-prescriptions of Naloxone. Pre and post questionnaire were given to measure the effectiveness of education. The IOWA Model of Evidence- Based Practice Implementation was used as the implementation framework and chart reviews were used to track the number of narcotic and Naloxone prescriptions.

Results: The findings revealed increased motivation, awareness, confidence, and knowledge with Naloxone co-prescription. The chart audit showed that out of 27 narcotic prescriptions during an eight-week period, 24 Naloxone prescriptions were written, which is 89% of compliance in co-prescription.

Implications for Practice: The findings of this DNP project indicate that the co-prescription of Naloxone can be promoted by educating providers on the significance of the intervention, thereby increasing the safety of the patients, reducing health care expenses, and upholding nursing values.

Key words: Narcotic overdose, Naloxone nasal spray, co-prescription, provider education, community setting

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Section I. Introduction

Background

Narcotic overdose-related complications and deaths are significantly increasing all over the world. According to the World Health Organization (WHO), about 275 million people worldwide used illicit drugs at least once during 2016 (World Health Organization [WHO],2020). The United States of America (USA) reported 67,367, drug overdose deaths in 2018 (Centers for Disease Control [CDC], 2020). More than 12,000 North Carolina (NC) residents died from opioid overdoses from 1999 to 2016 (North Carolina Department of Health and Human Services [NCDHHS], n.d.). In Wake County NC, 210 deaths per 100,000 population occurred due to drug-related complications, as reported by the data from 2012 to 2014 (NCDHHS, n. d.). The Food and Drug Administration (FDA) of USA, approved Naloxone nasal spray as a life saving measure to reverse the effect of narcotic overdose in community settings by non -health care personnel (2019). An established family practice, located in Wake County, NC which renders medical services to adults, children, and families, served as the project partner for this Doctor of Nursing Practice (DNP) project. Narcotic medications are often prescribed for pain following the treatment guidelines. Naloxone co-prescription was not established in this practice. NCDHHS encourages the prescription of naloxone, an opioid antagonist, along with narcotics to prevent overdose-related deaths (NCDHHS, n.d.).

Organizational Needs Statement

Providers in the family practice are committed to serve the Wake County patient population with safe, high quality, and evidence-based care. The Site Champion for this DNP project is the director of the facility and he is inspired to ensure the safety of the patients who are receiving narcotic prescriptions for pain. In this practice, the providers prescribe narcotics to treat acute and chronic pain; however, they are not currently prescribing Naloxone nasal sprays

along with narcotics. Naloxone nasal sprays have proven to be useful in preventing opioid overdose complications and death (Parsons, 2019). NCDHHS has initiated a strategic plan for 2017 to 2021 to address the opioid overdose issue. Naloxone prescribing, along with the narcotics, is one of the recommended strategies (NCDHHS,n.d.). The providers at this family practice recognize the importance and need to participate in the statewide efforts to reduce opioid overdose complications.

This family practice aims to increase providers' and staff knowledge regarding the new Naloxone spray co-prescription practice policy and equip them with appropriate patient education materials. In NC, drug overdose deaths in 2018 were 20.4 for 100,000 people (North Carolina Institute of Medicine [NCIOM], 2020). According to 'Healthy North Carolina 2030', the target is to reduce deaths to at least 18 deaths per 100,000 people (NCIOM, 2020). The proposed DNP project may be an excellent tool for the family practice to participate in achieving the Healthy North Carolina 2030 goal.

Problem Statement

Increased narcotic overdose complications and deaths are becoming a global epidemic. In North Carolina, drug overdose deaths are increasing, requiring evidence-based prevention strategies (NCIOM, 2020). A family practice in Wake County recognizes a need for interventions to promote the safety of the patients who receive narcotic prescriptions for pain management. The facility was not providing any Naloxone prescriptions with narcotics.

Purpose Statement

The purpose of the proposed DNP project was to implement an educational intervention to increase Naloxone spray co-prescription, at least by 5% in a two-month period.

Section II. Evidence

Literature Review

A literature review was done using CINAHL and PubMed to understand the effectiveness and feasibility of Naloxone use in community settings. The keyword used for CINAHL was Naloxone nasal spray. The advanced search was chosen, full text and the English language were the limiters, and the articles published from April 2015 to April 2020 were selected. This search revealed 32 results. After reading the full texts, four research articles (n=4) were chosen for review as they were directly related to the Naloxone spray use in community settings. The search words used in PubMed were Naloxone nasal spray and opioid overdose. The filters used for this search were ‘published in the past five years’ and ‘English’. This search gave a result of 44 articles. After reading the full text, ten directly related articles were chosen (n=10). The articles which were not directly relevant to the population were excluded such as the studies focused on the hospital or Emergency Department settings and for the specific populations such as use by Emergency Medical Technicians. The articles with lower than level- two evidence were also eliminated (n=2). Four articles were common in both the databases. Including PubMed and CINAHL, the final number of articles reviewed was 14. In addition to that, the North Carolina Naloxone Distribution Toolkit was reviewed to understand local resources and state standing orders. (North Carolina Division of Public Health- Injury and Violence Prevention Branch, 2019). See Appendix A and B for an overview of the literature search.

Current State of Knowledge

Increased provider awareness and availability of easy to use Naloxone preparations, along with supporting state laws and policies, will encourage providers to prescribe more Naloxone for community use (Dunne, 2018). An open-label randomized five-way cross over Pharmacokinetics study including, 38 healthy volunteers, highly supports intranasal administration of concentrated

naloxone preparations for narcotic overdose (McDonald et al., 2018). Another pharmacokinetic study using an open-label randomized four-way cross over design, including twelve healthy volunteers, compared intranasal naloxone spray bioavailability with that of intravenous and sublingual preparations. This study reveals substantial bioavailability of intranasal preparation and recommends its use in emergencies in the community (Mundin et al., 2017). Lewis and colleagues (2017) conducted a systematic literature review regarding intranasal Naloxone use by non-medical personal in community settings. They recommend education and training, distribution of naloxone nasal sprays to high-risk population and families, reduction of barriers in prescribing, and elimination of legal recrimination fears as strategies to promote naloxone use for narcotics overdose emergencies in the community (Lewis et al., 2017). Skulberg and colleagues (2019) conducted an open, randomized four-way cross-over trial to understand the pharmacokinetics of intranasal Naloxone. The research concluded that intranasal Naloxone provides adequate systemic concentrations to treat opioid overdose compared with intramuscular Naloxone 0.8 mg (Skulberg et al., 2019). A prospective, single-site, open-label, randomized usability assessment by Eggleston and partners concluded that Naloxone is a safe and effective antidote for reducing opioid overdose deaths when it is distributed in the community (Eggleston et al., 2018). Ryan and Dunn (2018) conducted a systematic review regarding intranasal and injectable Naloxone forms for community use, which supported the practice of providing prescriptions for community use to reduce future risk of overdose in people who are receiving chronic opioid therapy for pain management. Another randomized controlled trial, to compare the pharmacokinetics of Naloxone using the FDA approved intranasal and intramuscular devices with the Improvised Nasal Naloxone Device (INND) reached the conclusion that FDA approved intranasal Naloxone is easier to use and reaches to the highest plasma concentrations compared

to intramuscular dose (Krieter et al., 2019). Strang and his colleagues (2016) conducted a three-stage analysis of candidate routes of administration of Naloxone. This study recommends the development and approval of non-injectable forms of Naloxone to facilitate community use (Strang, 2016). Vanky and team (2017) conducted a randomized control trial testing the pharmacokinetics of a single dose Naloxone spray in twenty healthy volunteers which revealed a faster absorption of intranasal Naloxone to maximum concentration compared to the injectable form (Vanky et al., 2017). An open randomized triple cross over trial by Tyllescar et al. (2017) also supports rapid systemic absorption and higher bioavailability of the nasal formulation compared to the other formulations. The findings from a prospective single-site open label randomized usability assessment assessing Naloxone administration by untrained community members suggests that administration by a nasal spray device was the easiest and the administration was conducted most rapidly compared to the intramuscular kit and improvised nasal atomizer kit (Eggleston et al., 2020). When Wright Quintin and team (2020) examined the effect of community education and distribution of Naloxone by pharmacists. The teaching was found to be effective, even though a smaller percentage of the public had to use the Naloxone in the two to four months follow up (Wright et al., 2020). Ida Tyllescar and team (2019) conducted a study regarding bystander use of Naloxone nasal spray for the opioid overdose. The authors reported that the bystander administered single-dose Naloxone spray in high concentrations can prevent deaths from opioid overdose (Tyllescar et al., 2019). See Appendix C for literature matrix.

Current Approaches to Solving Population Problem(s)

While conducting the literature review, the author found multiple approaches to overcome the opioid overdose epidemic, such as prescription drug monitoring, nonpharmacological and

non-opioid pain management methods, and referrals to pain management specialists. Naloxone usage to prevent overdose complications and death was one of the strategies highly recommended (Tyllescar et al.,2019). Naloxone is available in many formulations such as intramuscular, intravenous, sublingual, and intranasal (Mundin et al., 2017). The easiest and most effective administration method by the laypersons in the community is intranasal preparations as it is a needle-free approach (Lewis et al., 2017). The bioavailability of the intranasal preparation of Naloxone is much higher compared to the sublingual administration, which is another needle-free approach (Mundin et al., 2017). North Carolina State law allows medical providers to issue standing orders to dispense and distribute Naloxone to the population at higher risk for overdose (NCDHHS, n.d.).

Evidence to Support the Intervention

The DNP project site is a family practice in North Carolina. North Carolina has a standing order to use naloxone nasal sprays in the community (NCDHHS,n.d.) The providers in the practice, have the legal authority to prescribe Naloxone nasal sprays for the population at risk for overdose (NCDHHS,n.d.). The tool kit from NCDHHS is easily available and extremely helpful for the patient and family education (NCDHHS,n.d.).The majority of patients attending this practice depend on Medicare/Medicaid or self -pay for their medications. Most insurances and Medicare cover Naloxone spray costs (Medicare, n.d.). Naloxone nasal sprays are available in local pharmacies. Intranasal naloxone kits are available in North Carolina local health departments for free of cost (NCDHHS,n.d.). Intranasal naloxone preparations are easy to use by non -medical community members and are effective in treating narcotic overdose emergencies in community settings (Lewis et al., 2017). Research suggests that people who received Naloxone

co-prescription from their primary care providers had rarer narcotic-related Emergency Department visits (Coffin et al., 2016).

Evidence-Based Practice Framework

Identification of the Framework

The IOWA Model of Evidence-Based Practice Implementation was used to execute the DNP project in practice (University of Iowa Hospitals & Clinics, 2020). The IOWA model includes multiple steps of the quality improvement process (University of Iowa Hospitals & Clinics, 2020). These steps are problem identification, understanding the need or priority of this project to the organization, development of a team, gathering, analyzing and synthesizing the research related to the topic, implementing the change, and evaluating the results (University of Iowa Hospitals & Clinics, 2020). The IOWA model was selected because the chosen DNP project requires all the above- mentioned elements and steps to successfully implement the evidence - based practice in the clinical setting. The proposed DNP project was based on an identified problem in the local community, the increased narcotic overdose deaths (NCDHHS, n. d.). Developing a team of motivated providers and other staff, providing education about the evidence- based research and state resources, promoted their cooperation.

Ethical Consideration & Protection of Human Subjects

The proposed DNP project was an evidence-based practice implementation project designed to implement an educational intervention to promote co-prescription of Naloxone nasal spray with narcotics. The benefit of the project was offered to all the providers and staff who work at the organization. Participation in the educational intervention was voluntary and participants could withdraw from the project without any penalty. NCDHHS promotes Naloxone nasal spray use for Narcotic overdose in the community and North Carolina has a standing order

in place (NCDHHS, n.d.). The educational intervention helped to educate and prepare providers and staff at the family practice to implement the proposed evidence-based practice. The educational intervention was intended to promote quality and safety in the clinical setting, and it was not expected to cause any harm to any participants involved. A pre and post educational survey was done to evaluate the effect of education. Providers and the staff were not asked to reveal their identity while responding to the survey. The Project Leader prepared herself to observe ethical considerations during the proposed DNP project implementation by taking CITI modules through East Carolina University. The project site did not have a formal Institutional Review Board (IRB) process in place. The project was reviewed through the East Carolina University IRB process and deemed a Quality Improvement/Program Evaluation project, not requiring IRB review.

Section III. Project Design

Project Site and Population

A family practice in Wake County NC was the project site for the proposed DNP project. It is a family practice, specializing in allergy and internal medicine. Providers in this practice provide comprehensive primary care, including medical services to adults, children, and families (██████████, personal communication, June 26, 2020). The organization provides services to people of all ages. The providers in this practice prescribe narcotics to treat patients with acute and chronic pain. Co-prescription of Naloxone nasal spray along with opioids to prevent narcotic overdose complications and deaths is one of the effective evidence-based interventions that was not established in this family practice. NCDHHS highly recommends this evidence-based practice to improve the safety of the patients who receive narcotics. The director of this facility identified the need to implement the intervention in this practice, to enhance

patient's safety. When the Project Leader conducted a Strengths-Weaknesses-Opportunities-Threats (SWOT) analysis, the strengths of this project in this site were motivated educator and project site champion, strong support from the management and the providers, and active involvement of the staff. The weaknesses were lack of electronic health record system, shortage of staff, and time-consuming processes. The opportunities recognized were the availability of research articles on this subject revealing effectiveness of Naloxone spray in preventing narcotic overdose related deaths, the variety of teaching materials on the subject, the North Carolina State standing order, and the NCDHHS website with a tool kit for providers to use for guidance. Some threats were recognized, such as the current COVID-19 pandemic situation which required social distancing and avoiding mass gathering for educational interventions.

Description of the Setting

The family practice is in Wake County, NC. This practice provides primary health care services, including management of acute and chronic pain. The service accepts patients of all ages, cultures, socio-economic statuses, and variety of diagnoses. In this facility, the providers accept most insurance, Medicare, Medicaid, and self-pay. Providers in this practice provide care for about 60 patients per week, and about 8% of those patients receive narcotics for pain management. ([REDACTED], personal communication, June 26, 2020).

Description of the Population

The target population for the DNP project was the providers and staff of the family practice. This practice has three advance practice providers, including the director. There are two Registered Nurses, eight Certified Medical Assistants, and five office staff. Two Nurse practitioner students receiving training in this facility were also present during the educational intervention.

Project Team

The project team consisted of three members. The author, who is a DNP student, was leader of the project. The Project Leader analyzed and synthesized the research related to the topic, implemented the educational intervention, and evaluated the results through weekly chart audits. The Site Champion was the director of the family practice. The Site Champion allowed space and time to conduct the educational intervention, supported the project and provided suggestions to overcome the barriers. A faculty member from the East Carolina University College of Nursing was the Project Coach for the project and provided mentorship during the duration of the project.

Project Goals and Outcome Measures

The project goal was to educate and equip providers and staff in the facility regarding the co-prescription of Naloxone spray with narcotics to prevent narcotic overdose emergencies and deaths. This evidence-based intervention is well established in other primary care settings and has wide variety of supportive research, as described in the literature review. The Project Leader conducted an educational intervention to encourage providers to follow the protocol as detailed by the NCDHHS. A pre and post educational survey was done to assess the effectiveness of the educational intervention. The chart audits helped to further evaluate the effect of the intervention. The IOWA Model of Evidence-Based Practice Implementation was used to execute the DNP project in practice (University of Iowa Hospitals & Clinics, 2020). A ‘run chart’ tool using bar chart was used as the tracking tool, to track the number of narcotic prescriptions and the Naloxone co-prescriptions. The author prepared herself, taking the Collaborative Educational Training Initiative (CITI) modules to understand the ethical considerations associated with conducting evidence-based project implementations. The author submitted the DNP project plan

to the East Carolina University's Institutional Review Board (IRB) for approval before implementing it and obtained a waiver.

Description of the Methods and Measurement

The IOWA Model of Evidence-Based Practice Implementation was used to execute the proposed DNP project (University of Iowa Hospitals & Clinics, 2020). This tool appeared to be the most appropriate tool for the proposed DNP project as the elements and steps of the IOWA model were precise and directly applicable in this project. The providers in the family practice were prescribing narcotics for pain management; however, they were not co-prescribing Naloxone along with the Narcotics to prevent opioid emergencies and death. The director of the facility identified this problem and wished to implement a project to motivate the providers. Developing a team of motivated providers and other staff and providing education about the evidence-based research and state level resources were used to promote their cooperation. The Project Leader analyzed and synthesized research data regarding the topic and documented it concisely using a literature matrix. See Appendix C for the literature matrix table.

An educational intervention was planned and conducted. The educational intervention emphasized the significance of the drug overdose problem globally and domestically. The Project Leader reviewed the North Carolina State strategic plans to reduce overdose death rates and introduced the providers and staff to NCDHHS Naloxone Distribution Toolkit. Providers and staff were educated on the evidence-based research findings and explained why Naloxone nasal sprays are preferred over other Naloxone formulations for use in the community. Hard copies of Naloxone Distribution Toolkit were given to all participants and a copy was placed in a folder at the clinic workstation for reference. Providers and staff were educated on how to access the toolkit electronically. The Naloxone Distribution Toolkit contains the following information:

background and rationale about the drug overdose problems, Naloxone access law, dispensing and distribution standing orders, Naloxone frequently asked questions and answers, types of naloxone, comparing and contrasting Naloxone formulations, purchasing options, available Naloxone kits, sustainability planning, public awareness efforts, Naloxone administration instruction with pictures, NC's Good Samaritan Law, and standing order templates for distribution and dispensing (North Carolina Division of Public Health- Injury and Violence Prevention Branch, 2019).

The pre and post educational surveys helped to evaluate the effect of the educational program, See Appendix D for pre-educational survey and Appendix E for the post- educational survey forms. See Appendix F for the pre-educational survey results and Appendix G for the post-educational survey results. The educational intervention goal was to help providers and staff to understand the need for Naloxone co-prescriptions and motivate them. The outcomes of the proposed DNP project were measured by conducting weekly chart audits. The Project Leader conducted chart audits for a two- month (8 weeks) period. Weekly chart audits were used to track the progress of the project by counting the number of Naloxone sprays prescribed with narcotics. The project implementation tool was revised biweekly to meet the anticipated outcomes.

Discussion of the Data Collection Process

A pre and post educational survey was done on the day of the educational event to understand the effectiveness of education. The pre and post educational questionnaire measured three aspects including motivation, awareness, and confidence concerning narcotic overdose and Naloxone nasal spray co-prescription. Chart audit was used to evaluate the impact of the intervention overtime. A weekly chart audit of all patients attending the clinic was done to see if any narcotics were prescribed. For the patient with narcotic prescriptions, co-prescription of

naloxone was verified. See Appendix H for the chart audit form. The data was placed in a bar chart format to evaluate trends, see Appendix I for the data tracking tool. The author contacted the prescribers frequently to assess the barriers and need for further education.

Implementation Plan

Using the IOWA Model as the project framework, the project implementation was conducted from August 2020 to October 2020. After identifying the problem and need for intervention, the Project Leader, gathered and synthesized research information regarding Naloxone nasal spray co-prescriptions. The educational intervention was conducted to help the providers and staff to understand the need for Naloxone co-prescriptions and motivate them to prescribe it. The staff were trained on patient education. The effect of the educational intervention was evaluated using pre and post educational questionnaires. Further evaluation was done conducting pre and post chart audit counting the narcotic and Naloxone prescriptions. The results were tracked weekly on a bar graph. The project leader continued follow up and when a drop in the number of Naloxone co-prescriptions were noted for two consecutive weeks, the barriers were explored. The process was revised biweekly using the IOWA Model of Evidence-based Practice Implementation Framework.

Timeline

The expected timeline for this project was three months from August 2020. The pre-data got collected for a four-week period, starting in August. The educational intervention was done on 08/27/2020, and the data collection for evaluation of the project was done for the following eight weeks, starting from 09/02/2020. The chart audits were done on 09/02/2020, 09/09/2020, 09/16/2020, 09/23/2020, 09/30/2020, 10/07/2020, 10/14/2020 and 10/21/2020. Meetings with the Project Coach and Site Champion were done once in every two weeks to update on the progress of the project and obtain further suggestions for improvement. See Appendix J for the timeline.

Section IV. Results and Findings

Results

Counting the number of Naloxone nasal spray prescriptions against the total number of narcotic prescriptions provided the DNP project's fundamental outcome measures. Prior to the intervention, the providers at the project site were not writing any Naloxone co-prescriptions. The educational intervention's original goal was to introduce Naloxone nasal spray co-prescription to the site and achieve at least a 5% compliance in writing the prescriptions in two months. The post-implementation data collection revealed that, out of 27 narcotic prescriptions during the eight weeks, 24 Naloxone prescriptions were written: representing 89% compliance in prescribing Naloxone along with the narcotics. Frequent reminders, constant follow up, and visual prompts served as the contributing factors for success. The Project Leader visited the site weekly; to collect the number of Narcotic and Naloxone co-prescriptions.

Outcomes Data

The outcomes data included the count of narcotic and Naloxone prescriptions in the project site, for a period of eight weeks. The process measurement was done following the IOWA Model and modifying the plan as required. The final step of the IOWA is evaluating the results of the intervention. Counting of the Naloxone spray prescriptions and narcotic prescriptions and tracking them helped in the project evaluation. The outcomes of the educational intervention were initially evaluated by providing pre and post-education questionnaire to learn if the education was effective enough to start the new evidence -based practice. A total of 20 staff participated in the educational intervention, of which 15% of participants were providers, 10% were nurse practitioner students, 10% were nurses, 40% were medical technicians, and 25 % were office staff. The pre and post educational questionnaire

measured motivation, awareness, and confidence, regarding Naloxone nasal spray co-prescription. The post data revealed increased motivation, awareness, and confidence. Seventy (70%) of the attendees answered the knowledge question correctly at the beginning of the intervention, whereas 100% of the attendees answered it correctly at the end of the educational session. The pre-data collection and post-data collection of counting the narcotic prescriptions helped to further measure the educational intervention outcomes. The narcotic prescriptions and Naloxone prescriptions were counted weekly and the numbers were placed in a bar graph format to track the progress. The Project Leader recognized the need for further action when the number of Naloxone prescriptions were less than the number of narcotic prescriptions during the second and third weeks of post intervention. After talking with the providers and perceiving the need for reminders, the Project Leader introduced visual prompts in the examination rooms and on the prescription pads, which helped to remind the providers about Naloxone co-prescriptions.

Discussion of Major Findings

The initial analysis revealed the project exceed the preliminary goal for the project. The educational intervention was effective. As elaborated in the Appendix G, the educational intervention helped to boost motivation, awareness, and confidence of the participants. The knowledge level regarding Naloxone was also measured using a knowledge question. One hundred (100 %) of the attendees were able to answer the knowledge question correctly at the end of the education. The narcotic prescriptions and Naloxone prescriptions were counted weekly to ensure the education was helping with the implementation of the evidence -based practice. The Project Leader tracked the data using a bar graph format for easily visualization and recognition of the results. During the first week of post intervention, the Naloxone prescriptions were the same numbers compared to the narcotic prescriptions. However, during the second and third weeks of post implementation, the Naloxone prescriptions were less than

the number of narcotic prescriptions. The Project Leader contacted the providers to understand the challenges and barriers associated with the decline in the co-prescriptions. A need for further action was recognized as the unintentional non-compliance was due to forgetfulness. The Project Leader met with the Site Champion and explored options for reminding the providers to prescribe Naloxone along with narcotics. Multiple options were considered to overcome this barrier, such as more site visits by the Project Leader, reeducation, and visual reminders. The visual triggers were identified as the best option secondary to feasibility, practicality, and cost-effectiveness. Wall posters and stickers stating ‘Naloxone saves lives’, were placed throughout the office, which triggered the attention of the providers. The Project Leader reinforced the education during weekly site visits, to establish further compliance and to include more staff. The post interventional data for weeks four through eight indicated constant compliance in co-prescribing Naloxone along with the narcotics. The count of narcotic prescriptions and Naloxone prescription numbers were the same signaling success of the intervention. To conclude, the compliance of prescribing Naloxone along with narcotic prescriptions, was found to be higher than the initial expectation as presented in the data collection tool. See Appendix I for the bar graph presentation of the data.

Section V. Interpretation and Implications

Cost -Benefit Analysis

The project involved a substantial amount of time, effort, finances, and staff involvement. First and foremost, a dedicated leader should be available who can spend time researching the benefits versus costs of the project, its importance, current research data available, multiple forms of Naloxone and selecting the most appropriate form of Naloxone in the community. Further study on the availability of educational materials, and the individual state laws, are required. It is important to inquire about the availability of Naloxone in the local pharmacies.

The activities mentioned above require a significant amount of time, approximately 12 hours per week for about four months. Financial expenses involved in this project include the costs for printing the educational materials and order sets, which was around \$125 in total. The educational intervention was conducted in the staff breakroom in the form of a ‘lunch and learn’ format, which added expenses. The cost for the lunch was \$288 including tax and delivery to the site and will depend on the number of participants. Costs for the wall posters and stickers used as visual reminders were the additional monetary expenses. The total cost was \$150. Please see Appendix L for the detailed budget.

The project did not bring any direct financial benefit to the site, but it will potentially improve the safety of the patient population who received narcotics treatment from this family practice. Naloxone is a life -saving measure in overdose emergencies. As the patients recognize the intervention’s advantage, it may eventually impact the trust and appreciation of the public towards the family practice.

A major barrier to implementation was the current COVID -19 pandemic situation. Due to the public gathering restrictions and safety precautions, the educational intervention was repeated multiple times during the day to avoid gathering as a large group in the conference room. This required additional time and undertaking from the Project Leader. The educational intervention was conducted several times to involve all staff, observing the social distancing guidelines and state laws for safety precautions. The Project Leader spent a total of six hours in the clinic to educate everybody in the clinic, instead of the initially anticipated two hours of educational intervention.

Considering the significance of potentially reducing drug overdose deaths in the community, the project’s benefits far outweigh the costs and efforts involved.

Resource Management

In addition to the financial resources, providers' and staff's time contributed to the success of the project. The Site Champion, the Project Leader, and several other staff members were involved in this project, including the office staff who helped with the data collection, nursing staff who assisted with the patient education, and a volunteering leader/champion from the site to assist with the program's sustainment. The aforementioned staff invested an immense amount of their time in getting involved in the successful implementation and sustainment of the project. The Site Champion spent 30 minutes for each meeting with the Project Leader which is a total of five hours. Office staff spent approximately 15 minutes at each visit to help the Project Leader with data collection, equaling 3 hours in total. Nursing staff spent an average of 5 minutes to teach each patient about narcotic overdose and Naloxone. Twenty- four Naloxone prescriptions were written during the evaluation period, which required a total of 2 hours of patient education. A volunteering project champion spent 30 minutes with the Project Leader to get trained for the sustainment of the project in the setting. Printers were available at the site to print photocopies of NCDHHS patient education materials if required. This author did not use the printers from the site as the materials were already printed and prepared.

If the site had resources such as a larger conference room, it could have been used for the educational intervention. The organization has a waiting area for the patients which can be used for further patient education and display of the patient education materials. The waiting area was not used during the current project, as the project's main purpose was to educate staff and providers. Additional patient and community education will be the subsequential step of the project, which should be accomplished through the providers and staff. The Site Champion and

staff are aware of the benefits of using the waiting area for patient education and displaying the education material.

Implications of the Findings

The findings of this DNP project indicate the ability to change practice and improve quality and safety of the patient care if a project is implemented with the support of evidence-based research findings. The Project Leader should be dedicated and willing to spend time and energy for the project implementation and evaluation. It is equally important to develop a team who is motivated to work towards the goals. Constant follow up and timely interventions are the keystones for the success of any quality improvement projects. This particular project helped to introduce an evidence-based practice to a primary care setting aimed at avoiding narcotic overdose complications and deaths. This project is highly beneficial for the patient population who uses narcotics for pain control. It helps to uphold nursing values while ensuring safety and efficacy of care.

Implications for Patients

Naloxone nasal sprays are life saving measures for the patient population at risk for overdose-related complications. The patients and families need to be able to recognize overdose symptoms, have the medicine available, and know how to appropriately use the Naloxone in case of overdose incidents. As a result of this educational intervention, providers and staff are educating and empowering the patients.

Implications for Nursing Practice

Safety and quality improvement are the essential components of nursing practice. This intervention upholds the nursing values by ensuring patients' safety and educating the community to prevent complications and death.

Impact for Healthcare System(s)

The health care system in the United States is striving to be more focused on prevention strategies. Narcotic overdoses and complications can be life-threatening and usually involve complicated care in the Emergency Department and intensive care units, which will be physically, financially, psychologically, and socially overwhelming to families, communities, and the health care system. Avoiding or limiting the complications can significantly help save lives, reduce financial costs, and ensure safety.

Sustainability

The organization is planning to sustain the project. A nurse practitioner from the family practice has volunteered to take the lead in sustaining the project and acting as a Project Champion. The Project Champion plans to sustain the project in the organization. The Project Champion plans to track the number of narcotic and Naloxone prescription numbers using the same tools as the Project Leader used. The family practice has committed to permitting the time necessary for the providers to write prescriptions and staff to educate patients. The practice has also committed maintaining a continuous supply of patient education materials and NCDHHS resources. The practice has a printer available and can afford the costs associated with printing the educational material. The Site Champion has the website addresses and sample copies.

Dissemination Plan

The current dissemination plans are to present the poster at the project site by the end of April 2021. The second plan for dissemination will be presenting to the East Carolina University College of Nursing in April 2021. Additionally, project will be presented in the NC Opioid Misuse and Overdose Prevention Summit, which will be held virtually in May 2021. Further dissemination plans include a podium presentation of this project at the Indian American Nurses

Association of North Carolina (IANA-NC) Nurses Week Celebration. The event date is not confirmed yet for the year of 2021. The abstract will be submitted to the event managing committee and continuous education committee. See Appendix M for the dissemination plan details.

Section VI. Conclusion

Limitations

Current COVID-19 pandemic circumstance was a barrier in conducting the educational event in a classroom format. There were some limitations encountered during the implementation of the project. When the educational intervention was done in a smaller room, it had to be conducted multiple times throughout the day to follow the COVID19 restrictions, which limited the opportunities for classroom discussion among the attendees. Time constraint was another limitation in evaluating the project. If the project's duration was longer, data could have collected from the patients to assess the amount patients/families who used Naloxone for narcotic overdose incidents. It may take years to collect detailed data, which is beyond the DNP student's program expectation.

Recommendations for Others

For future students planning to conduct similar projects, the recommendation would be to focus on patient education. A project aimed at patient education can be conducted in a community level, state level, or national level. The students can collect and distribute patient education materials or demonstrate Naloxone nasal spray administration in a virtual conference or meeting. The presentation of the project at a conference as a podium or poster presentation has potential to captivate a large audience. Future students could also focus on the comparison of different Naloxone forms in the community and the barriers and facilitators of using them.

Recommendations for Further Study

Based on the current experience, this author advocates for more studies regarding the limitations and obstacles in prescribing Naloxone sprays in the community. As a future nurse practitioner, the author is enthusiastic to know, the number of Naloxone sprays used in the community by the trained lay individuals such as patients, family, or friends during an overdose crisis. The other recommended areas of research are to explore the options to involve community health care team, home health care services, and pharmacists in the distribution and education of Naloxone forms in the community.

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Appendix A

Literature Search from CINAHL

**CINAHL**

Key Word
'NaloxoneNasal
spray'

Filters : Advanced
search,Full text
and English
Language

April 2015-April
2020

**Search Results**

32 Articles

**Inclusion and
Exclusion
Criteria**

After reading the
full text of the
articles **4**
articles directly
related to the
community and
outpatient
settings were
chosen.Articles
for settings such
as Emergency
Department, pain
management,
correctional
settings and
addiction centers
were discarded.

Appendix B**Literature Search from PubMed****Pub Med**

Key Words used:
'Naloxone Nasal
Spray' and 'Opioid
overdose'

Filters used were
'published in the
last 5 years' and
'English Language'

Articles from April
2015 to April 2020

**Search Results**

44 Articles

**Inclusion/
Exclusion Criteria**

After reading the full text of the articles, 10 articles directly related to the community and outpatient settings were chosen. Articles for settings such as Emergency Departments, pain management, correctional settings and addiction centers were discarded. Articles less than level 2 evidence were also excluded. 4 articles were also same as in the CINAHL search. So the duplication was avoided by counting them once only.

Appendix C

Literature Matrix

No	Authors	Year of Publication	Article Title	Summary
1.	Dunn, Robert	2018	Prescribing Naloxone for Opioid Overdose Intervention	Co-prescription of Naloxone should be considered along with opioids in primary care and pain management if exceeding a threshold daily dose and in patients with risk factors for overdose.
2	McDonald, Rebecca; Lorch, Ulrike; Woodward, Jo; Bosse, Björn; Dooner, Helen; Mundin, Gill; Smith, Kevin; Strang, John	2018	Pharmacokinetics of concentrated naloxone nasal spray for opioid overdose reversal: Phase I healthy volunteer study	Clinicians and policymakers will need to consider the potential merits of the different time-course profiles (including speed of onset and duration of effect) of intranasal. versus injectable naloxone and may also see implementation advantages with intranasal. naloxone for broad-based take-home naloxone provision.

3	Mundin, Gill; McDonald, Rebecca; Smith, Kevin; Harris, Stephen; Strang, John	2017	Pharmacokinetics of concentrated naloxone nasal spray over first 30 minutes post-dosing: analysis of suitability for opioid overdose reversal	Concentrated naloxone nasal spray has a promising pharmacokinetic profile, with substantial bioavailability.
4	Lewis, C. R., Vo, H. T., & Fishman, M.	2017	Intranasal naloxone and related strategies for opioid overdose intervention by nonmedical personnel: a review	Education and training, distribution of Naloxone, reduction of barriers in prescribing, and elimination of legal recrimination fears can promote Naloxone use in the community.
5.	Arne Kristian Skulberg, Anders Åsberg ^{3,4} , Hasse Zare Khiabani ⁵	2019	Pharmacokinetics of a novel, approved, 1.4-mg intranasal naloxone formulation for reversal of opioid overdose—a randomized controlled trial	Intranasal 1.4 mg naloxone provides adequate systemic concentrations to treat opioid overdose compared with intramuscular 0.8 mg
6	Eggleston, William; Podolak, Christine; Sullivan, Ross W.; Pacelli, Lauren; Keenan, Michael; Wojcik, Susan	2018	A randomized usability assessment of simulated naloxone administration by community members	Estimated and compared the rate of successful administration between IM, single- step and multistep nasal spray devices. Naloxone is a safe and effective antidote for reducing opioid deaths in the community.

7	Ryan SA, Dunne RB	2018	Pharmacokinetic properties of intranasal and injectable formulations of naloxone for community use: a systematic review.	Providing prescriptions for community-use naloxone may reduce future risk in patients who are receiving chronic opioid therapy for pain control
8	Philip A Krieter 1, C Nora Chiang 1, Shwe Gyaw 1, David J McCann	2019	Comparison of the Pharmacokinetic Properties of Naloxone Following the Use of FDA-Approved Intranasal and Intramuscular Devices Versus a Common Improvised Nasal Naloxone Device	The ease of use and higher plasma concentrations achieved using the 4-mg FDA-approved spray, compared with the INND, should be considered when deciding which naloxone device to use.
9	John Strang, Rebecca McDonald, Abdulmalik Alqurshib, Paul Royal, David Taylor, Ben Forbes	2016	Naloxone without the needle – systematic review of candidate routes for non-injectable naloxone for opioid overdose reversal	Development and approval of reliable non-injectable formulations will facilitate wider naloxone provision across the community internationally.
10	E. Vanky L. Hellmundt U. Bondesson S. Eksborg S. Lundeberg	2017	Pharmacokinetics after a single dose of naloxone administered as a nasal spray in healthy volunteers	A faster uptake of intranasal naloxone to maximum concentration compared with previous studies although with a marked variation in maximum concentration

11	Tylleskar I, Skulberg AK, Nilsen T, Skarra S, Jansook P, Dale O	2017	Pharmacokinetics of a New, Nasal Formulation of Naloxone	The objective for this study was to describe the nasal pharmacokinetics of a new high-concentration/low-volume nasal formulation of naloxone. The study supports rapid systemic absorption and higher bioavailability of the nasal formulation compared to other formulations.
12	Eggleston W, Calleo V, Kim M, Wojcik S.	2020	Naloxone Administration by Untrained Community Members	The objective of this study was to assess the ability of untrained individuals to administer naloxone successfully in a simulated opioid overdose setting. Administration by a nasal spray device was the easiest and the administration was conducted most rapidly compared to the intramuscular kit and improvised nasal atomizer kit.
13	Quintin E Wright, Suzanne Higginbotham, Elizabeth	2020	The Impact of a Pharmacist-Led Naloxone Education and Community Distribution Project on Local Use of Naloxone	To assess the use and public perception of naloxone through distribution and

	Bunk, Jordan R Covvey			education by pharmacists at local health screenings in low-income communities in Western Pennsylvania. The teaching was found to be effective, even though a smaller percentage of the general public had to use the Naloxone in the two to four months follow up.
14	Ida Tylleskar, Arne Kristian Skulberg, Turid Nilsen, Sissel Skarra, Ola Dale	2019	Naloxone Nasal Spray - Bioavailability and Absorption Pattern in a Phase 1 Study	The pilot study indicated that the highly concentrated nasal spray may provide a therapeutic dose of naloxone with a single spray actuation. The findings led to further commercial development of the medication.

Appendix D
Pre-Education Survey

Instruction: Please circle your best answer

1. I feel motivated to educate the patients and families regarding narcotic overdose
 - a. Strongly Agree
 - b. Agree
 - c. Neither agree nor disagree
 - d. Disagree
 - e. Strongly disagree

2. I have awareness about opioid overdose complications and death
 - a. Strongly Agree
 - b. Agree
 - c. Neither agree nor disagree
 - d. Disagree
 - e. Strongly disagree

3. I have the confidence to prescribe/teach patients regarding Naloxone nasal spray administration
 - a. Strongly Agree
 - b. Agree
 - c. Neither agree nor disagree
 - d. Disagree
 - e. Strongly disagree

4. What are the signs of Narcotic overdose (choose the best answer)

- a. Unresponsiveness
- b. Slow or shallow breathing
- c. Blue fingernails or lips
- d. All the above

Appendix E
Post-Education Survey

Instruction: Please circle your best answer

1. I feel motivated to educate the patients and families regarding narcotic overdose
 - a. Strongly Agree
 - b. Agree
 - c. Neither agree nor disagree
 - d. Disagree
 - e. Strongly disagree

2. I have awareness about opioid overdose complications and death
 - a. Strongly Agree
 - b. Agree
 - c. Neither agree nor disagree
 - d. Disagree
 - e. Strongly disagree

3. I have the confidence to prescribe/teach patients regarding Naloxone nasal spray
 - a. Strongly Agree
 - b. Agree
 - c. Neither agree nor disagree
 - d. Disagree
 - e. Strongly disagree

4. What are the signs of Narcotic overdose (choose the best answer)
 - a. Unresponsiveness
 - b. Slow or shallow breathing
 - c. Blue fingernails or lips
 - d. All the above

Appendix F
Pre-Education Survey Results

	Motivation	Awareness	Confidence
Strongly Agree	10	8	3
Agree	7	8	5
Neither agree nor disagree	3	4	5
Disagree	0	0	7
Strongly Disagree	0	0	0

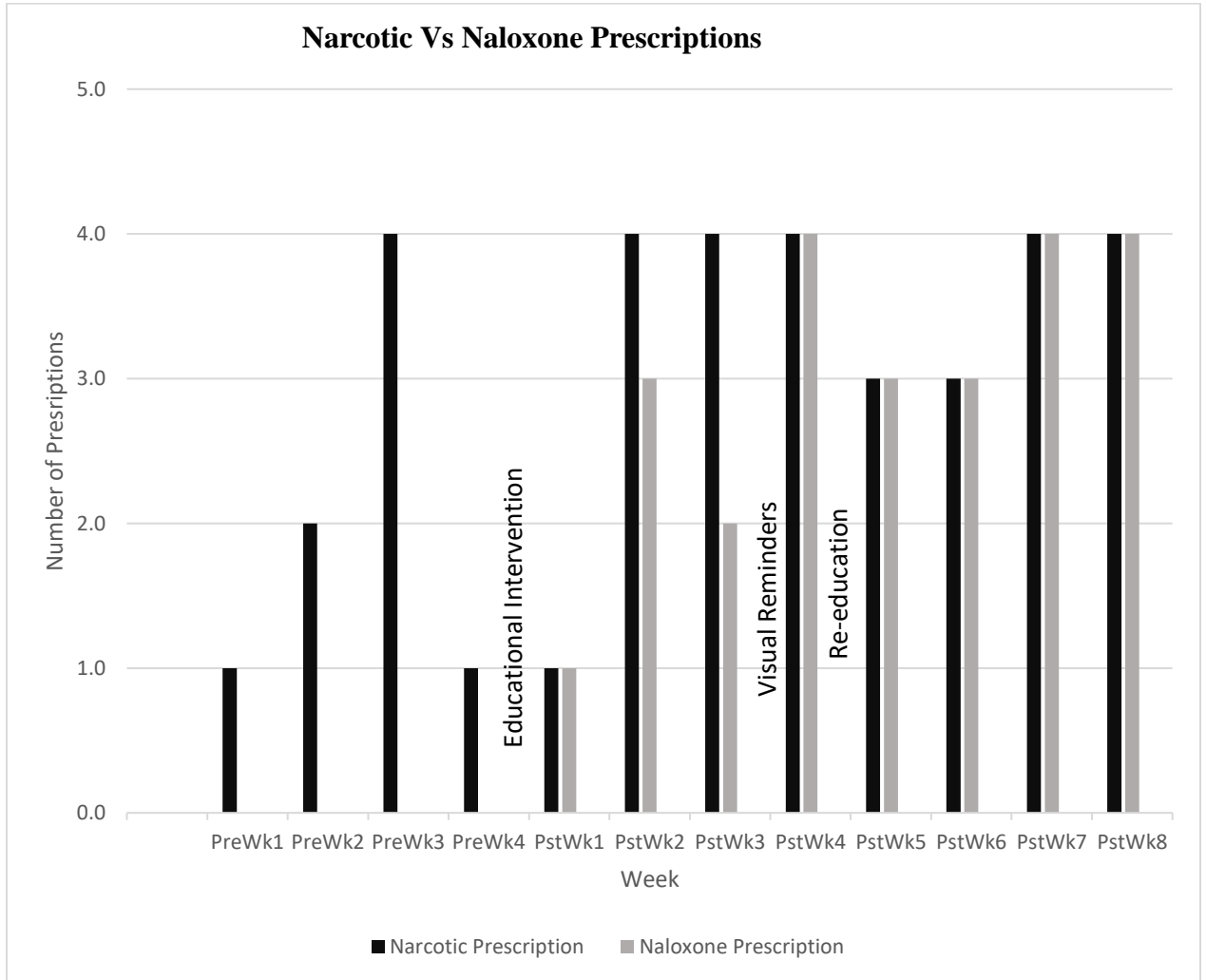
Appendix G**Post-Education Survey Results**

	Motivation	Awareness	Confidence
Strongly Agree	14	18	15
Agree	4	2	3
Neither agree nor disagree	2	0	2
Disagree	0	0	0
Strongly Disagree	0	0	0

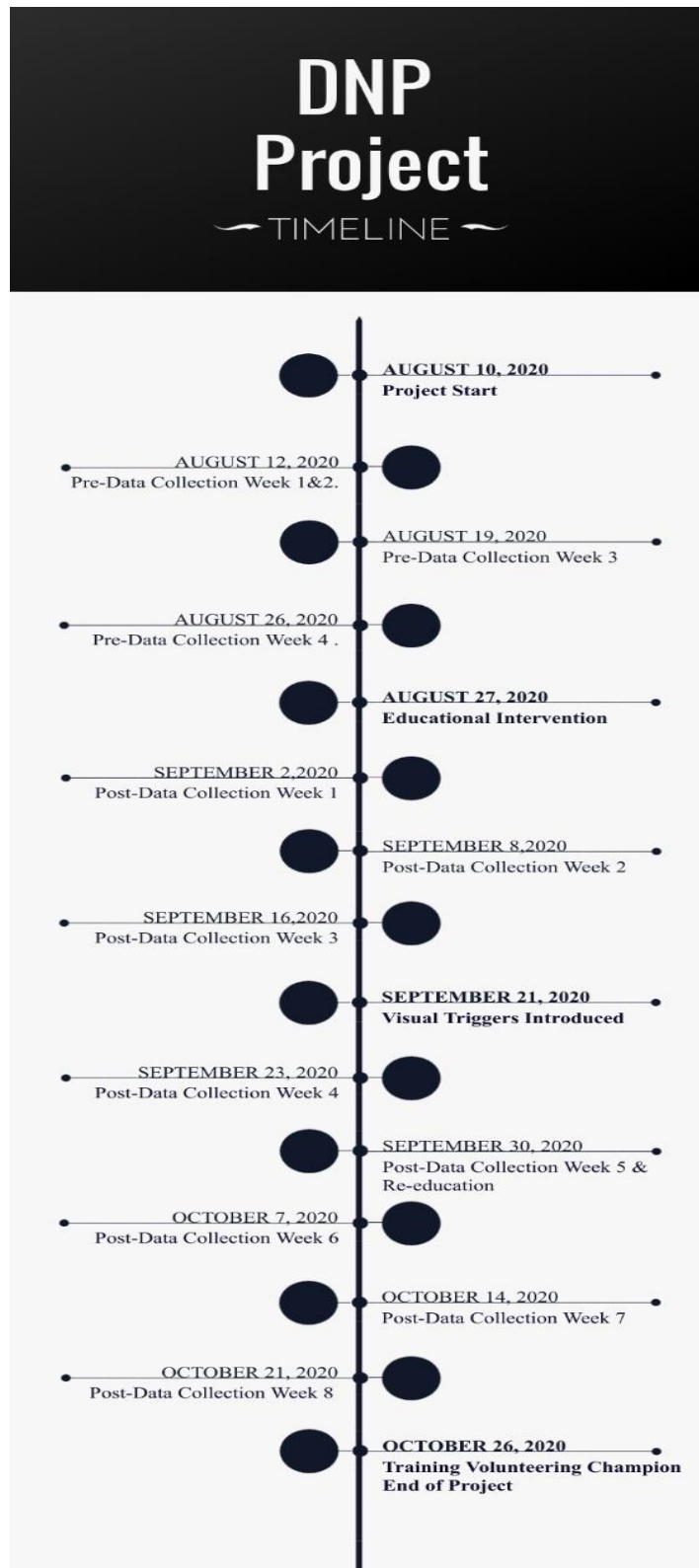
Appendix H
Chart Audit Form

1. Any narcotics prescribed?
2. Any Naloxone nasal sprays prescribed with narcotics?
3. If Naloxone not prescribed with the narcotics, mention reason

Appendix I Data Tracking Tools



Appendix J Project Timeline



Appendix K

Doctor of Nursing Practice Essentials

	Description	Demonstration of Knowledge
Essential I Scientific Underpinning for Practice	<p>Competency – Analyzes and uses information to develop practice</p> <p>Competency -Integrates knowledge from humanities and science into context of nursing</p> <p>Competency -Translates research to improve practice</p> <p>Competency -Integrates research, theory, and practice to develop new approaches toward improved practice and outcomes</p>	During this DNP project, this author analyzed different data bases, evidence -based practice guidelines and state standing orders to translate the knowledge and implement the intervention to practice setting.
Essential II Organizational & Systems Leadership for Quality Improvement & Systems Thinking	<p>Competency –Develops and evaluates practice based on science and integrates policy and humanities</p> <p>Competency –Assumes and ensures accountability for quality care and patient safety</p> <p>Competency -Demonstrates critical and reflective thinking</p> <p>Competency -Advocates for improved quality, access, and cost of health care; monitors costs and budgets</p> <p>Competency -Develops and implements innovations incorporating principles of change</p> <p>Competency - Effectively communicates practice knowledge in writing and orally to improve quality</p> <p>Competency - Develops and evaluates strategies to manage ethical dilemmas in patient care and within health care delivery systems</p>	During the DNP project, the author was able to develop and demonstrate leadership skills by leading the project, conducting meetings with multiple stakeholders involved in the process and advocating for patient’s safety and quality of care. The author was able to develop effective communication skills through academic writing and poster presentation to translate the knowledge to audience. The CITI modules and IRB process for the DNP project, increased the awareness about ethical dilemmas in health care delivery systems and research.
Essential III Clinical Scholarship & Analytical Methods for Evidence-Based Practice	<p>Competency - Critically analyzes literature to determine best practices</p> <p>Competency - Implements evaluation processes to measure process and patient outcomes</p> <p>Competency - Designs and implements quality improvement strategies to promote safety, efficiency, and equitable quality care for patients</p>	Literature search was done using multiple databases and guidelines. The articles were read and critiqued and the levels of evidence were explored before adapting the practice for implementation. Successful implementation was conducted using the knowledge gained through

	<p>Competency - Applies knowledge to develop practice guidelines</p> <p>Competency - Uses informatics to identify, analyze, and predict best practice and patient outcomes</p> <p>Competency - Collaborate in research and disseminate findings</p>	<p>Evidence-Based Research articles. These findings will be disseminated to various sites through poster and podium presentation to increase the awareness of the health care workers and community. The current plans for disseminations include NCDHHS Opioid Misuse and Overdose Prevention Summit and Indian American Nurses Association, Nurses Week Celebration.</p>
<p>Essential IV Information Systems – Technology & Patient Care Technology for the Improvement & Transformation of Health Care</p>	<p>Competency - Design/select and utilize software to analyze practice and consumer information systems that can improve the delivery & quality of care</p> <p>Competency - Analyze and operationalize patient care technologies</p> <p>Competency - Evaluate technology regarding ethics, efficiency and accuracy</p> <p>Competency - Evaluates systems of care using health information technologies</p>	<p>The technology such as Microsoft word, EXCEL, Power point and various health care software applications and databases such as CINAHL and PubMed were used to plan, prepare, and evaluate the DNP project. The technological assistance will be continually used for future disseminations also. Privacy and confidentiality were maintained adequately by appropriate use and password protection.</p>
	Description	Demonstration of Knowledge
<p>Essential V Health Care Policy of Advocacy in Health Care</p>	<p>Competency- Analyzes health policy from the perspective of patients, nursing and other stakeholders</p> <p>Competency – Provides leadership in developing and implementing health policy</p> <p>Competency –Influences policymakers, formally and informally, in local and global settings</p> <p>Competency – Educates stakeholders regarding policy</p> <p>Competency – Advocates for nursing within the policy arena</p> <p>Competency- Participates in policy agendas that assist with finance, regulation and health care delivery</p>	<p>The current policy and state laws and standing orders for Naloxone were analyzed and introduced to all stakeholders involved in the DNP project. The costs and benefits of the process in terms of finances, value of life and safety of patients were discussed during the educational intervention. Patient safety and quality were reinforced.</p>

	Competency – Advocates for equitable and ethical health care	
Essential VI Interprofessional Collaboration for Improving Patient & Population Health Outcomes	<p>Competency- Uses effective collaboration and communication to develop and implement practice, policy, standards of care, and scholarship</p> <p>Competency – Provide leadership to interprofessional care teams</p> <p>Competency – Consult intra-professionally, and inter-professionally to develop systems of care in complex settings</p>	During this DNP project the author was able to collaborate with the team members, site champion and the staff. Further interprofessional collaboration is being done for the dissemination of the project by contacting the community leaders and stakeholders.
Essential VII Clinical Prevention & Population Health for Improving the Nation's Health	<p>Competency- Integrates epidemiology, biostatistics, and data to facilitate individual and population health care delivery</p> <p>Competency – Synthesizes information & cultural competency to develop & use health promotion/disease prevention strategies to address gaps in care</p> <p>Competency – Evaluates and implements change strategies of models of health care delivery to improve quality and address diversity</p>	During this DNP project, the author used World Health Organization, Centers for Disease Control and North Carolina Department of Health and Human Services sites to obtain data regarding drug overdose and related deaths in the community. This data was helpful in assessing the need for intervention to improve population health and analyzing the educational needs of the targeted population. More study was done on the prevention strategies reading the evidence-based research articles. The information was synthesized and translated to practice to prevent complications and death in the patient population receiving narcotics for pain control. Based on the knowledge acquired and using IOWA model, an educational intervention was conducted aiming at improving the current situation. The results of the intervention were measured to evaluate the effectiveness.

<p>Essential VIII Advanced Nursing Practice</p>	<p>Competency- Melds diversity & cultural sensitivity to conduct systematic assessment of health parameters in varied settings Competency – Design, implement & evaluate nursing interventions to promote quality Competency – Develop & maintain patient relationships Competency –Demonstrate advanced clinical judgment and systematic thoughts to improve patient outcomes Competency – Mentor and support fellow nurses Competency- Provide support for individuals and systems experiencing change and transitions Competency –Use systems analysis to evaluate practice efficiency, care delivery, fiscal responsibility, ethical responsibility, and quality outcomes measures</p>	<p>The DNP project was designed and implemented using the advanced clinical judgement to improve the safety of the patients who is receiving narcotic prescriptions. The outcomes were measured systematically to ensure the practice change. Through the DNP project intervention, the author was able successfully educate the providers, fellow nurses, and other team members regarding the Naloxone Nasal Spray co-prescription to prevent narcotic overdose deaths. The privacy and cultural sensitivity were maintained while implementing an evaluating the project. Equal opportunities were given to all staff to participate in the project.</p>
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Appendix L
Project Budget

Item	Quantity	Unit cost	Total
Project Supplies			
Pre and post Questionnaires (printing cost)	50	\$0.5	\$25
Brochures for patient education (printing cost)	100	\$0.5	\$50.00
Pen	25	\$1.03	\$25.75
Marker	2	\$ 0.98	\$1.96
Educational Expenses			
Educational packet for providers and staff education	25	\$2.00	\$50.00
Flash Drive	1	\$8.99	\$8.99
High Lighter	2	\$1.50	\$3.00
Lunch expenses (Optional)	25	\$10.00	\$250.00
Delivery expenses of food to the site	1	\$20.00	\$20.00
Tax for the lunch	1	\$18.12	\$18.12
Expenses for Visual Reminders			
Wall posters	5	\$25	\$125
Stickers 'Naloxone saves lives'	25	\$1	\$25
Total			\$602.82

Appendix M
Dissemination Plans

No.	Site	Abstract Submission	Presentation
1	ECU CON	March 2021	April 2021
2	Project Site	April 2021	April 2021
3	NC Opioid Misuse and Overdose Prevention Summit	February 17 2021	May 4 2021
4	Indian American Nurses Association of North Carolina Nurses week celebration	April 2021	May 2021