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Opioid Naloxone Education Clinical Practice Guideline

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
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Abstract

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MSN, Walden University, 2015

BSN, Georgetown University, 2005

Project Submitted in Partial Fulfillment

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Abstract

As a result of an institution-wide campaign to train providers on the administration of opioid reversal agents within a large medical center in the northeastern United States, the practice problem emerged that there was no patient/family education document for healthcare providers to use as a guide to educate patients on opioid risk and proper administration of naloxone to prevent opioid overdose in the outpatient setting. This scholarly project used an interprofessional team to develop comprehensive opioid naloxone education guidelines to close the gap in clinical practice. The purpose of this project was to develop a patient education clinical practice guideline for patients/families receiving naloxone for potential opioid overdose that meets the quality expectations of the AGREE II instrument as determined by a panel of experts. Using the RAND modified Delphi approach and the AGREE II tool, consensus was achieved. The Opioid Naloxone Education Clinical Practice Guideline (ONECPG) was then reviewed by three professional experts who determined that the guideline meets the quality expectations for use in clinical practice. Reviewers scored scope and purpose (100%), stakeholder involvement (94%), rigor of development (92%), and clarity of presentation (100%) as the highest rated scores. Applicability (60%) and editorial independence (86%) rated lowest due to the inapplicability of the items listed within Domains 5 and 6 to the scope of the guidelines. This guideline has the potential to improve clinical care for those using opioids by involving family in the early intervention in cases of potential overdose. This is consistent with social change and social justice for community action to address opioid overdoses and their impact of society at large.

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Dedication

To my mother, the definition of “unbought and unbossed.”

To my Love and my children.

To the memory of my father, Willie M. Worthy.

Acknowledgments

First, I give thanks and honor to God. Without his love and faithfulness, I would not have made it through this journey. Secondly, I would like to thank myself. Typically, acknowledgments are to someone other than yourself. However, I finished this project during the COVID-19 pandemic, multiple missions with the United States Public Health Service, working full time, and fifth/second-grade virtual learning for Alyc'Yana Grace and Jacob O'Neil. These are all accomplishments that should not go unrecognized.

I want to send a special shout-out to my husband, John. Although 800 miles away, working to create a legacy for our family, John has remained unwavering in his support during this process. I want to acknowledge my mother, who made sure the children did not burn down the house, washed our clothes (the colored clothes now have white spots), and prepared beautiful family meals (when she felt like it). Without your support Mama, I would not have been able to keep everything going. A special thanks to my sister Sonia who made sure I was "still living and conscious" daily.

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Section 1: Nature of the Project

Introduction

The Centers for Disease Control and Prevention (CDC, 2018) reported that opioid overdose rates increased by 30 percent from July 2016 to September 2017. Prescription opioid-related deaths have doubled since 2010 (Office of the Surgeon General (OSG), 2018). Today, amid the COVID-19 pandemic, researchers have observed a substantial increase in opioid-related deaths since March 2020 (Blaney-Koen, 2021). According to the National Institute on Drug Abuse (NIDA, 2021), more than 93,000 deaths related to opioid overdose have occurred since 2020, a 30% increase from 2019. The increase in opioid overdose rates emphasizes the need to implement preventable measures for overdoses and immediate treatment of an overdose. According to the CDC (2018), education and access to opioid reversal agents, such as naloxone, can potentially decrease the rate of deaths significantly. The opioid antagonist properties of naloxone make the medicine the best option to use when trying to reverse the signs and symptoms of opioid overdose. These signs and symptoms include slowed or labored breathing, unconsciousness, snoring or gurgling sounds, and changes in skin color (Rzasa & Galinkin, 2018). Naloxone should be administered intranasally every 2 minutes, alternating nostrils with each dose. It should be used whenever an overdose is suspected. There are no adverse effects if administered to someone who is not experiencing an overdose, and naloxone is safe to administer to ages from newborn to the elderly.

Incorporating naloxone into prescription pain medication regimens, teaching patients to prevent overdosing (e.g., avoiding use with alcohol, proper administration, and

safe handling), and educating them on how to recognize the signs and symptoms of opioid overdose are vital to minimizing the risk for opioid-related deaths. In addition, providing instruction on administering naloxone at home is vital to minimizing the risk of death related to opioid use in patients prescribed opioids (CDC, 2018). Implementing practice changes to include opioid screening questions and naloxone educational resources is equally essential (Adams, 2018).

Education empowers patients to improve their health and caregivers the opportunity to partner with patients to achieve the desired health outcomes. Nurses play an essential role in this patient education. The nursing profession has a responsibility to take the lead in addressing the global opioid crisis by developing nurse-led opioid education programs. Positioning nurses at the forefront of screening and prevention education will increase the outreach to patients who are prescribed opioids and help to increase awareness of opioid risk, ultimately improving the quality of care rendered to patients who are prescribed opioids (National Institutes of Health [NIH], 2018).

This Doctor of Nursing Practice (DNP) scholarly project aimed to develop an evidence-based clinical practice patient education guideline for nurses, physicians, advanced practice practitioners, and pharmacists to use when educating patients/families on the use of naloxone in the outpatient setting. The long-term impact of this project is to encourage a standard of care practice for patients managed with opioids for chronic pain disorders and to promote the development of clinical practice guidelines relating to co-prescribing opioids and naloxone nasal spray in the outpatient setting. Early intervention and increased provider–patient communication about the risks associated with opioid use

can safeguard patients and their family members from opioid overdose and, ultimately, opioid-related deaths (Department of Health & Human Services [HHS] 2019). According to the Agency for Healthcare Research and Quality (2019), these opioid overdose prevention and surveillance strategies can potentially promote social change relating to the opioid epidemic.

Problem Statement

The problem identified in this DNP project was the need to add an evidence-based patient education clinical practice guideline on opioid education and naloxone administration for patients/families who are prescribed opioid take-home medications. Patient populations in the clinic for which this education guideline is needed suffer from oncology diseases, sickle cell anemia (SCA), and significant musculoskeletal pain frequently treated with prescription opioids (Treede et al., 2019). The prolonged use of opioids in these patient populations places them at a greater risk for addiction and accidental overdose, which could result in death.

In addition to prolonged use, patients in these at-risk populations are at an even more significant threat of opioid-related deaths due to tolerance, misuse, and polypharmacy. Patients with other sedating medications may have drug–drug interactions and suffer from an opioid overdose (World Health Organization, 2021). Based on current literature and the advisory issued by the Office of the U.S. Surgeon General, opioid overdose education, along with access to naloxone, are critical factors in decreasing the risk of opioid-related deaths (Adams, 2018). Although there is literature to support the implementation of a comprehensive education plan in hospital-based clinics, the standard

of practice varies from institution to institution, and in some hospital-based clinics is nonexistent. The education provided is inconsistent in assessing and managing overdose signs and symptoms; education on how to mitigate an opioid overdose at home is rarely documented in the electronic health record (Miller et al., 2020). There is not a standard process in place at the Clinical Center to provide education to outpatients prescribed opioids. There is literature about opioids and their risk. However, no comprehensive document addresses the risk, signs, and symptoms of an overdose and what to do in the event an overdose is suspected.

Targeting high-risk populations, providing patient education, increasing access to naloxone reversal agents, and communicating the action plan verbally and in writing are central to reducing the risk of opioid-related deaths. Access to naloxone in community health settings has significantly decreased opioid-related death rates (NIDA, 2017). The literature shows that in settings where naloxone kits are distributed and provided to patients with opioid prescriptions, family members could temporarily reverse the effects of an opioid overdose, specifically in patients with labored or obstructed breathing (NIDA, 2017).

Increasing the awareness and availability of this medication is a crucial part of the public health response to the opioid epidemic. Naloxone is a safe and effective antidote to a suspected overdose. The availability of naloxone, paired with overdose prevention education, directly correlates to decreased overdose-related death rates (Brown, 2021). The opioid crisis continues to be a significant problem; however, it is preventable with suitable measures in place (CDC, 2020). The identified gap in practice is the lack of an

evidence-based patient education practice guideline for clinicians to use when educating patients who are prescribed naloxone with prescription opioids. Patients and their family members or care partners would benefit from education focused on increasing the awareness of opioid overdose signs and symptoms, providing access to naloxone nasal spray, and instruction on the proper administration of naloxone.

The local health department has developed similar programs with public safety workers to provide free naloxone training kits to the community to address the current opioid epidemic. Adopting similar practices at the Clinical Center, if implemented, within the targeted patient population would set a standard of practice for patients and their caregivers that various disciplines across the Clinical Center can utilize. Setting a standard of practice for patient education may also encourage formal training for providers in the form of annual competencies. If approved and implemented by the leaders of the health care organization, the education program centered around increased awareness of the prevalence of the opioid crisis and expanding access to naloxone will be a significant call to action for nurses, physicians, and advanced practitioners, and pharmacists. Such an initiative would represent a powerful commitment to save lives and provide options to patients prescribed opioids in the outpatient setting.

Purpose Statement

This scholarly project aims to meet the quality expectations of the Appraisal of Guidelines for Research and Evaluation (AGREE II) Instrument by developing comprehensive opioid naloxone education guidelines to close the gap in clinical practice as it relates to the care of patients sent home with opioid prescriptions. The gap in

practice was identified because of an institution-wide campaign to train providers on the administration of opioid reversal agents within a large medical center in the northeastern United States. During the training, providers were educated about naloxone and various administration techniques; however, they did not have access to naloxone through the hospital's outpatient medication formulary. Therefore, they could not make naloxone available when prescribing take-home opioids. There were limited outpatient and caregiver education resources developed by the organization to address the opioid epidemic and the use of naloxone. Education guideline recommendations would provide registered nurses, nurse practitioners, physicians, and pharmacists, with the tools needed to deliver more comprehensive care to patients/families at risk for a drug overdose. The development of a naloxone distribution program with an algorithm for prescribing the medication to patients identified as being at risk will be instrumental in helping staff decrease the risk of opioid-related deaths in the outpatient setting (Funke et al., 2021).

This is the practice-focused question that will be addressed: Will developing a patient education clinical practice guideline for patients/families receiving naloxone for potential opioid overdose meet the quality expectations of the AGREE II instrument as determined by a panel of experts? A high-quality AGREE II score suggests the quality expectations have been met, and the Opioid Naloxone Education Clinical Practice Guideline (ONECPG) addresses the gap in practice at the healthcare organization.

Nature of the Doctoral Project

Evidence

A preliminary literature review showed three waves of opioid-related deaths (CDC, 2020). The first wave occurred in the early 1990s due to the increase in prescribed natural semisynthetic and methadone opioids (CDC, 2020). In 2010, there was a precipitous increase in opioid-related deaths, resulting in a second wave (CDC, 2020). In 2013, there was a substantial increase in synthetic drugs, specifically fentanyl, contributing to the third wave of opioid-related deaths (CDC, 2020). The CDC (2020) reveals that the market for fentanyl continues to change, and the combination of drugs it is paired with constantly evolves to include heroin, cocaine, and counterfeit pills. Polysubstance use is also contributing to the vast number of opioid-related deaths.

The increased availability of synthetic drugs and the COVID-19 pandemic have contributed to the rise in opioid use and opioid-related deaths. Social isolation, devastation, and limited access to health care providers are risks associated with opioid use disorder (CDC, 2021). Opioid-related deaths have increased more than six times since 1999 (CDC, 2021). The CDC (2021) reported a significant increase in overdose-related deaths during 12 months. More than 90,000 Americans have died as a result of opioid overdose from September 2019 to September 2020.

Pain is the most common reason patients suffering from chronic disorders like SCA visit their physicians or the emergency departments. Thorough consideration of the benefits and risks of treatment options is vital when prescribing pain treatment. Pain triggers assessed regularly created better outcomes (CDC, 2020). Increasing opioid

education with each written prescription will enhance patient knowledge and understanding and promote safety, which has the potential to help mitigate the opioid crisis by reducing the rate of opioid use disorder and accidental overdoses (CDC, 2020).

The Clinical Center has a large population of patients with SCA. Patients with SCA often go unrecognized in managing an opioid disease. The literature highlights that uncontrolled pain is a hallmark of SCA. Comprehensive pain management plans are warranted to adequately and safely manage the chronic pain associated with this disorder (Osborne et al., 2021). SCA is a genetic disorder of red blood cells characterized by the inability to carry oxygen-rich cells to all body parts (CDC, 2020). The C-shape of the cell, called a sickle cell, makes traveling through the bloodstream difficult, resulting in an accumulation of cells and a halt in their circulation through the body. The accumulation of cells, or *vaso-occlusive crisis*, causes pain and other medical emergencies for people suffering from SCA (CDC, 2020). This patient population is often sent home with opioids and other sedating medications. SCA patients deserve comprehensive pain regimens that control their pain and are paired with an opioid naloxone education plan.

According to Strange et al. (2019), naloxone is essential for responding to the global overdose problem. The commitment to improving access and education is an even more significant essential element to ending the problem. Access to naloxone in community health settings has shown significantly decreased opioid-related deaths. The literature shows that in settings where naloxone kits were given out with opioid prescriptions, lay people could temporarily reverse the effects of an opioid overdose (Strange et al., 2019). Increasing the awareness and availability of this medication is a

vital part of the public health response to the opioid epidemic. Naloxone, an antidote for opioid overdose, is safe and effective. If given promptly, naloxone can be the difference between life and death. The availability of naloxone and overdose prevention education directly correlates to decreased overdose-related deaths (Adams, 2018).

Approach

In addition to the proposed change in practice, developing an opioid education consult team organized to provide education and follow-up for patients treated with opioids would be the ideal strategy to ensure continuity of the education provided and continuation of the prevention initiative for years to come. If such a team were created, providers on that team could utilize skills acquired from provider-focused education training and transfer knowledge to their patients about the risk associated with opioid use and the proper administration of naloxone in nonclinical settings.

This project followed the Walden Manual for Clinical Practice Guideline Development. An internal review of the hospital's policy on dispensing opioids in the outpatient setting was prompted after a gap in practice was identified during a naloxone provider training course that was completed in response to a nationwide campaign to reduce deaths related to opioids overdose (OSG, 2018). Providers were instructed on how to use the medication; however, the drug was not made available through the hospital outpatient formulary, despite opioid prescriptions written to outpatients. The first step was to conduct an internal review of the education process for patients sent home with opioid prescriptions and the accessibility of naloxone nasal spray in the outpatient setting.

A review of the current practices and policies regarding opioid medication and the distribution of naloxone kits for outpatients was found to be nonexistent.

A literature search was then conducted to seek best practices for patients sent home with prescription opioids. During the literature evaluation, the following databases were reviewed: NCBI, CINAHL, PubMed, and Medline. The guidelines from the NIDA at the NIH and the CDC were considered and used as a resource to develop policies for the proposed practice change. The keywords used during the literature search were *opioid use disorder*, *chronic pain disorder*, *pain*, *and opioids*, *sick cell crisis*, *sickle cell anemia*, *polysubstance*, *naloxone*, *naloxone administration*, *naloxone education*, *opioid prescribing guidelines*, *patient opioid education*, and *caregiver role opioid overdose*. Other sources for the guidelines include national clinical practice guidelines identified by Bruneau et al. (2018) and economic evaluation and guidelines outlined by Chao and Loshak (2019). In addition, guidelines from the National Association of State Emergency Medical Officials regarding naloxone administration and distribution were reviewed (Williams et al., 2019).

The overwhelming amount of information generated to support a change in practice prompted the need to synthesize the evidence found in the literature. I used the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) tool to synthesize search findings. GRADE is a highly regarded and respected evaluation tool and framework used to develop summaries for presentations of evidence-based information (Goldet & Howick, 2013). A journal of articles was created to organize the literature. The articles were categorized based on levels of quality from very low to high

(Goldet & Howick, 2013). This process helped me to stay on task with the goals of the project and create a list of data to support a change in clinical practice based on articles that were ranked high quality and evidenced based.

The summaries formulated during this process were evidence-based information that was organized and presented when advocating for the development of the ONECPG. GRADE was used to categorize the information gathered and determine the quality of evidence found to support recommendations for a clinical practice change (Goldet & Howick, 2013). The literature supported the recommendations to develop a more comprehensive patient/family-focused education guideline. Based on the literature review, I developed a list of priorities for the ONECPG. The common theme of the literature was to increase awareness, increase access to naloxone and teach proper use. Once the problem was identified and the priorities were organized, the population was defined based on the patient population at the most significant risk for opioid overdose. It was also based on the interest of the internal stakeholders. The pharmacy analyzed the number of prescriptions written for opioids. The project team determined that the SCA group had the most patients managed on opioids; therefore, providers that work with this patient population would be instrumental in collecting the feedback needed to create a comprehensive ONECPG.

The project team, comprised of an advanced nurse practitioner, registered nurse, pharmacist and medical doctor, met online, using the Zoom videoconferencing platform (https://zoom.us), to discuss the proposed ONECPG and provide input on the clinical science, education methods, and feasibility of the guideline. The AGREE II instrument

was used as a framework to develop the guideline. Once consensus was reached, the ONECGP was shared with a group of three nurse experts with advanced practice degrees working in inpatient, outpatient, and research institute settings. These experts were from various backgrounds of nursing and reviewed the guideline through the lens of a clinical nurse specialist, nurse educator, and nurse leader. The nurse experts evaluated the guideline using the AGREE II instrument to assess the quality of the ONECPG. The team reviewed the guideline for the following elements: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence as outlined in the AGREE II criteria (Agree Trust, 2017).

Two of the nurse experts recommended the ONECPG without any modification. The clinical nurse specialist advised changing a word in the administration steps. The six domains of the AGREE II instrument were independent of each other and had a total of 23 items that were assigned quality points. The points ranged from 1 through 7, with 7 being the highest quality score possible. The following scores were assigned to the six domains of the AGREE II instrument based on the user's manual (Agree Trust, 2017):

- Domain 1. Scope and Purpose (100%)
- Domain 2. Stakeholder Involvement (94%)
- Domain 3. Rigour of Development (92%)
- Domain 4. Clarity of Presentation (100%)
- Domain 5. Applicability (60%)
- Domain 6. Editorial Independence (86%)

Domains 5 and 6 were rated the lowest due to inapplicability to the guidelines. The overall consensus from all three expert nurses was to recommend the ONECPG for use in clinical practice. See Appendix C for score calculations.

Significance

Providers

Implementing the ONECPG will greatly benefit outpatient physicians, advanced practitioners, pharmacists, nurses, the patients they manage, and the organization's ability to meet national patient safety goals. Currently, there is variation in the quality of education and guidelines clinicians receive regarding prescribing, opioid screening, and intervention strategies (Leventhal et al., 2019). Prescribers are the gatekeepers for minimizing the risk of opioid-related deaths (American Nurses Association [ANA], 2016). The development of a comprehensive program that is consistent with evidence-based practice is vital to improving the care of outpatients managed on opioids. Since opioid overdose is a national crisis, a standard for educating patients and their caregivers on the signs and symptoms of opioid overdose and the proper administration of naloxone should be established. The idea of an opioid education consult team would help provide a structured, evidenced-based forum for clinicians to dialogue about prevention strategies and create an opportunity to develop consistent, high-quality, evidence-based resources for the patients they manage.

Nurses

Nurses play a critical role in the health and wellness of every patient population. The same is true for patients impacted by the opioid epidemic. Nurses are central to the

nation's efforts to eliminate the opioid problem. Nurses help to educate patients and their families, teaching them about the risk associated with prescription opioids and other medications to manage their disease. They help prescribers assess potential problems by completing screening questionnaires and medication reconciliations (Manworren & Gilson, 2015). Nurses also help to monitor patients' medication use with follow-up calls to improve patient outcomes (Manworren & Gilson, 2015). Carrying out the nursing process is essential when caring for patients prescribed opioids. Advanced practice nurses assume responsibility for assessing, diagnosing, and managing patients with disorders requiring opioids; they play a critical role in mitigating the opioid epidemic (ANA, 2018).

Historically, nursing professionals have led to prevention strategies, early recognition, and patient and family-centered care approaches (ANA, 2016). According to the ANA (2018), nurses often lead the way in an attitudinal transformation toward pain management by incorporating change models into their everyday nursing process. Since the roles of nurses are so vast and multilayered, they are in a pivotal position to help increase the knowledge, understanding, and access to the tools needed to decrease the rate of opioid-related deaths (ANA, 2016). As healthcare providers, educators, and patient advocates, nurses are in a matchless position to help patients understand the risk associated with opioid use, how to prevent opioid-related deaths, and increase their awareness of alternative therapies for pain management. Nursing creates and drives change, particularly in today's healthcare climate. Our nation's healthcare needs are complex and ever-changing (Moran et al., 2019). The role of nursing is imperative to the

advancement of health care practice and the success of quality improvement initiatives. Nurses deliver care based on best practices, which suggests a continual need to update or make changes to practice. Positioning nurses to lead in the fight against the opioid epidemic will help to ensure the most up-to-date strategies are being used and that the initiative is successfully implemented in a thoughtful and organized approach.

Nurses help establish the partnerships required to create lasting change in health care. Nurses are often the direct line of communication between patients and their medical team. Establishing trusting relationships is what leads to improved health outcomes. Involving patients in their care will increase compliance and adherence to the recommended interventions. Increasing knowledge and awareness is a central element of nursing practice. The nursing profession has a responsibility to take the lead in eradicating the global opioid crisis by developing nurse-led opioid education programs. Essential education initiatives that are transferable to any health care organization will set the basis for a certain level of standard for education provided to every patient managed with opioids. Education empowers patients to improve their health and caregivers the opportunity to partner with patients to achieve the desired health outcomes. Positioning nurses at the forefront of opioid screening and prevention education will increase patient outreach and help to increase awareness of opioid risk, ultimately improving the quality of care rendered to patients prescribed opioids (NIH, 2018).

Patients and Families

In March 2021, the CDC (2021) reported that opioid overdose related deaths quadrupled in the United States since 1999. As of June 2022, approximately 932,000

people have died since 1999 from opioid-related drug overdose (CDC, 2022). Decreased access to providers and an increase in self-management of pain have also contributed to the number of opioid-related deaths. Pain is the most common reason populations like SCA patients or other groups with chronic non-cancer pain visit their physicians or the emergency departments. Receiving appropriate pain treatment based on carefully considering the benefits and risks of treatment options is vital for these patient populations. Consistent access to the primary care team, evaluation of the patient's pain control, and pain triggers should be performed regularly. Refreshing opioid education with each written prescription will also help to enhance patient knowledge and understanding and promote safety.

In addition to education, the distribution of opioid reversal kits has proven to be effective in mitigating opioid overdose (Kerensky & Walley, 2017). According to Strange et al. (2019), naloxone is essential for responding to the global overdose problem. The commitment to improving access and education is an even more significant essential element to ending the problem. Access to naloxone in community health settings has significantly decreased opioid-related deaths (Kerensky & Walley, 2017). The availability of naloxone and overdose prevention education directly correlates to decreased overdose-related deaths (Kerensky & Walley, 2017).

Summary

Increased education and the distribution of opioid reversal kits have proven effective in mitigating opioid overdose. The value of the opioid antagonist naloxone in reversing the effects of opioid overdose is immeasurable. A comprehensive assessment

and education plan has been proposed consistent with the U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose to improve care quality and safety for outpatients. Although the causes of the opioid epidemic are complex and determined by various components, the solution is simple—prevention through education and access to naloxone nasal spray to prevent opioid-related deaths.

The ONECPG will provide a framework centered on evidence-based information for healthcare providers to supply their patients with the information they need to safeguard themselves when managed with opioids in the outpatient setting. The goal of this initiative is not only to educate but to increase access to naloxone nasal spray. Increasing the awareness and availability of this medication is a crucial part of the public health response to the opioid epidemic. Section 2 will provide the background and context for this project. Section 2 will highlight the intent of the education guideline and the expected outcomes.

Section 2: Background and Context

Introduction

The site for this project is an outpatient clinic within a large medical center in the northeastern U.S that was identified has having a gap in clinical practice as it relates to patients prescribed opioids for the treatment of chronic pain disorders and access to naloxone to reduce the risk of opioid overdose while at home. This scholarly project aimed to develop an evidence-based patient education clinical practice guideline for nurses, physicians, advanced practice practitioners, and pharmacists to use when educating patients/families on the use of naloxone in the outpatient setting. The practice-focused question was: Will developing a patient education clinical practice guideline for patients/families receiving naloxone for potential opioid overdose meet the quality expectations of the AGREE II instrument as determined by a panel of experts? This project addressed the gap in practice at the healthcare organization. The recommendations highlighted in the guideline have the potential to help safeguard against opioid-related overdose and death in patients/families taking opioids in the outpatient setting.

The ONECPG is a comprehensive document of best practices that promote an increase in the quality of care provided to outpatients suffering from chronic pain disorders and sent home with prescription opioids to manage their pain. The guideline promotes the use of best practices in the care of patients at risk for opioid use disorder and overdose. The recommendations included in the guideline could potentially help decrease the risk of opioid-related deaths in at-risk patient populations.

The healthcare organization of focus for this project is a large multidisciplinary institution servicing patients nationally and internationally. Patients managed at this organization come from all over the world, with various demographics, insured and uninsured. The organization does not have a comprehensive education guideline for managing patients sent home with opioids to manage chronic pain. A nurse-led multidisciplinary team developed the ONECPG to provide a concise education resource for health professionals and their patients to establish an education standard of practice for patients sent home with opioids. The project is intended to help achieve the goal of safeguarding patients managed with opioids while at home from opioid-related deaths. In this section of the project, I will discuss the conceptual model for the recommended education program, the relevance to nursing practice, the local context, and the role of the DNP student.

Concepts, Models, and Theories

The health belief model (HBM) is used for this DNP project. This model focuses on patient compliance and preventative health practices. HBM is a middle-range theory that functions to explain trends and events and serves as a conceptual inspiration to many nurse researchers (McEwen et al., 2019). HBM serves to explain and predict health behaviors. The conceptual components of this model include perceived susceptibility, perceived severity, perceived benefits, cost, motivation, and enabling or modifying factors (McEwen et al., 2019). According to Tilford (2020), the HBM helps determine trends in patients prescribed naloxone. Tilford (2020) conducted a study to compare composite scores of perceived benefits, perceived barriers, self-efficacy, risk severity,

and risk susceptibility in groups educated on naloxone. The study yielded insight on the barriers to increasing the use of naloxone and highlighted that understanding the barriers is key to education and eliminating the opioid overdose problem.

Increasing knowledge and awareness is a central element of nursing practice. Components of the HBM were observed and measured through the nursing process implementation. Examples of this would be assessing and defining a patient's level of risk for opioid overdose or assessing the patient's understanding of the risk associated with taking opioids in the outpatient setting. The assessment of the patient's attitude towards the problem, their understanding of the problem, and their individual beliefs are key indicators that can be used by the provider, advance practitioners, or pharmacist when prescribing opioids in the outpatient setting. This knowledge will be very helpful in developing a plan of care that will promote patient compliance and adherence, ultimately improving the safety of patients managed on opioids. Including patients in their plan of care not only increases communication between the provider and the patient but is also the basis for provider/patient relationships built on trust.

Information about the patient's physiological, psychological, and sociological needs are variables that can be used when creating and implementing the plan of care. That will encourage change. In Tilford's (2020) study, the patient's level of knowledge was assessed, and the information collected shed light on the population's needs. The study revealed that information about naloxone was not being acquired through dependable channels, which increased the risk for stigma and minimized the importance of implementing overdose prevention and using opioid antagonizing medications like

naloxone. The study also highlighted the gap in practice as it related to education provided by a medical professional on the importance of access to naloxone and proper use of the antagonist when an opioid overdose is suspected. According to the literature, educational opportunities and interventions should already be transpiring between providers and patients at risk for opioid overdose and those with friends and family members taking prescription opioids (Tilford, 2020).

Components of the HBM can be used in the outpatient setting during the care of patients with chronic pain who are managed on opioids. Implementing an education plan that will increase the patient's knowledge and understanding of the potential problem or risk associated with opioids will help to ensure medication compliance and hopefully decrease the risk of opioid misuse. When patients understand the benefits of taking medications as recommended and have a naloxone rescue plan, they have a preventative plan of action that will help decrease the risk of opioid-related overdose and deaths in nonclinical settings.

The HBM has positive effects on health promotion and compliance. The model's effectiveness has been proven over time with many different patient populations and disciplines (Bechard et al., 2021). The HBM has been used to explain health-related behaviors—particularly those related to prevention or behavior in response to a diagnosed disease. It is a method of explaining and predicting compliance with health care recommendations. Research has shown that patients who understand their risks and benefits are more likely to comply with preventative health practices (McEwen et al., 2019).

Educating the patients on risks associated with opioids and reversal plans of action is an example of using the HBM. The perceived threat of overdose could encourage patients to be more careful when taking opioids and other sedating medications, which would motivate them to learn about the side effects of opioids and become educated on how to reverse side effects. Understanding the risk could motivate them to comply with the medication administration instructions, communicate with their health care teams if the pain is not controlled, and partner with their provider to find a more satisfactory care plan. This open line of communication has the potential to change the way care provided and ultimately identify other opportunities for practice changes.

To encourage a change in practice and improve medical outcomes in patient populations prescribed opioids in the outpatient setting, providers, advanced practitioners, and pharmacists must understand the barriers to implementing change within the health care organization, the population of focus, and the needed resources. The HBM will be the model to help guide the practice change and improve the quality of care provided to the patients and families. The development of education resources on opioid overdose prevention and proper administration of naloxone is key to the success of the proposed change in practice.

Although beyond this project's scope, the proposed systematic approach for implementing an education guideline would be a three-step change theory (Perri & Strike, 2020). This theory involves unfreezing, moving, and refreezing. During the unfreezing stage, awareness of the problem is increased, a needs assessment is performed, and the capacity to change is evaluated. Once the problem is identified, the

next step towards improving the quality of care for patients managed with opioids would be the moving phase.

In the moving phase, healthcare providers and organizations must transition into a new state of existence. The moving phase has been the most challenging step of the implementation process, as this is the phase that requires a renewed view or way of thinking. The transition requires excellent planning and organization to minimize resistance. According to McEwen and Wills (2019), change prompts individuals to have feelings of uncertainty, anxiety, and confusion. This critical step requires reassurance and reinforcement.

The influences that impact change during the moving phase are the driving and restraining forces. Education and open dialogue about the practice of change are the forces motivating the implementation of the change initiative. Evidence-based practice has significantly minimized resistance to change due to the vast amount of supporting literature. Evidence-based practice has helped to solidify the buy-in from stakeholders. The more knowledge and understanding the staff has of the initiative, the more readily they are to embrace the change in practice. The focus of the moving phase should be on the benefits of the change when implemented.

Another driving force of change is the support from the organization's leadership. There must be support from leadership to implement a change of this magnitude. Recognizing the problem and the need for change from leadership is crucial during the moving phase and key to the refreezing stage of Lewin's theory. In addition, resource allocation will be very instrumental during this phase. Support from the organization's

executive leadership will be essential to facilitate the proposed change in practice. The final phase of this theory is refreezing. The newly developed change becomes the new practice norm during the refreezing phase. It is imperative that refreezing does not take place until the practice is fully implemented. The purpose of refreezing is to stabilize the change and balance the driving and restraining forces. Refreezing can be accomplished through developing and implementing guidelines, policies, and new standards of practice (Bakari et al., 2017). If refreezing does not occur, then regression may occur. Leadership support and resources continue to be vital during this theory phase. Strong education and training around the new practice are vital to maintaining the project.

Nurses apply theory in daily practice through two key elements: assessment and patient education (Arora, 2015). Nurses deliver care based on best practices, which suggests a continual need to update or make changes to practice. Although implementing change is challenging, it can be accomplished using the proper framework to structure the necessary change. Successful implementation of this project will require thoughtful and organized change. The HBM and Lewin's Change Theory will help to bridge gaps in practice, as they will function to explain trends and events and serve as conceptual inspiration to health care organizations across the board. This process for development and assuring agreement on the education guidelines will use the consensus model developed by the RAND modified Corporation to plan, implement, and evaluate community-based prevention programs, and observe and measure components in practice.

Although beyond this project's scope, it is essential to note that evaluation of the implementation process is vital to the project's success. It is a means of measuring the level of improvement that has occurred within the program. The evaluation process will be instrumental in determining whether the goals and objectives of the initiative were achieved, as well as the level attainability of the intended goals (Key et al., 2019). In addition, it will help to improve leadership insight and general health care practices, measure learning, and help to determine the usefulness of implementing an organization-wide initiative. The evaluation process will also help highlight what additional changes need to be made for the proposed change to be more conducive to the needs of the target population, stakeholders, and other disciplines outside the sample population. Finally, the evaluation process will help to provide meaningful feedback as to how the proposed change will impact patient care, staff resources, and the institution's financial resources, both short-term and long-term (Key et al., 2019).

Relevance to Nursing Practice

The ANA (2018) declared that nurses change behaviors, attitudes, and beliefs toward pain management. Patient education is essential for building patients' and caregivers' knowledge, understanding, and preparedness for self-management (Khorfan et al., 2020). The literature highlights that nurses' involvement in patient education surrounding the opioid crisis will be instrumental in preventing opioid abuse and misuse (Costello et al., 2016). Patients and their caregivers have a better understanding of the use of prescription opioids and the proper administration of reversal agents when nurses also

clearly understand best practices for patients managed with opioids (Costello et al., 2016).

The lack of knowledge and awareness of the risk associated with the use of opioids, the potential for drug–drug interactions, and the proper administration of the opioid reversal agent, naloxone, are among many contributing factors to the rise of opioid misuse, abuse, and opioid-related deaths (Costello et al., 2016). The literature emphasizes the need for nurses to be educated on the most up-to-date practices that should be implemented to reduce the opioid problem (Castello et al., 2016). There is substantial evidence of the importance of nursing's role in increasing patient knowledge and awareness of the opioid problem, as well as the correlation between the increase in nursing's knowledge and the increase in the patient's knowledge surrounding the opioid epidemic (Castello et al., 2016).

Nurses are the direct line of communication between patients and their medical providers. Equipping nurses with the proper knowledge and understanding of the most up-to-date practices will empower them to assist patients and families by providing the most up-to-date information on the safe use of opioids and proper administration of naloxone nasal spray in the outpatient setting (Castello et al., 2016). Expanding the patient's knowledge by increasing the nurses' knowledge and awareness is a crucial response to the opioid epidemic.

A change in nursing practice is warranted to improve the quality of care provided to patients managed on opioids in the outpatient setting. Physicians must partner with nurses to conquer the problem. Since nurses are on the front lines of patient care, their

inclusion in the fight against the epidemic is vital (Castello et al., 2016). They are the first to interact with patients and usually the first to identify those at risk. There is great benefit in providing specialized training to nurses, as they have foundational knowledge, understanding, and the relationship with patients to help overcome the epidemic. If nurses are provided with resource tools such as a standardized risk assessment and intervention plans, it will help medical providers treat more patients with substance abuse.

Nurses would be able to reinforce instructions on proper medication administration and educate patients on the risk associated with opioid use and their interaction with other sedating medications. Finally, they would be able to solidify the teaching by providing patients with specialized training on recognizing an overdose and using naloxone nasal spray if an overdose is suspected.

An intervention that would significantly address the opioid epidemic is establishing a nurse-led opioid action plan (N–LOAP). The idea of N–LOAP is a specialized training program for nurses that would include a risk assessment tool, specialized naloxone administration training, and access to a physician-prescribed order set for nurses to dispense naloxone to at-risk patient populations. N–LOAP would prepare nurses to be an additional resource for physicians and create an opportunity for more patients with chronic pain to receive prescription medications and be adequately assessed, educated, and managed to decrease their risk of opioid-related death. Critical contributing factors to the opioid crisis are inadequate patient education and lack of individualized pain management for patients suffering from chronic pain. Nurses play a vital role in pain assessment and management. Equipping nurses with the specialized

knowledge to assess opioid overdose risk and critical safety tips to teach their patients before administering opioids or dispensing opioid prescriptions will help eliminate the opioid epidemic.

N–LOAP would include a standard pain assessment and direct questions specifically worded to identify the level of opioid risk. Implementing a pain assessment tool that includes diagnosis, intensity, location, description, precipitators, and a full assessment of current medications are the first steps of N–LOAP. Once the level of risk is determined and documented, they would ask pain medication-related questions to gauge the patient's understanding and level of medication administration compliance.

Understanding the patient's level of knowledge and awareness is vital to medication safety and compliance. Well-informed patients should be able to articulate prescribed dosages and the frequency of their medication. They should also be aware of potential interactions with other sedative medications, like benzodiazepines, that may potentiate the risk for an overdose. Assessing the patient's knowledge and understanding will help identify individual risk factors contributing to their opioid risk. Certain health behaviors, lack of education, literacy, compliance, and inadequate pain management are all factors that have a direct impact on a patient's level of risk.

Local Background and Context

The site for this project is an outpatient clinic within a large medical center in the northeastern United States. This area has high opioid use and death rates. The medical center also treats many inpatient and outpatient diseases, where acute and chronic pain is prevalent. The setting of focus for the project will be the Oncology and Hematological

Outpatient Clinic at the Clinical Center. The intended audience will be health educators from the nursing department, clinical pharmacy, advanced practice providers, patients, and family members. The clinic will make space available for a small group review and simulated use of the patient/caregiver guideline for the staff.

Role of the DNP Student

As a public health nurse, it is my responsibility to increase awareness and promote preventative health practices. My training as a public health nurse will help fulfill my responsibilities as the DNP student leading this project. In my role as the DNP student, I will execute a literature search and review evidence-based information that supports the proposed change in practice, which focuses on developing a patient/caregiver clinical practice opioid and naloxone education guideline for healthcare providers to use when prescribing opioids to their patients in outpatient settings. I will serve as the project lead in planning, monitoring, and facilitating the development of the patient/caregiver education guideline. I will be accountable for the entire project scope, and the project team, consisting of 3–4 healthcare providers/educators from various backgrounds. As the team lead, I do not have any potential bias from affiliations, funding, or financial holdings that will impact my objectivity. The initiative is for the Clinical Center, and I work for a separate institute/branch.

Role of the Project Team

Following the RAND Modified–Delphi approach, a project team of members with various levels of expertise, knowledge, and perspectives was developed to shape and create a comprehensive clinical practice guideline that included input from well-respected

healthcare experts (Khodyakov et al., 2020). The project team included a medical provider, advance nurse practitioner, registered nurse, and pharmacist. This team reviewed the ONECPG for completeness before sending the document to the panel of 3 nurse experts for analysis and scoring. Each member of the project team brought a different perspective. The pharmacist outlined the process for acquiring naloxone and the cost associated with implementing the recommended change in practice. The pharmacist also defined the impact on pharmacy staff resources if tasked with incorporating education for naloxone administration into their daily routine. The medical doctor, along with the advanced practice nurse, helped to define the scope of practice as it relates to who should be identifying the populations at risk and completing that initial education with the patient and their family member. They also confirmed the benefits of having naloxone co-prescribed with opioids. The registered nurse in the outpatient setting brought a holistic perceptive to the group. The nurse posed questions as it relates to medication reconciliation and communication with the primary care providers and care management of patients on multiple sedative medications and opioids, as well as the safety implications. The nurse was also instrumental in identifying the impact the guidelines would have on nurse staffing resources. As a result of the project team meetings, a more comprehensive tool was developed, and the effect of implementing ONECPG on hospital resources was considered.

Summary

Based on current literature and the U.S. Surgeon General's advisory on naloxone and opioid overdose, education and access to naloxone are vital factors in decreasing the

risk of opioid-related deaths (OSG, 2018). The opioid-related deaths are steadily increasing, especially amid the global pandemic COVID-19 (Khatri & Perrone, 2020). Due to the advancements in medical treatments, patients with chronic disorders like SCA and various cancers are living longer and dealing with the health implications of their chronic disease. One of the significant health implications is chronic pain (Dahlhamer et al., 2018). More and more individuals are being managed on opioids for chronic pain. Patients with chronic pain are at an even greater risk of opioid-related deaths due to prolonged use, tolerance, and misuse. Even when taking their pain medications as prescribed, these patients are at increased risk of accidental overdose and drug–drug interactions with other sedating medications.

Opioid use in the United States directly correlates to the increasing rate of opioid addiction and opioid overdose-related deaths. Prescribers are being asked to implement a change in practice when caring for patients receiving opioid medications to help eliminate this national crisis. Combining co-prescribing opioids and naloxone and increasing provider, patient, and caregiver knowledge and awareness are the initial steps to addressing the opioid problem. Access to naloxone in the outpatient setting is essential to the public health response to the opioid epidemic. The project focuses on mitigating the opioid epidemic, increasing awareness of the problem, increasing access to naloxone nasal spray in the outpatient setting, and increasing understanding of how to use naloxone during a suspected overdose properly. Section 3 will discuss the collection and analysis of evidence.

Section 3: Collection and Analysis of Evidence

Introduction

The identified problem was a lack of evidence-based patient/family education on naloxone administration in the outpatient setting, and a clinical practice guideline for prescribing opioid antagonist naloxone to patients prescribed opioids as take-home medications. This scholarly project aims to meet the quality expectations of the AGREE II Instrument by developing comprehensive opioid naloxone education guidelines to close the gap in clinical practice as it relates to the care of patients sent home with opioid prescriptions. The gap in practice at the Clinical Center was identified as a result of an institution-wide campaign to train providers on the administration of opioid reversal agents. A training program was developed for healthcare providers and administrative staff throughout the hospital and medical campus-wide; however, the training was not transferred to patients and caregivers. In addition, naloxone was unavailable in the outpatient pharmacy for providers to prescribe to their patients.

The ONECPG guideline includes evidence-based recommendations on proper naloxone administration for patients/family or care partners to utilize in case of a suspected opioid overdose. The literature highlights that educating and increasing patient/family awareness will help to safeguard patients from opioid overdose in nonclinical settings. The project team was created based on expertise and knowledge of the opioid problem. Representatives from medicine, nursing, and pharmacy were assembled to optimize opioid overdose prevention strategies by analyzing existing evidence-based information collected by the DNP student.

Practice-Focused Question

The guiding practice-focused question was: Will developing a patient education clinical practice guideline for patients/families receiving naloxone for potential opioid overdose meet the quality expectations of the AGREE II instrument as determined by a panel of experts? In order to meet the quality expectations and formulate recommendations that were complete and addressed all aspects of the problem, the focus of the search for information was on improving provider, patient, and caregiver opioid education resources and open access to naloxone in the outpatient setting.

Sources of Evidence

Sources of evidence included journal articles, literature reviews, clinical research studies, and analysis, in combination with provider experiences. The literature was retrieved using NCBI, CINAHL, PubMed, and Medline databases. The recommended guidelines from the NIDA at the NIH, the CDC, the Food and Drug Administration (FDA), and the Pain and Palliative Group at NIH have been taken into consideration and used as a resource to develop guidelines for the proposed practice change. Through an extensive search of peer-reviewed articles, I have examined past and present approaches to eliminating opioid-related overdoses.

I conducted a comprehensive analysis of peer-reviewed articles that focus on the importance of provider prescribing standards, patient/caregiver education, and access to naloxone opioid reversal agents. An evaluation of the literature, starting from the inception of the opioid problem to the present date, was explored. The articles were limited to full text, English-only peer review articles published from 2016. A journal of

articles was created to organize the literature. The articles were categorized based on levels of quality from very low to high (Goldet & Howick, 2013).

Clinical practice guidelines from credible sources are included in the review. Key search terms include *opioids*, *opioid overdose*, *drug tolerance*, *opioid use disorder*, *chronic pain*, *co-prescribing*, *naloxone*, *the opioid epidemic*, *polypharmacy*, *opioid patient education*, *provider education*, *sickle cell anemia*, *collaborative practice*, *drug misuse*, *drug addiction*, and *non-pharmacological therapy*.

Literature Review

Opioid overdose is one of the significant contributors to death in the United States (Kerensky & Walley, 2017). Opioid overdose is recognized as a significant public health concern, and the quality of the evidence supporting strategies to mitigate the problem is excellent. Reputable health agencies like the HHS, CDC, FDA, and NIH stand in agreeance that three essential components required to prevent opioid overdose and death are opioid prescriber education, increased access to naloxone in the outpatient setting, and increased patient and caregiver awareness of the risk associated with taking opioids (Kerensky & Walley, 2017). These three factors are the elements required to establish overdose prevention strategies.

The GRADE tool was used to synthesize search findings. The evidence is of high quality and based on randomized controlled trials and observational studies producing evidence that increasing dialogue with patients about overdose reduction strategies directly impacts the rate of opioid-related deaths (Bohnert et al., 2016). In a randomized controlled trial, 204 adult participants who were randomly selected to undergo interview

sessions with education at baseline and then again 6 months post-intervention had significantly lower levels of opioid risk behaviors than those that did not have the additional education (Bohnert et al., 2016).

Bohnert et al. (2016) established that behavioral interventions directly correlate to reduced risk of opioid overdose and death. In several nonrandomized trials conducted in the emergency department and clinic settings in various states, patients had noticeable drops in the frequency of opioid-related visits. Coffin et al. (2016) reported that in an observational study of 1,985 emergency department patients that were educated and co-prescribed naloxone and opioids, all had a decrease in the number of emergency room visits than they did before being educated and co-prescribed. According to Coffin et al. (2016), overdoses reported in an emergency department on a U.S. Army base declined from 8 cases per month to 0 after implementing naloxone co-prescription programs. This information suggests that opioid naloxone education and co-prescription programs may have directly impacted the overdose rate by influencing patient and provider behaviors. The findings of these observational studies are consistent with multiple high-quality randomized trials supporting the implementation of opioid overdose prevention strategies in community settings.

Whether randomized or observational, there is little variability in the results of the different types of trials. Both randomized controlled trials and observational studies investigating opioid prevention programs on various patient populations have demonstrated noticeable and comparable reductions in the number of opioid overdose-related hospital visits and opioid-related deaths. Regardless of the patient population,

treatment indication, or the setting, the implementation of opioid prevention strategies, including increased education and naloxone access, has proven beneficial to producing positive outcomes in patients who take opioids and, therefore, is a recommended change in practice.

Although the change in practice may increase provider responsibilities and cost, the desirable effects of the recommendations to improve provider and patient education and the proposal to establish practice guidelines and increased access to naloxone outweigh any undesirable effects of the proposed change in practice. With all factors taken into consideration, the desirable effects of the proposed change in practice outweigh resources utilized to educate the patient, additional resources required to develop and maintain annual competencies for providers, and the additional cost of adding naloxone to outpatient formularies. Including medical doctors, advance practice practitioners, and representatives from the pharmacy in the planning phase of the project helped me to understand the healthcare institution's current process. This level of stakeholder involvement helped access the operation data needed to support the change in practice.

Education and accessibility are essential to overcoming the opioid crisis. It is emphasized in the literature that education, increased knowledge, and awareness of the opioid problem are central to producing favorable patient and provider-driven health outcomes (Phillips et al., 2017). Patient involvement is an integral part of the education process.

Healthcare providers are responsible for staying up to date on best practices and sharing knowledge acquired to increase patient awareness and understanding. In turn, this education process will help patients, and their caregivers make informed decisions about their care. The transfer of knowledge from provider to patient, regardless of the healthcare setting, will help to foster a healthcare environment that delivers safe and quality patient care.

One of the main strategies presented in the literature to help facilitate patient education is understanding the needs of the target population. Assessing patients' attitudes and individual beliefs will help guide interactions and serve as the basis for fostering provider/patient relationships. Once information about the patient's physiological, psychological, and sociological needs is gathered, these variables can be used to structure a plan of action geared towards patient compliance and positive patient outcomes.

Historically, nurses have worked with professionals from various disciplines to deliver quality, safe, comprehensive care that addresses patients' needs on multiple levels. Nurses are highly instrumental in gathering vital patient information to guide care plans (Simonette, 2020). Nurses are on the front line, most often the direct line of communication between physicians and patients, identifying perceived risks and benefits associated with specific health problems. Nurses work to formulate plans of action and put measures in place to minimize barriers and improve patient compliance and health promotion initiatives. Nurses can anticipate barriers to achieving the intended health outcomes by defining their patient population. The benefit of a nurse-led multi-

professional team is improved outcomes, increased access to health information, enhanced patient satisfaction, improved care coordination, and increased educational opportunities for patients and providers (Champagne, 2020).

Protection of Human Subjects

This DNP project will not have direct interaction with patients. The medical center considered this part of their patient quality improvement efforts and allowed the Walden Institutional Review Board (IRB) to supervise the project. All team participants are volunteers from the medical center who have been appraised of the purpose and scope of work. The project was submitted to the Walden IRB for approval before implementation.

Analysis and Synthesis

The system used to analyze and synthesize the patient education guideline developed was the Delphi Method (Barrios et al., 2021). This method will allow individual reviews to be collected in one source document. Stakeholders can answer questions, give feedback, and meet a consensus on best practices for managing patients treated with opioids in the outpatient setting and access to naloxone take-home kits with education on proper use (Barrios et al., 2021). The first draft of the guideline was developed for the team to use in building consensus. Once the group reached a consensus, a team of expert reviewers was asked to assess the guidelines using the AGREE II instrument. The checklist maintains the AGREE II's structure of six quality domains and its 23 essential items, providing a methodical and consistent process for reporting vital information. Specific reporting criteria are provided for each of the 23 items (Agree

Trust, 2017). The education guidelines will then be sent to the appropriate governing bodies for approval.

Summary

The opioid epidemic is one of the most significant health crises impacting healthcare systems nationally and internationally. There is strong confidence in the benefits of implementing clinical practice education standards for patients prescribed opioids in the outpatient setting. Providers and patients' preferences support changing clinical practice standards to include education and opioid prescribing guidelines. The proposed intervention represents a wise use of resources that may positively impact patient safety and quality improvement initiatives (Alonso-Coello et al., 2019). Implementing clinical practice standards, including annual provider education/training, patient and caregiver education, co-prescribing recommendations, and education on the proper administration of naloxone nasal spray kits, is highly recommended to improve the quality and safety of care provided to patients in the outpatient setting.

Naloxone is a life-saving medication that can reverse the effects of an opioid overdose. Providers, advance practitioners, pharmacists, and nurses must ensure patients receive naloxone. The literature highlights that patients and caregivers are willing to learn; however, they need reputable data-driven information to improve compliance and change health behaviors. A guideline for health care providers to use when educating patients is a vital tool central to maintaining quality health care that safeguards patients and their families against opioid overdose and death. Increasing education and access to naloxone in high-risk patient populations and among community members is a powerful

and responsible ethical decision. The development of an opioid naloxone education guideline will increase awareness of the opioid problem, promote increased access to life-preserving medication and improve the quality of care provided to vulnerable populations.

Educating patients and their families about the risks of opioid overdose and how to administer naloxone properly is an emerging clinical practice that may reduce fatalities from overdose and enhance safeguard measures for providers prescribing opioids. The AGREE Instrument was used to evaluate the practice guideline's development process. The patient/caregiver guideline will be based on three main elements identified by the CDC, clinical and contextual evidence, increased communication, education, and access to naloxone take-home kits. This project aims to eliminate the gap in practice at the Clinical Center by developing recommendations for patient and caregiver education guidelines. Section 4 will highlight the proposed practice change's findings, recommendations, and implications.

Section 4: Findings and Recommendations

Introduction

The site for this project is an outpatient clinic within a large medical center in the northeastern United States that was identified has having a gap in clinical practice as it related to patients prescribed opioids for the treatment of chronic pain disorders and access to naloxone to reduce the risk of opioid overdose while at home. Naloxone is a life-saving medication that can reverse the effects of an opioid overdose (CDC, 2018). A draft of the ONECPG was developed and disseminated to the team for review and analysis using the AGREE II Instrument. The patient/caregiver guideline was developed based on elements identified by the CDC. Based on clinical and contextual evidence, the following components are recommended when developing opioid prevention programs:

- Provider assessments to determine when it is appropriate to prescribe opioids in addition to the identification of alternative therapies for the management of chronic pain (CDC, 2018).
- Increased providers/patient communication regarding the type of opioid selected, prescribed dosage, duration, potential risk, follow-up, and need for discontinuation (CDC, 2018).

Increased education on the potential harms of opioid use, how to reduce the risk of opioid overdose while at home, and proper administration of naloxone reversal agent (CDC, 2018).

Findings and Implications

The guideline developed for this project will focus on the third component (see Appendices A and B for the ONECPG). Prime candidates for naloxone nasal spray are patients sent home with opioids to manage chronic pain. When patients are scheduled for discharged home with opioids for the management of chronic pain disorders, they should receive opioid and naloxone education by the physician, advanced practitioner, pharmacist, or nurse.

Understanding the patient's medical history and psychological and sociological factors are helpful information for the medical team to collect and use as a guide for creating a care plan for patients sent home with prescription opioids (Salvador et al., 2020). Understanding the target population's needs will help guide patient and caregiver education (Salvador et al., 2020). In addition, the patient's medication list should be assessed for other sedative medications like sleep aids or anxiety medications and over-the-counter medications. Herbal therapies should also be considered for drug interactions (Feng et al., 2017). The provider should assess whether the patient has any concurrent medical conditions that would potentiate the risk of overdose, like lung disease, kidney or liver disease, sleep apnea, or mental health conditions. For example, if the patient has a history of alcohol or other drug use, they may benefit from having access to naloxone nasal spray kits and alternative pain management therapies. A comprehensive pain assessment will help ensure risk factors are considered, and education is developed based on the patient's needs.

Once the healthcare provider has completed an opioid risk assessment, the provider should order the naloxone nasal spray kit containing two naloxone nasal sprays. Special instructions should be included in the medical order to educate the patient and their caregiver on the proper administration of naloxone. Educating the patient and their caregiver on the proper administration of naloxone is essential. Providers must stress the importance of patients developing a plan with their families to prevent opioid overdose. Family members should be made aware that the patient has access to naloxone in the event of an opioid overdose, as well as the importance of securing their opioid medications if they have others living in their home. Finally, all education should be documented in the electronic medical record. Communication is critical for continuity of care.

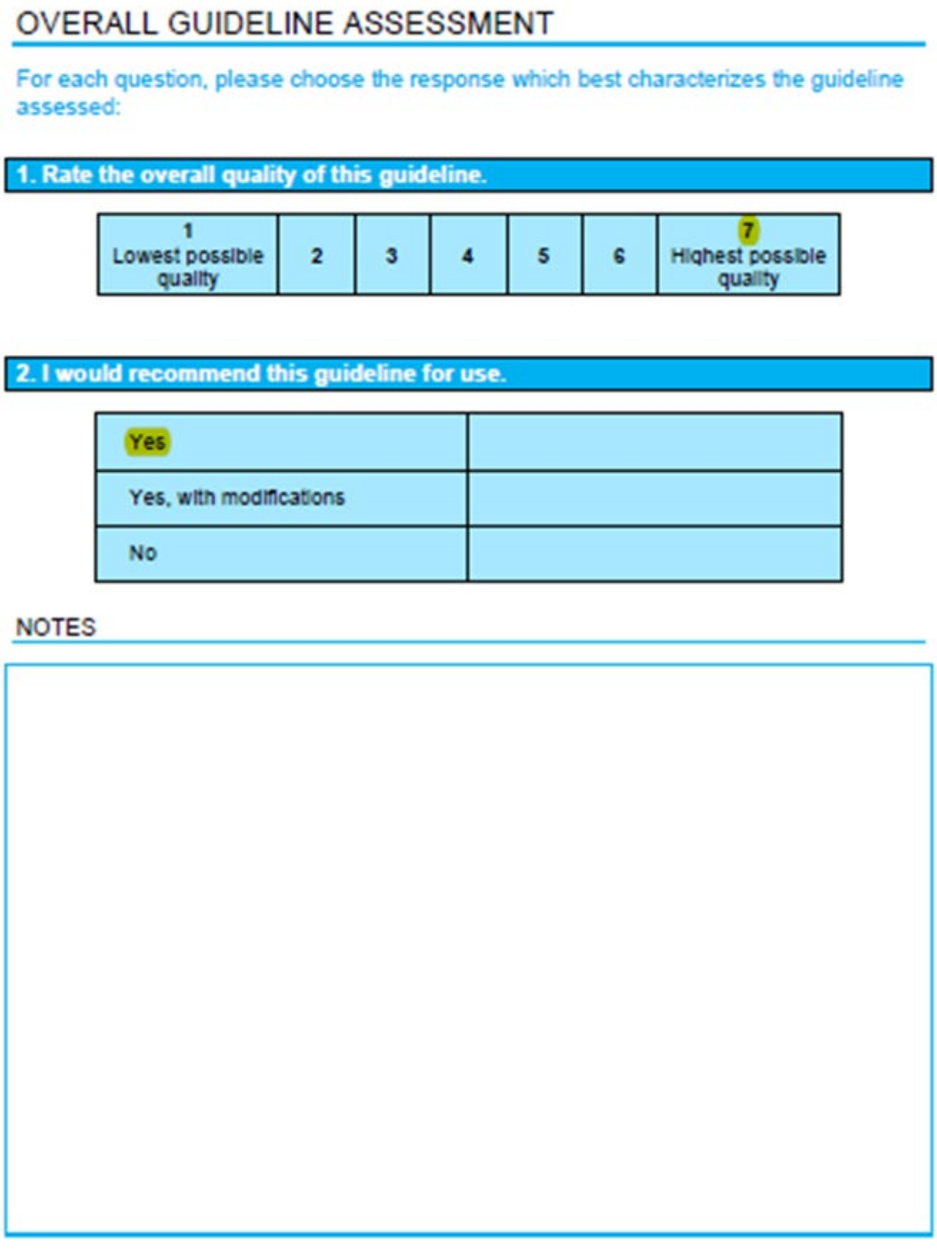
Members of the project team were from various healthcare backgrounds. There was a nurse, a medical doctor, an advanced practitioner, and a pharmacist. The team met via teleconferencing due to various schedules and the ongoing pandemic to review the naloxone instruction guideline (as shown in Appendix 1A and 1B). They compared the recommendations outlined by the CDC and other reputable sources. Each team member provided insights from their professional discipline. When the group reached a consensus, the guideline was sent to three senior nurse leaders with a background in education, hospital management, and training in the specialized care of patients with chronic pain disorders. The experts worked in the inpatient, outpatient clinic, and research institute settings of the Clinical Center.

The inpatient nurse reviewed the guideline from the perspective of an inpatient nurse discharging a patient home with opioids. The outpatient nurse reviewed the guideline from the perspective of an outpatient nurse assessing medication lists and opioid risk in the outpatient setting. Finally, the institute nurse reviewed the education guideline from a perspective of a clinical nurse specialist managing the care of the whole patient and medication interactions with other medications. The panel of experts assessed the guidelines using the AGREE II instrument. The checklist consists of the AGREE II's structure of six quality domains and its 23 essential items, providing a methodical and logical process for reporting essential information. For each of the 23 items, a summary statement and a bulleted list of specific reporting criteria were provided (Agree Trust, 2017).

The nurse experts independently reviewed the document and gave high-quality reviews based on the six quality domains: scope, purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. Figures 1–3 show all recommendations and suggested changes (see Appendix C for AGREE II scores from nurse experts).

Figure 1

Clinical Nurse Specialist



OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality

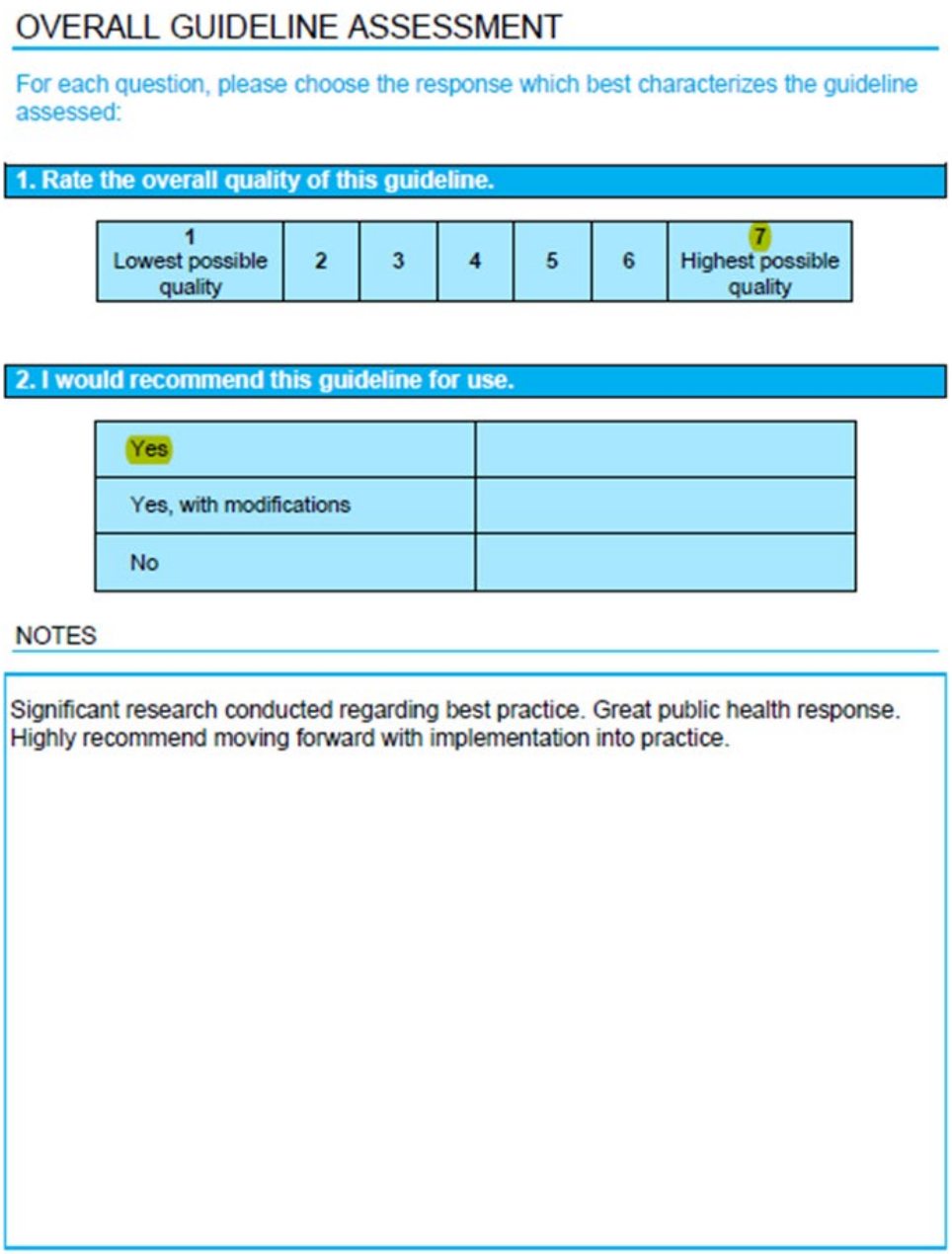
2. I would recommend this guideline for use.

Yes	
Yes, with modifications	
No	

NOTES

Figure 2

Inpatient Nurse Practitioner



OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality

2. I would recommend this guideline for use.

Yes	
Yes, with modifications	
No	

NOTES

Significant research conducted regarding best practice. Great public health response. Highly recommend moving forward with implementation into practice.

Figure 3

Institute Senior Nurse Researcher

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	2	3	4	5	6	7 x Highest possible quality

2. I would recommend this guideline for use.

Yes	x
Yes, with modifications	
No	

NOTES

These guidelines were implemented out of necessity due to there being no existing guidelines or educational materials related to naloxone and its use. Prior to this project the pharmacy did not have naloxone on formulary and it was not dispensed to patients with opioid prescriptions. Thanks to this project providers are now aware to order naloxone with opioids, pharmacy has naloxone on formulary and available to patients and there are very simple, clear, and specific naloxone guidelines for patients recieving opioids. Family members can also be educated using these guidelines hopefully decreasing the number of unnecessary deaths related to opioid overdose and lack of knowledge regarding naloxone use.

Recommendations

The panel of experts highly recommended the Opioid Naloxone Education Guideline for use in clinical practice. Each expert acknowledged that the opioid epidemic is one of the most significant health crises impacting national and international healthcare systems. They were in agreeance that a comprehensive improvement approach is warranted. The common theme of the literature is increased patient/family opioid education, awareness of the opioid problem, and access to naloxone reversal agents. National campaigns have been initiated to train healthcare providers and laypeople on managing a suspected overdose. The recommendations presented in this project align with those of health promotions and evidence-based practices. Naloxone nasal spray is considered the standard for treating opioid-induced respiratory depression. There is growing interest in translating opioid overdose education and naloxone distribution into healthcare settings, particularly outpatient settings (Adams, 2018).

Naloxone is a life-saving medication that can reverse the effects of an opioid overdose (CDC, 2018). The transfer of knowledge and awareness from physicians, nurses, advanced practitioners, and pharmacists to their patients is critical to mitigating the opioid problem. The literature highlights the willingness of patients and their caregivers to learn more about the risk and how to safeguard themselves against opioid-related deaths (Chao et al., 2019). However, it is up to providers to share the knowledge and tools they need to protect themselves in nonclinical settings. Educating patients and their families about the risks of opioid overdose and how to administer naloxone properly

is an evolving clinical practice that may reduce fatalities from overdose and enhance safety measures for providers prescribing opioids.

Increasing access to naloxone for high-risk patient populations, their caregivers, families, and community members is a powerful and responsible ethical decision. From an ethical standpoint, if the recommended standard of practice is adopted, healthcare providers would deliver evidence-based care focused on safety and quality. Co-prescribing of naloxone with opioids will increase access to life-preserving medication in vulnerable populations.

The literature confirms that a naloxone distribution program will increase awareness and understanding of the opioid epidemic. These distribution programs have been central in the public health response. Individuals prescribed opioids are still faced with barriers to access and education on adequately administering the opioid reversal agent in the event of a suspected overdose (Schneider et al., 2021). Implementing a patient/family education plan would be a proactive approach to removing the identified barriers and eliminating the opioid problem.

Contribution of the Doctoral Project Team

The project team helped to guide all aspects of the DNP project, making the process flow smoothly and progressively. Although the implementation of the proposed recommendations is beyond this project's scope, the advanced practice provider from the SCA team expressed an interest in piloting the Opioid Naloxone Guideline with their patients identified as being at high risk for opioid overdose. They gave feedback on ways to improve the guideline, the timing of implementation, and how they would work the

guideline into daily care plans for their patients. The project pharmacist created an opportunity for the problem to be presented before the Medical Executive Committee (MEC). The MEC is a monthly meeting of various clinical directors of medical programs and other senior administrative staff at the Clinical Center. Members of this meeting advise the hospital's director on policy development governing standards of medical care at the hospital. Once the recommendations were presented before the MEC, a unanimous decision was made to add naloxone nasal spray to the outpatient formulary. The advanced nurse practitioners and registered nurses collaborated to create the ONE note. This note is an acronym expansion that can be added to the electronic medical record for nurses and other providers to chart opioid naloxone education provided to outpatients quickly and comprehensibly. Medical and nursing experts contributed their knowledge, expertise, and experience to all aspects of the project. They were enthusiastic and willing to move forward with presenting the recommendations to the various shared governance groups as a step towards implementation into daily practice.

Strengths and Limitations of the Project

Initially, nursing leadership was less than supportive of the project, but with guidance and advocacy by the DNP preceptor and DNP project team, the perception of the program changed, and the understanding of the need for the program improved. The DNP team was able to help eliminate knowledge deficits surrounding the proposed project, negative attitudes, lack of motivation, and willingness to provide resources that were required to move forward with the project.

In addition, the COVID-19 pandemic presented obstacles to meeting team members in person. Therefore, virtual meetings were created. Determination and motivation for a change that would improve the safety and quality of care provided to patients sent home with prescription opioids were the driving forces of the project. Changing the attitudes of stakeholders and their perceived need for a change in practice and having the experts in the field serve on the project team were vital to the project's progression. Evidence-based information was central to minimizing resistance to change and helped solidify stakeholders' buy-in.

Section 5: Dissemination Plan

Members of the project team and the expert panel agree that the primary care team should implement recommendations from the ONECPG into practice, first by ordering naloxone with take-home opioid medication and second by including special instructions in the medication order for patient/family education. The education can be provided by any knowledgeable healthcare provider and documented in the patient's electronic medical record. The medical team, nursing, and pharmacy all have the knowledge and expertise to educate patients on naloxone administration.

Providers with the SCA team have identified patients who would benefit from having naloxone prescribed with their opioid medication. The SCA medical providers suggested that the target population for their group be patients on prescription opioids and other sedating medication. Based on the recommendations supported in the literature, providers within the SCA group plan to order naloxone with each opioid prescription. Once it is ordered, a provider, nurse, or pharmacist will educate the patients on how to adequately administer naloxone, using recommendations highlighted in the ONECPG as the basis for their discussion with the patient.

Based on the information collected, the Department of Pharmacy created an algorithm on when and how to order naloxone to control cost. The positive feedback from the SCA team has prompted discussions with leadership to move forward with dissemination to the other disciplines throughout the hospital. Once the proposed change is implemented in a small sample of SCA patients, feedback will be gathered. A summary

of the findings will be presented in each professional forum as a step towards making the recommendations identified in this project a permanent change in clinical practice.

Analysis of Self

The DNP essentials have been central to each processing element and my learning experience throughout the DNP program. They have served as the blueprint for my journey through the DNP process. The DNP essentials have helped to organize my thoughts and, ultimately, my decision to pursue a clinical practice change initiative as the focus of my DNP project. I have a greater appreciation for the facilitation of partnerships across disciplines. Without partnerships across the health care spectrum, DNP Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes would not be possible. This was evident in my project. It was not until I received the support of professionals from various healthcare disciplines with like minds that the project could move forward. The contributions of experts in the field made it possible for the success of this project.

The amount of insight and knowledge gained over the last few years is immeasurable. My DNP journey was complicated by the COVID-19 pandemic, forcing my learning experience to be primarily virtual with a crash course in DNP Essential IV, testing my ability to use information systems and technology. I have a different level of confidence in my role as a nurse and now an advanced practice nurse.

Achieving the goals of the DNP project has confirmed that I can successfully lead a multilayered performance initiative while helping to create a lasting impact within healthcare and the nursing profession. Functioning in the role as a DNP student has

introduced me to other opportunities within my healthcare organization. It has also shown me that I enjoy participating in healthcare improvement initiatives. I hope to work with other healthcare leaders to improve the quality of care rendered to patients at the Clinical Center in the future. I am excited about the opportunities and thankful for my journey as a DNP student.

I look forward to identifying opportunities that align with DNP Essential VIII: Advanced Nursing Practice. I believe that nurses are the glue that keeps health care together. My goal is to create opportunities for nurses to lead and make real change that promotes DNP Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health.

Summary

As previously mentioned, the opioid epidemic is one of the most significant health crises impacting healthcare systems nationally and internationally. The literature highlights the benefits of implementing opioid naloxone education standards for patients prescribed opioids in the outpatient setting. Implementing an education guideline, annual provider education/training, co-prescribing recommendations, documentation structured notes for patient education, and access to naloxone nasal spray are vital elements of a comprehensive opioid education program in the outpatient setting. Implementing such a program is highly recommended to improve the quality and safety of outpatients treated with opioids.

The literature and research have proven that naloxone is a life-saving medication that can reverse the effects of an opioid overdose. Providers, advance practitioners,

pharmacists, and registered nurses play a critical role in safeguarding patients against opioid-related deaths. Providing reputable and timely data-driven information to patients and increasing access to naloxone is the basis for improving compliance and changing health behaviors. Increasing education and access to naloxone in high-risk patient populations and among community members is a robust and responsible response to the opioid epidemic.

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Appendix A: Opioid Naloxone Education Clinical Practice Guideline (ONECPG)

Opioid Naloxone Education Clinical Practice Guideline (ONECPG)

Naloxone Nasal Spray: What you Need to Know…

You or someone for whom you provide care has received a prescription for an opioid medication used to help relieve moderate-to-severe pain. While these medications can be an important part of treatment, they also have some serious risk such as addiction and overdose especially with prolonged use or if paired with other sedating medications (HHS, 2018). Naloxone nasal spray has also been prescribed if you or someone for whom you provide care experiences an overdose as a result of taking an opioid.

What is Naloxone Nasal Spray?

Naloxone nasal spray is a prescription medication used for the treatment of a known or suspected opioid overdose emergency with signs of breathing problems and severe sleepiness or not being able to respond (CDC, 2022).

Naloxone nasal spray should be administered immediately, and emergency services should be called after the first dose is administered (CDC, 2022).

Naloxone nasal spray temporarily reverses the effects of an opioid overdose. Naloxone has no effect on people not taking opioids.

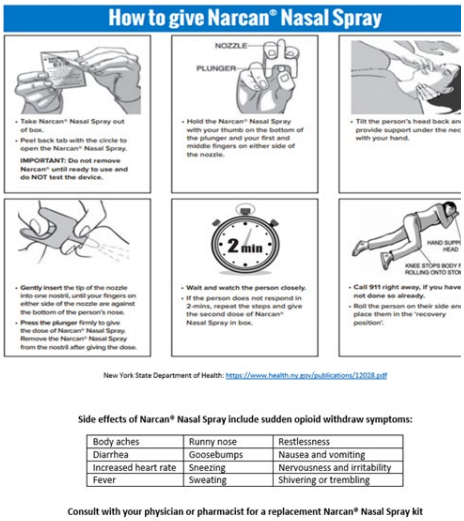
Always carry naloxone nasal spray with you and tell your caregiver where to find the medication if an opioid overdose is suspected (CDC, 2022). Naloxone nasal spray delivers 4 mg of naloxone HCL, which can reverse the effects of a life-threatening opioid overdose in minutes.

Signs of an opioid overdose

- Unusual sleepiness
- Not responsive to voice or touch
- Slow, irregular or lack of breathing
- Pinpoint pupils
- Bluish or purple lips and fingernails
- Slow or decreased heart rate
- Low blood pressure

Administration of Naloxone Nasal Spray

- Call 911
- Administer Naloxone Nasal Spray
- Open, Position, Push (OPP)



New York State Department of Health: https://www.health.ny.gov/publications/12028.pdf

Side effects of Narcan® Nasal Spray include sudden opioid withdraw symptoms:

Body aches	Runny nose	Restlessness
Diarrhea	Goosebumps	Nausea and vomiting
Increased heart rate	Sneezing	Nervousness and irritability
Fever	Sweating	Shivering or trembling

Consult with your physician or pharmacist for a replacement Narcan® Nasal Spray kit

- Open the packaging
- Place the person on their back to receive a dose of naloxone (CDC, 2022)
- Hold the device with your thumb on the bottome of the plunger and two fingers on the top sides of the nozzle (CDC, 2022)
- Tilt the person's head back and support their neck (CDC, 2022)
- Position and hold the tip of the nozzle in one nostril until your fingers touch the bottom of their nose (CDC, 2022)
- Push the plunger firmly to administer the dose into the nose
- After administering the dose, remove the plunger from the nose (CDC, 2022)
- Position the person on their side, placing their hands under their head (CDC, 2022)
- Call emergency medical services and continue to observe the person until they arrive(CDC, 2022)
- If needed, start resuce breathing or cardiopulmonary resucutation (CPR) while waiting for emergency help (CDC, 2022)
- Administer the second dose in the opposite nostril if the person is not responsive or breathing normally after 2-3 minutes, administer the second dose of naloxone nasal spray (CDC, 2022)
- Additional doses may be administered every 2-3 minutes until they respond or until medical services arrive (CDC, 2022)
- Discard naloxone in a place that is away from children (CDC, 2022)

Appendix B: AGREE II Scores

Domain 1: Scope and Purpose

	Item 1	Item 2	Item 3	
Appraiser 1	7	7	7	
Appraiser 2	7	7	7	
Appraiser 3	7	7	7	
Total	21	21	21	63

Maximum possible score = 7 (strongly agree) x 3 (items) x 3 (appraisers) = 63

Minimum possible score = 1 (strongly disagree) x 3 (items) x 3 (appraisers) = 9

The scaled domain score will be:

Obtained score – Minimum possible score

Maximum possible score – Minimum possible score

63 (Obtained score)–9 Minimum possible score

63 (Maximum possible score)–9 (Minimum possible score)

Total score= 100%

Domain 2: Stakeholder Involvement

	Item 4	Item 5	Item 6	
Appraiser 1	7	4 (not applicable)	7	
Appraiser 2	7	7 (providers were asked)	7	
Appraiser 3	7	7	7	
Total	21	18	21	60

Maximum possible score = 7 (strongly agree) x 3 (items) x 3 (appraisers) = 63

Minimum possible score = 1 (strongly disagree) x 3 (items) x 3 (appraisers) = 9

The scaled domain score will be:

Obtained score – Minimum possible score

Maximum possible score – Minimum possible score

60 (Obtained score)–9 Minimum possible score

63 (Maximum possible score)–9 (Minimum possible score)

Total score= 94%

Domain 3: Rigour of Development

	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	
Appraiser 1	7	7	7	7	7	7	7	6	
Appraiser 2	7	7	7	7	7	7	7	7	
Appraiser 3	7	7	7	7	7	7	7	7	
Total	21	21	21	21	21	21	21	10	157

Maximum possible score = 7 (strongly agree) x 8 (items) x 3 (appraisers) = 168

Minimum possible score = 1 (strongly disagree) x 8 (items) x 3 (appraisers) = 24

The scaled domain score will be:

Obtained score – Minimum possible score

Maximum possible score – Minimum possible score

157 (Obtained score)– 24 Minimum possible score

168 (Maximum possible score)– 24(Minimum possible score)

Total score 92%

Domain 4: Clarity of Presentation

	Item 15	Item 16	Item 17	
Appraiser 1	7	7	7	
Appraiser 2	7	7	7	
Appraiser 3	7	7	7	
Total	21	21	21	63

Maximum possible score = 7 (strongly agree) x 3 (items) x 3 (appraisers) = 63

Minimum possible score = 1 (strongly disagree) x 3 (items) x 3 (appraisers) = 9

The scaled domain score will be:

Obtained score – Minimum possible score

Maximum possible score – Minimum possible score

63 (Obtained score)–9 Minimum possible score

63 (Maximum possible score)–9 (Minimum possible score)

Total score= 100%

Domain 5: Applicability

	Item 18	Item 19	Item 20	Item 21	
Appraiser 1	5 (this was done prior to project being implemented)	7	7	4 (not applicable)	
Appraiser 2	1 (not applicable)	7	7	1 (not the responsibility of this project. This will be done once the project is complete)	
Appraiser 3	1 (N/A)	7	7	1 (not applicable)	
Total	7	21	21	6	55

Maximum possible score = 7 (strongly agree) x 4 (items) x 3 (appraisers) =84

Minimum possible score = 1 (strongly disagree) x 4 (items) x 3 (appraisers) = 12

The scaled domain score will be:

Obtained score – Minimum possible score

Maximum possible score – Minimum possible score

55 (Obtained score)–12 Minimum possible score

84 (Maximum possible score)–12 (Minimum possible score)

Total score= 60% (Domain 5 is beyond the scope of the project)

Domain 6: Editorial Independence

	Item 22	Item 23	
Appraiser 1	4 (not applicable)	6 (Done in the beginning of the project)	
Appraiser 2	7 (All conflict of interest policies were completed per NIH policy)	7 (This was discussed at the onset of the project. Roles and responsibilities were clarified.	
Appraiser 3	7	7	
Total	18	20	38

Maximum possible score = 7 (strongly agree) x 2 (items) x 3 (appraisers) =42

Minimum possible score = 1 (strongly disagree) x 2 (items) x 3 (appraisers) = 6

The scaled domain score will be:

Obtained score – Minimum possible score

Maximum possible score – Minimum possible score

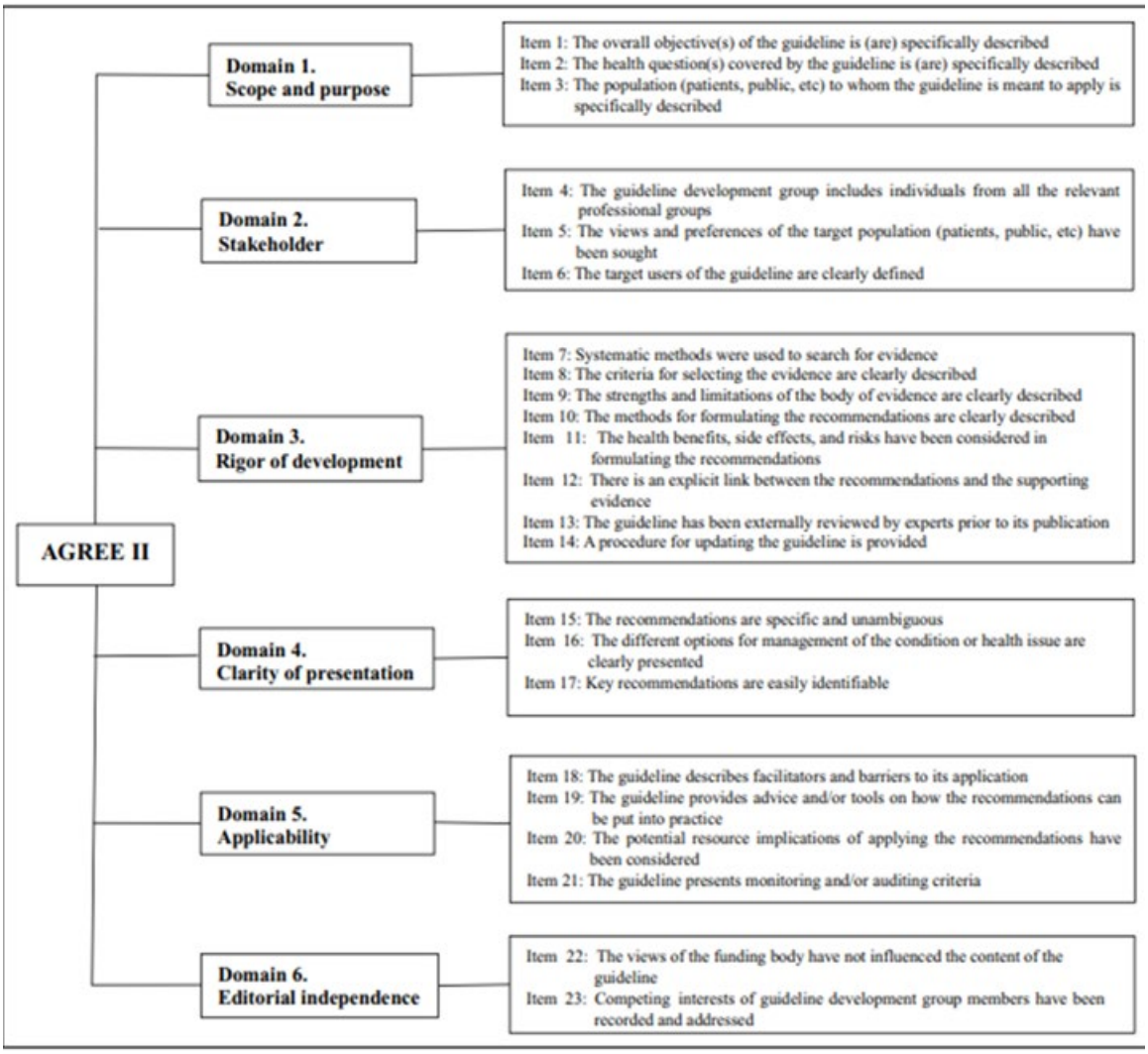
38 (Obtained score)–6 Minimum possible score

43 (Maximum possible score)–6 (Minimum possible score)

Total score= 86%

Two appraisers recommended the ONECPG without any modification. One appraiser recommended changing a word in the administration steps. Scope and purpose (100%), stakeholder involvement (94%) and Rigour of Development (92%) and clarity of presentation (100%) were rated the highest scores. Applicability (60%) and Editorial Independence 86% were rated the lowest, due to inapplicability to the guidelines.

Appendix C: AGREE II 6 Domains and 23 Items



Appendix C is an outline from Zhang er al. 2019 of the six domains and 23 items used for scoring in Appendix B. Based on the AGREE II instrument, the quality of the ONECPG is consistent. (Zhang et al. 2019).