A DNP PROJECT

Protocol for Treatment of an Opioid Overdose

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Abstract

Purpose: This DNP project analyzed how developing and implementing an opioid overdose management protocol based on evidence-based guidelines along with didactic training for employees can improve staff confidence in handling an opioid overdose.

Methodology: To analyze the effectiveness of the protocol implementation and didactic training on opioid overdose management, a questionnaire was distributed to the medical and non-medical staff members (N=32) at an inpatient drug rehabilitation facility after training was provided. The questionnaire assessed the staff members’ confidence in handling an opioid overdose.

Results: After the opioid overdose treatment protocol with staff training was implemented, the employees reported above average scores in their confidence to handle an opioid overdose situation.

Implications for Practice: This project provided much needed data on implementing an evidence-based opioid overdose management protocol and staff education within a private residential substance abuse facility. It provided the staff with the knowledge they need to handle an opioid overdose and save the lives of potential opioid overdose patients.
Protocol for Treatment of Opioid Overdose

Introduction

Opioid abuse remains a health crisis in the United States (U.S.), causing a significant mortality rate. According to the Centers for Disease Control and Prevention (CDC), from 2017 to 2018 opioid related deaths decreased 5% overall for prescriptive opioids and illicit synthetic opiates in the U.S. (Centers for Disease Control and Prevention, 2018). However, this data excludes the deaths caused by the use of illicit manufactured fentanyl (IMF). IMF is cheaper than pure opioids such as heroin and prescriptive opioids; therefore, it is currently being combined with heroin as well as being made into fake prescriptive opioid pills and sold illicitly (Gladden et al., 2019). IMF is 50-10,000 times more potent than heroin, causing a significant increase in deaths (Shaw et al., 2019). Between the year 2017 and 2018, IMF related deaths increased by 11%. The opioid related deaths in the U.S. increased 90% due to deaths relating to IMF between the years 2013 to 2017. In New Jersey, the mortality rate from opioid overdose increased more than 50% between the years of 2014 to 2017, with the death rate for each year consecutively being 1,253 persons in 2014, 1,454 people in 2015, 2,056 people in 2016, and ending with 2,685 persons in 2017 (Centers for Disease Control and Prevention, 2018).

Naloxone is approved by the FDA to prevent overdose by opioids including heroin, morphine, oxycodone, and fentanyl. It has been proven to be a safe medication to administer with minimal adverse reactions. Naloxone should be given immediately to someone who is suspected of an opioid overdose as it is proven to cause no harm if given to a person who is not suffering from an opioid overdose (Substance Abuse and Mental Health Services Administration, 2019). Naloxone can be administered by non-medical and medical personnel even prior to EMS arrival (Lynn & Galinkin, 2017). It can take a few minutes for a person with an opioid overdose to die
from respiratory depression and EMS can take several minutes to arrive to the site of an emergency. Therefore, it is lifesaving to have a clinical protocol in place for treatment of opioid overdose at the drug rehabilitation treatment facility. This protocol contains standing orders approved by the clinical director to describe and highlight what the staff should do during a potential opioid overdose situation. This DNP project implemented an evidence-based protocol and educated the staff about management of an opioid overdose. The DNP project was analyzed based on the staff’s self-rated confidence in handling an opioid overdose.

**Background and Significance**

People with opioid use disorders, especially people who use opioids intravenously, are dying of opioid overdose. The surge of IMF being used is causing a significant increase in opioid related deaths. In the drug rehabilitation treatment setting, clients sometimes arrive to the clinic for admission while they are under the influence of opioids. There is also a possibility for potential clients to bring drugs (contraband) into the treatment facility during admission that may be overlooked during the intake body search or may be provided by visitors to the facility. In 2017, the State of Massachusetts shut down several rehab facilities after nine deaths were reported from on-site overdoses. Recovery Centers of America was one of the rehabs closed by the state following two deaths by overdose. The rehab facility reported that the overdoses were from clients bringing contraband into the facility (Allen & Armstrong, 2017). These behaviors could result in an overdose on the clinical site. Therefore, both medical and non-medical staff members should be properly trained to handle an opioid overdose situation.

Naloxone is a medication approved by the U.S. Food and Drug Administration (FDA) to reverse the toxic effects of opioid overdose. Therefore, a development of a clinical evidence-based protocol for opioid overdose can help guide the staff in an opioid overdose emergency. Naloxone
works on the mu-receptor sites which opiates bind to. It competes with the opiates’ attachment to the receptor sites, thus reversing the toxic effects of opioid overdose. Naloxone is given to someone who is suspected of an opioid overdose (Lynn & Galinkin, 2017). The common signs and symptoms of an opioid overdose are decreased respirations, pinpoint pupils, and unconsciousness. Naloxone is available in different formulations including intramuscular injection (IM), intranasal (IN) spray, and intravenous (IV) solution. The naloxone manufacturer recommended dose is 2-4mg IN or 0.4-2mg IM and subcutaneously, and the dose can be repeated every 2-3 minutes if the person remains unresponsive after the first dose (Weaver et al., 2017). Naloxone remains effective for opioid overdose reversal even if other sedatives or stimulants are involved in conjunction with opioid use. However, it will not reverse the effects of any benzodiazepine or other stimulants. Naloxone is a safe medication since it will not cause any detrimental effect if the suspected overdose patient does not have any opioids in their system. It is also safe to administer to pregnant women with close monitoring (Substance Abuse and Mental Health Services Administration, 2019).

Dudley et al. (2017) reviewed 312 charts to compare the success rate of naloxone when the first dose was given prior to the advanced cardiac life support (ACLS) personnel arrival versus when it was given after ACLS arrival. The researchers found that patients who received the first dose of naloxone prior to ACLS arrival had improvements of 89.2% with 94.8% arriving to the hospital alive and 5.2% pronounced dead. For the patients who received the first dose of naloxone after ACLS arrival, only 43.4% showed improvement with 80.8% arriving to the hospital alive and 19.3% pronounced dead. These results show that administration of naloxone by personnel prior to EMS arrival can increase the patient’s survival rate. Therefore, staff working with potential overdose patients in drug treatment facilities need guidance in the early administration of
naloxone. The rehabilitation treatment facility, in which the quality improvement project took place, lacked such guidance. There was a need to develop a clinical protocol for opioid overdose. This project’s protocol development increased the staff’s confidence and efficacy on identifying a patient with opioid overdose and administering naloxone to save a patient’s lives.

**Needs Assessment**

Naloxone has been approved to be administered by EMS personnel in all 50 states in the U.S. including Puerto Rico, Guam, and the District of Columbia (National Institute on Drug Abuse, 2018). The New Jersey Department of Health issued a waiver in 2015 to approve all certified EMS and paramedics to administer naloxone to people suspected of an opioid overdose (State of New Jersey Department of Health, 2015). New Jersey Department of Health Office of Emergency Medical Services (EMS) has an EMT treatment protocol in place for opiate overdose which was last updated on September 20, 2017. This protocol requires the EMS to use naloxone IN or IM according to the naloxone manufacturer’s instructions (State of New Jersey Department of Health, 2017). The manufacturer recommends administering the single-dose nasal spray (naloxone 2mg) into one nostril or injecting the intramuscular naloxone auto-injection (Envio 2mg) to the anterolateral aspect of the thigh, through clothing as necessary. If a patient does not respond or relapses into respiratory depression after the first dose, then additional doses is given as needed every 2-3 minutes until EMS arrives (U.S. Food and Drug Administration, 2016).

Most states have approved naloxone to be available for family, friends, and other laypersons to use on someone suspected of an opioid overdose. In New Jersey, The Pharmacy Practice Act (N.J.S.A 45:14-67.2) and the Overdose Prevention Act (N.J.S.A 24:65-1) created a standing order proposal to allow pharmacies to dispense naloxone to individuals without a prescription (State of New Jersey Department of Health, 2018). In Middlesex County, where the
drug rehabilitation treatment facility for this project is located, there are 99 participating pharmacies with standing orders to dispense naloxone without a prescription (State of New Jersey Department of Law and Public Safety, 2020). Furthermore, the Overdose Prevention Act and the Good Samaritan Law in New Jersey provides immunity for criminal liability of patients, non-healthcare and healthcare professionals, and pharmacists for dispensing, prescribing, and/or administering naloxone (State of New Jersey Department of Health, 2018).

There are several clinical guidelines available that offer recommendations for the management of an opioid overdose, including Substance Abuse & Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and Opioid Overdose Education and Naloxone Distribution Program (OEND). These guidelines are used by healthcare clinics to aid in developing their clinical practice protocol for treatment of an opioid overdose. There was no evidence-based clinical protocol implemented at the drug rehabilitation treatment facility addressed by this project to guide the staff on what to do when a suspected opioid overdose occurs. This lack of clinical guidelines leaves room for the assumption that the staff knows how to handle an opioid overdose situation; in reality, they may not know what to do or are unable to handle such situation with confidence. This potentially increases the chance of error.

There are several evidence-based practice guidelines for the treatment of an opioid overdose that are reviewed and discussed in conjunction with evidenced-based research on naloxone administration to help develop a protocol for this facility. The site of the project where the implementation took place was equipped with a staff of nurses, residential assistants, a clinical director, a medical director, a psychiatric nurse practitioner, counselors and other non-medical staff. The staff were knowledgeable and able to apply this proposed clinical protocol for treatment of an opioid overdose. Within this facility with a population of people with opioid use disorders,
there is a possibility of clients sneaking in opioids and using opioids on the clinical site which can result in potential overdose, making the project important and needed.

**Problem Statement**

The problem was the lack of a protocol at the drug rehabilitation facility to prepare the staff on how to manage an opioid overdose. The lack of staff preparation contributes to the lack of confidence within the staff and possible negative consequences of an opioid overdose.

**Clinical Question**

For medical and non-medical staff in a substance abuse rehabilitation inpatient treatment facility, did the implementation of an evidence-based protocol for management of an opioid overdose and staff education improve their confidence in treating a patient with opioid overdose?

**Aims and Objectives**

The aim for the project was to develop a clinical protocol for the management of an opioid overdose to improve medical and non-medical staff confidence in recognizing and treating a patient with opioid overdose. This may decrease the mortality rate of patients effected by toxic levels of opioids.

Our aim was accomplished by the following objectives:

A) Develop and introduce a clinical protocol for the management of opioid overdose based on evidence-based research and guidelines suitable for our clinical site.

B) Provide staff training to educate the staff about the new opioid overdose management protocol.

C) Evaluate the confidence level of the staff in applying the management of an opioid overdose protocol.
D) Develop and introduce a policy for the substance abuse rehabilitation facility to implement the clinical protocol for management of an opioid overdose.

**Literature Review**

**Search Strategy**

A literature review using the search engines Ovid, EBSCO host, Cinahl, Google Scholar, Cochrane, and Rutgers QuickSearch database was performed using the following search terms: “Naloxone AND Prehospital AND administration,” “Naloxone AND Dose,” “Naloxone AND Repeat Dose,” “Naloxone OR Narcan AND precipitated withdrawal NOT Buprenorphine,” “Naloxone AND staff education,” “Naloxone AND health facility transfer,” “Naloxone AND Prehospital AND Protocols OR Guidelines,” “Naloxone AND opioid overdose AND prehospital AND treatment,” “Employee training for opioid overdose,” and “Implementing an overdose education program.” The search yielded a total of 1,318 research articles that were further narrowed down to 473 research articles based on the following inclusion criteria.

The inclusion criteria used to filter the research articles was adult population including men and women. Child and adolescent populations were not included based on the project’s site population being adult patients. Research articles were also filtered to articles written in the past five years, published as a peer-reviewed article, and written in the English language. Exclusion criteria were articles that did not meet the prehospital setting. Articles that did not offer information about the following subcategories were excluded, leaving 16 studies to be reviewed: a) analysis of the effectiveness of staff education on opioid overdose management after clinical protocol implementation, b) common signs and symptoms of an opioid overdose, c) route of administration of naloxone, d) naloxone dosage, e) giving repeat dose of naloxone f) opioid withdrawal precipitated by naloxone g) safety concerns about transport versus non-transport to a healthcare
facility after naloxone administration, and h) guidelines and protocols about treatment of an opioid overdose. See Appendix A for Prisma diagram.

Existing evidence-based guidelines and protocols about treatment of opioid overdose were hand searched using credible organizations including the Center for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA), and Opioid Overdose Education and Naloxone Distribution Program (OEND). A manual search was done for the Federal Drug Administration (FDA) prescribing information for Narcan (naloxone hydrochloride nasal spray) and Evzio (naloxone HCl injection).

**Opioid Overdose Protocol Implementation and Education**

Few research studies that assessed the effectiveness of staff education on opioid overdose management after clinical protocol implementation were found during the literature search. The majority of research literature found and reviewed were of clinical sites who have adopted the harm reduction measures of the OEND program. However, within the limited research, many pre-hospital settings and clinical sites including community-based organizations, public health departments, pharmacies, local law enforcement, and EMTs have showed statistically significant change in the participants’ ability to manage opioid overdose situations after implementing opioid overdose staff education programs (Olivia et al., 2017). Refer to Appendix B for review of literature.

The OEND program has been created by the Department of Veteran Affairs using the SAMHSA Opioid Overdose Prevention Toolkit and Harm’s Reduction Coalition’s Guide to Developing and Managing Overdose. The OEND program training consists of a PowerPoint presentation describing the opioid crisis and medication treatment of an opioid overdose in conjunction with a 6-step protocol for opioid overdose management. The following research
literature about the OEND implementation demonstrated significant increase in the pharmacy students’ knowledge about opioid overdose and their confidence in educating others about how to respond to an opioid overdose (Kwon et al., 2020). Similarly, there was a significant increase in recognizing an opioid overdose and in comfort with overdose response amongst family members of people with substance use disorders within a residential program (Pade et al., 2016). Four cases of successful opioid overdose reversals was demonstrated by a healthcare team within a public shelter setting (Dahlem et al., 2016).

Other opioid overdose educational programs besides that of the OEND program have also demonstrated high satisfaction and confidence amongst the participants. Online opioid overdose training provided to first responders resulted with 93.8% feeling confident in handling an opioid overdose (Simmons et al., 2016). Small group opioid overdose educational lectures within a substance use disorder treatment program showed significant improvement in knowledge about opioid overdose and naloxone administration among the opioid users who were at high risk of an opioid overdose (Lott & Rhodes, 2016).

Some barriers found regarding opioid overdose protocol implementation and education were based on the stigma about naloxone being considered enabling opioid abuse and the expensive cost of naloxone which affects its availability (Winstanley et al., 2016). Most states have approved naloxone to be available for family, friends, and other laypersons to use on someone suspected of an opioid overdose, which makes naloxone easily accessible. Concerns about liability also served as a barrier (Simmons et al., 2016). However, the Overdose Prevention Act and the Good Samaritan Law in New Jersey provides immunity for criminal liability of patients, non-healthcare and healthcare professionals, and pharmacists for dispensing, prescribing, and/or administering naloxone (State of New Jersey Department of Health, 2018).
**Opioid Overdose Protocol Development**

Several research studies, opioid overdose guidelines, and the FDA prescribing information for naloxone were synthesized based on the following criteria that were found to be important for proper management of a person experiencing an opioid overdose. The criteria that needed to be met included identification of common signs and symptoms of an opioid overdose, route of administration of naloxone, naloxone optimal dosage for reversal of opioid toxicity, criteria for repeat dose of naloxone, and transport to a healthcare facility after naloxone administration. Four evidence-based protocols were reviewed for the development of the opioid overdose treatment protocol. The protocols that were reviewed are Opioid Overdose Education and Naloxone Distribution (OEND) Program developed by the U.S. Department of Veterans Affairs, Responding to a Suspected Opioid Overdose Protocol developed by CDC, and Opioid Overdose Prevention Toolkit developed by SAMHSA.

**Identifying common signs and symptoms of an opioid overdose.** Opioid overdose occurs when someone ingests an abundance of opioids which creates a life-threatening situation. In high doses, opioids can lead to pinpoint pupils, unconsciousness, and respiratory depression described as the opioid overdose triad (World Health Organization, 2018). These common symptoms of opioid overdose are due to the fact that opioids affect the central nervous system (CNS) as well as part of the brain that regulates breathing. The respiratory depression leads to inadequate oxygenation that can cause additional clinical manifestations. The U.S. Department of Veterans Affairs (2016) identified additional signs and symptoms of an opioid overdose which include heavy nodding, difficulty to arouse, deep sleep, vomiting, bradycardia, snoring, gurgling, choking sounds, cyanotic lips, skin, and fingernails, and clammy skin. It is important for staff members at this inpatient drug rehabilitation facility to be able to identify these signs and
symptoms of an opioid overdose in order to provide the necessary treatment to potentially save a patient’s life.

**Route of administration of naloxone.** For the purpose of developing a protocol on the management of an opioid overdose for this project implementation, it was important to choose the most appropriate naloxone formulation to meet the non-medical clinical site needs. This site included both medical and non-medical employees. Since naloxone is now available for laypersons with no medical background, it was important to consider the non-medical employees in this decision.

One key aspect to consider when selecting the most appropriate route of administration was the efficacy of the intravenous (IV), intramuscular (IM), and intranasal (IN) formulations in reversing the toxic effects of opioids. Several studies concluded that all three formulations were capable of reversing the effects of an opioid overdose including respiratory depression and unconsciousness (Krieter et al., 2016; Lynn & Galinkin, 2017; McDonald et al., 2018; Mundin et al., 2017; Skulberg et al., 2019; Weaver & Bastianelli, 2017; Williams et al., 2019). However, each formulation differed in their absorption time, duration of effect, potential for repeat dose, and adverse effects due to their pharmacokinetics and dose concentrations.

The majority of the literature associated the naloxone IV route with being more predictable in the reversal of the toxic effects of opioids because the dose can be titrated to the necessary dose (Mundin et al., 2017; Skulberg et al., 2019; Krieter et al., 2019). However, IV access is needed, which may be difficult to obtain in IV drug users and can be time-consuming (Dahlem et al., 2015; Williams et al., 2019, Lynn & Galinkin, 2017). Additionally, non-medical laypersons do not have the required training or skills to start and administer medications IV in a prehospital environment. Furthermore, there is a rapid increase in plasma level followed by a rapid decline with naloxone
IV (McDonald et al., 2018). Due to this rapid decline, continuous IV infusion of naloxone is needed which was not possible in a community setting. Research of literature suggested that the IM and IN routes are just as effective, if not more so, in reversing opioid toxicity. One study found that the IM naloxone was 94% effective compared to the 90% effective rate of naloxone IV (Weaver & Bastianelli, 2017). Another study showed that 83% of the patients responded to an initial dose of IN naloxone with only 16% needing an additional dose of IV naloxone due to poor nasal absorption of the naloxone caused by nosebleeds or trauma to the nasal cavity (Lynn & Galinkin, 2017). Some existing evidence-based protocols recommended using intranasal naloxone based on its efficacy in reversing opioid overdose effects and its safety profile including prevention of needlestick injury and exposure to blood-borne pathogens (Dahlem et al., 2016; Williams et al., 2019).

**Naloxone optimal dosage for reversal of opioid toxicity.** For the purpose of this project, it was important to review literature regarding the correct dose for naloxone administration to reverse the effects of opioid overdose and to eliminate any confusion amongst the staff at the project’s clinical site. Since this facility does not require ACLS prepared staff, IV dosing information were excluded.

The FDA’s most up-to-date prescribing information for IN and IM naloxone were reviewed for dosage information. Evzio is an auto-injectable form of naloxone hydrochloride, first approved by the FDA in 2014 as a single-initial dose of 0.4mg intended for intramuscular and subcutaneous use to reverse the effects of an opioid overdose. However, in 2015 the FDA approved the latest dose for Evzio 2mg/0.4ml, which is five times the previously approved initial dose in efforts to accommodate the increased use of fentanyl and fentanyl-related deaths. In 2015, the FDA approved of a single-use 4mg/0.1ml naloxone nasal spray, Narcan, to eliminate the inconsistent
dosage from the off-label use of attaching a mucosal atomizer to a syringe to deliver naloxone nasally. In 2017, the FDA approved of the additional dose of 2mg/0.1ml Narcan in efforts to provide greater titration of naloxone administration to prevent precipitated withdrawal effects (U.S. Food and Drug Administration, 2016).

There were no studies found comparing the effects of different doses of the same formulation, demonstrating the need for additional research. However, the American Heart Association recommended using the lowest effective dose to prevent precipitated withdrawal (Lynn & Galinkin, 2017). This allowed better titration of the naloxone to prevent any adverse effects.

Criteria for repeat dose of naloxone. The manufacturers of naloxone recommended administering additional doses of naloxone every 2-3 minutes if the person does not respond to the first dose or they relapse back into respiratory depression after the initial response. Due to the increased use of fentanyl, repeat doses may be required for reversal of toxic effects. Due to the pharmacokinetics of naloxone, there is rapid elimination and blood-brain transfer. Depending on the type of opioids used, the severity and degree of respiratory depression and the other effects of the opioid overdose may last longer than the effect of the naloxone. Therefore, the naloxone may wear off and the person can fall back into respiratory depression and unconsciousness after initial improvement of symptoms (U.S. Food and Drug Administration, 2016).

Data from the 2015 National EMS showed an increase in the use of more than one naloxone from the 2012 data and many reports showed that fentanyl overdoses were not reversed with IN naloxone and required IV naloxone infusion (Lynn & Galinkin, 2017). One retrospective cohort study demonstrated the need of increasing dosage of prepacked naloxone kits (PNKs) with a decrease in the reversal of opioid overdose effects due to the increase use of fentanyl (Mahonski
et al., 2019). On the contrary, Carpenter et al. (2019) results showed no statistical significance in the amount of naloxone required to treat fentanyl and non-fentanyl related drug overdose cases. The research studies defined the appropriate response to naloxone administration as the return of respirations greater than 10 breaths per minute in determining if the naloxone was effective.

Precipitated opioid withdrawal may occur because of the abrupt release of opioids from the mu receptor sites by the administration of naloxone (U.S. Food and Drug Administration, 2016). The patient may exhibit nausea, vomiting, increased blood pressure, body aches, diarrhea, abdominal cramps, and agitation that may lead to the patient refusing to go to the hospital for further care and instead using illicit opioids to reverse the withdrawal effects. No research studies compared different dosages of the same route to determine an appropriate dose to prevent precipitated withdrawal. However, several research studies reported that IM naloxone caused more agitation and adverse effects than that of the IN naloxone (Carpenter et al., 2019; Lynn & Galinkin, 2017; Williams et al., 2019). One study resulted in more patients reporting agitation with IM naloxone (13%) compared to IN naloxone (2%) (Weaver & Batianelli, 2017). Additionally, one systematic review concluded that high doses of naloxone and rapid repeat dose of naloxone increases the chance of the patient experiencing precipitated withdrawal (Shaw et al., 2019).

The existing protocols and guidelines were reviewed for this project and agreed with repeating the dose of naloxone every 2-3 minutes if there was no reversal of respiratory depression. They also recommended a repeated dose if the patient regressed back into respiratory depression after the initial response regardless of the amount of time between the first and second dose. Williams et al.’s (2019) guideline recommended administering the lowest possible dose to maintain adequate ventilation even if the patient was not fully conscious in order to prevent
precipitated withdrawal. They noted that full level of consciousness was not required for the patient’s survival.

**Transport to a healthcare facility after naloxone administration.** Many research studies, guidelines, and naloxone manufacturers suggested sending the patient to the hospital for close observation due to the possibility of rebound toxicity (patient reverting back into respiratory depression) related to the short half-life of naloxone in comparison to the long duration of most opioids (Chou et al., 2017; Dudley et al., 2017; Levine et al., 2016; State of New Jersey Department of Health, 2017; Substance Abuse and Mental Health Services Administration, 2019; U.S. Food and Drug Administration, 2016; Williams et al., 2019). The patient might also develop severe side effects from naloxone including pulmonary edema, cardiac arrhythmias, or cardiac arrest which should be assessed in a hospital setting (Lynn & Galinkin, 2017). On the contrary, two studies demonstrated a low mortality rate in patients who were treated with naloxone and refused to go to the hospital. One study shown 3 out of 3875 patients who were treated and released by EMS died from rebound toxicity (Kolinsky et al., 2017); another study resulted with 1 out of 205 patients died within 24 hours of being treated and released (Levine et al., 2016). However, some of the research in these studies was conducted over 10 years ago and in European countries. With the increased use of IMF today in the U.S., the patient’s response to naloxone might be different. Also, there were no studies with clear and definitive reports to decide the adequate amount of time to observe an opioid overdose patient in a non-hospital setting.

**Conclusion**

In conclusion, this review of literature was used to develop and implement a protocol and staff educational training for the management of an opioid overdose. The training material addressed
the following clinical questions that were deemed important factors to consider with the management of an opioid overdose:

1) What are the signs of an opioid overdose?

2) What is the best route of administration of naloxone in a pre-hospital setting?

3) What is the proper dose of naloxone to reverse the toxic effects of an opioid overdose?

4) When should a repeat dose of naloxone be given?

5) What is the best way to prevent precipitated opioid withdrawal?

6) Should a person be transported to the hospital after the administration of naloxone?

Studies have showed that implementing a protocol and staff education about how to manage an opioid overdose improved the knowledge and confidence in the participants (Dahlem et al., 2016; Kwon et al., 2020; Lott & Rhodes, 2016; Pade et al., 2016; Simmons et al., 2016). Research studies recommended using intranasal naloxone based on its efficacy in reversing opioid overdose effects and its safety profile including prevention of needlestick injury and exposure to blood-borne pathogens (Dahlem et al., 2016, Lynn & Galinkin, 2017, Williams et al. 2019). They also recommended using the lowest recommended dose to allow better titration of the naloxone to prevent any adverse effects, repeating the dose of naloxone every 2-3 minutes if there was no reversal of respiratory depression, and transporting a person who was treated for an opioid overdose with naloxone to the hospital for further evaluation (Chou et al., 2017; Dudley et al., 2017; Levine et al., 2016; State of New Jersey Department of Health, 2017; Substance Abuse and Mental Health Services Administration, 2019; U.S. Food and Drug Administration, 2016; Williams et al., 2019).
Theoretical Framework

For the purpose of this research project, the Plan, Do, Study, Act (PDSA) cycle and model for improvement was used to develop and introduce an opioid overdose treatment protocol to medical and non-medical staff at the inpatient drug rehab. The intervention was evaluated based on the employees’ rating on their level of confidence about handling an opioid overdose after receiving education on the new protocol. This framework highlighted three key questions that were pertinent to quality improvement projects as well as the four stages of the PDSA cycle to help ensure successful implementation of the new opioid overdose protocol and improvement in staff confidence (Agency for Healthcare Research and Quality, 2015).

The PDSA key questions helped to identify what the protocol tried to accomplish, how the project showed that the change was an improvement, and what changes could be made based on the results to reflect further improvement (Agency for Healthcare Research and Quality, 2015). The PDSA was broken down into cycles that helped to clarify how this project was implemented. The steps of the PDSA cycle were to Plan for the change to be tested or implemented, Do by carrying out the test or change, Study or how the improvement was analyzed, and Act which entailed planning the next change cycle or fully implementing the intervention (Agency for Healthcare Research and Quality, 2015). See Appendix C for PDSA cycles model.

Methodology

The project used a quality improvement approach with a one-group posttest-only design using a 5-point Likert rating scale questionnaire that was distributed to the participants after receiving education about the evidence-based opioid overdose treatment protocol.
Setting

The protocol was implemented at an inpatient drug and alcohol detox and short-term residential treatment facility in the suburban community of South Amboy, New Jersey. This is a 52-bed facility that consists of male and female patients with opioid, alcohol, and/or sedative and anxiolytic disorders. Twenty-four beds are reserved for detox patients (12 female beds, 12 male beds) and 28 beds for short-term residential patients (14 female beds, 14 male beds). The majority of the patients are treated for opioid use disorders. There is currently a total of 32 employees at this clinical site. The employees consisted of medical personnel (nurses) and non-medical personnel (counselors, residential aides, and administrators).

Study Population

This project included a convenience sample of medical and non-medical employees at the rehab facility. Inclusion criteria were employees at this facility who provided direct care or services to the patients such as medical personnel (nurses, medical doctors, and a psychiatric nurse practitioner) and non-medical personnel (therapists, counselors, residential aides, and intake administrators). Exclusion criteria were employees who did not provide direct care or services to the patients such as housekeepers, maintenance workers, and kitchen staff. Additionally, for the purpose of developing the opioid overdose protocol, the population that was involved in approving and finalizing the protocol were the medical director, clinical director, and psychiatric nurse practitioner at the clinical site.

Employees who provide direct care or services to patients were invited to opioid overdose and naloxone training. There was a total of 32 employees at the project implementation site who provided direct care and services to the patients. All 32 employees attended the training and participated in the post-training questionnaire which resulted in a sample size of 32 participants.
Subject Recruitment

The employee education training on the treatment of an opioid overdose was discussed with the clinical director (who oversees the residential aides, therapists, counselors and intake administrators) and the medical director (who oversees the medical personnel including nurses and doctors). The clinical director notified the staff of the staff training. Flyers were posted at the station where the staff clocked into work to inform the staff of the training (See Appendix D for recruitment flyer). Sign-up forms that contained the different dates and times of the three training sessions were also located by the clock-in station, so the staff was able to choose the best time to attend the training to ensure they were motivated to learn. Since the rehab operated 24 hours a day, training session was presented on varying shifts to accommodate the staff. To avoid having the participants feel coerced to participate in the project’s study, recruitment for participation in the study’s questionnaire was completed after the staff training. The recruitment took place in the project’s clinical site conference room immediately after the education and naloxone training was provided. However, during the introduction to the training, the staff were prompted to stay after training for closing discussion to allow time to recruit participants.

Participants were given a printed handout of the project’s aims and objectives that included the contact information (email and phone number) of the primary investigator (PI) and co-investigators to address any concerns they may have had. The potential participants were informed that participation in the study was completely voluntary and their employment status was not affected.

Consent Procedure

The project was implemented by two Psychiatric and Mental Health DNP students at Rutgers University School of Nursing. A consent form was distributed to the participants after the
opioid overdose treatment training was provided (see Appendix E). The consent form summarized the purpose of the study to allow the potential participants to make informed consent. The participants were asked to provide their job title as identifiable information. This information was used strictly for the purpose of this project and were kept securely in a lock and key cabinet within the project site. Collected data was only accessible to the study personnel. Upon completion of the project, closure of the IRB, and final writing of the manuscript all data will be maintained by the study team for 6 years in accordance with Rutgers University guidelines. Hard copies of consents and aggregate data is kept in locked cabinet at Rutgers University for a maximum period of six years.

This project was voluntary, and the potential participants had the right to refuse to participate at any time during the survey collection which took approximately 10 minutes. A participant’s decision not to participate did not impact their training or job status. However, once the survey was submitted to the primary investigators, the participant could not withdraw their survey because their survey was not be able to be identified, as they were informed.

**Risks and Harms**

Participation in this study consisted of providing answers to a questionnaire. There was a minimal risk because there was no anticipated discomfort for the potential participants. No personal health information (PHI) was collected that allowed identification of the participants. In response to the current Covid-19 pandemic, CDC recommended social distancing. Each participant was required to wear a mask at all times and seating was arranged to meet the social distancing recommendations of being 6 feet apart and filled to 25% of the room capacity. To abide by these guidelines, the co-investigators had three training sessions, one on morning shift and two on evening shift, to accommodate all the employees on varying work shifts. The conference room can
hold up to 50 people comfortably. Therefore, 25% of the room capacity allowed approximately 12 participants. Each training session took approximately 1 hour to complete.

Subject Costs and Compensation

The budget for implementing an opioid overdose protocol with staff education included the cost of educational materials (including handouts), staff time to attend the training session, and light refreshments that were served. The co-investigators covered the costs for the education materials and light refreshments. The clinic covered the staff time for the training. The clinical director agreed that the employees who attended the training session were paid their hourly wage for the amount of time they attended the training. They were required to clock-in to their work shift at the beginning of the training session and clock-out once the training was completed. Staff members who attended the training during their work shift was approved by the clinical director and nursing supervisor beforehand to ensure that there was enough staff remaining on the unit to provide sufficient patient care.

Study Interventions

Protocol Development

A protocol for the treatment of an opioid overdose was developed using evidence-based guidelines for the treatment of opioid overdose from SAMSHA, VHA, and CDC. These existing protocols and guidelines were compared to the gathered research literature and FDA prescribing information for naloxone to formulate the most appropriate clinical recommendations for the treatment of an opioid overdose.

To develop a protocol for the management of an opioid overdose, the following clinical questions were explored and answered in protocol:

1) What are the signs of an opioid overdose?
2) What is the best route of administration of naloxone in a pre-hospital setting?

3) What is the proper dose of naloxone to reverse the toxic effects of an opioid overdose?

4) When should a repeat dose of naloxone be given?

5) What is the best way to prevent precipitated opioid withdrawal?

6) Should a person be transported to the hospital after the administration of naloxone?

The protocol was reviewed with the medical director, clinical director and the psychiatric nurse practitioner. The final protocol was developed after considering their feedback. The proposal was submitted to the project chair and then submitted to Rutgers IRB for project implementation approval. A copy of the protocol included in Appendix F. An algorithm with a simplified step-by-step guide was developed using the protocol. A printed and laminated copy of the algorithm was placed at each Narcan station site in the facility. Refer to Appendix G for illustration of the algorithm.

Staff Education and Training

The training curriculum was developed using the synthesized research literature, guidelines and FDA prescribing information on naloxone administration. An algorithm was developed from the protocol with step-by-step instructions for handling an opioid overdose situation. The training curriculum was presented by the DNP students using PowerPoint slides and an 8-minute video created by Narcan to demonstrate proper naloxone nasal spray administration. The PowerPoint presentation consisted of an overview of the opioid crisis in the U.S., identifying signs of an opioid overdose, information about naloxone, and step-by-step instructions of the opioid overdose treatment protocol. A copy of the PowerPoint slides could be found in Appendix H. Each staff member was provided a printed handout of the protocol.
Due to the Covid-19 pandemic, the education was divided into three separate training sessions to accommodate all medical and non-medical staff who provided direct care or services to the patients (N=32) in order to meet CDC recommendations on social distancing. Each training session took approximately 1 hour. Since the rehab operates 24 hours a day, training sessions were presented on varying shifts to accommodate the staff. The clinical director approved for the training to be part of the staff paid time workday to compensate for their attendance. A questionnaire was developed and distributed after each training session, and the staff were anonymously evaluated their ability to handle an opioid overdose situation.

**Policy Proposal**

After completion of the project, it was proposed to the clinical director to make a policy for all new employees to complete the training and for all current staff members to complete a yearly opioid overdose treatment training session. This ensures that the staff will stay current with their skills.

**Outcomes**

The purpose of this project was to improve staff confidence with treating an opioid overdose through implementation of an opioid overdose treatment protocol and didactic training. To measure this, a questionnaire was developed and distributed on paper to the staff after the training session. The questionnaire was developed using the Survey Fundamentals guide from the Office of Quality Improvement of the University of Wisconsin to produce questions that were reliable and valid. The questions were written with a 6th grade reading level and utilized a 5-point Likert rating scale. The topic of the questions included self-reported ratings of the staff’s ability to perform important techniques that were addressed in the protocol (see Appendix I). The five questions that included on the survey were:
Rate the following on a scale of 1 to 5 with 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree:

1) I am able to identify the signs of an opioid overdose.
2) I am able to follow the steps of the opioid overdose treatment protocol.
3) I am able to properly administer naloxone intranasally.
4) I am able to identify when to give a repeat dose of naloxone.
5) Overall, I am able to handle an opioid overdose situation.

**Project Timeline**

The timeline of this project was outlined using a GANTT Chart that could be found in Appendix J.

**Resources Needed**

The budget for implementing an opioid overdose treatment protocol with staff education included the cost of educational materials, including handouts, staff time to attend the training sessions, and light refreshments that were served. The DNP students covered the costs for the educational materials and light refreshments. The clinic covered the staff time for the training. Employee time sheets was collected to ensure that the staff clocked into their work shift at the beginning of the training and clocked out after the training was completed.

**Results**

This section presents the results of the data analysis which includes the quantitative data from the questionnaires collected from the participants. Descriptive statistics were compiled using the SPSS software to describe the demographics of the participants and highlight key findings.

The protocol created for the treatment of an opioid overdose was implemented at the inpatient drug rehabilitation facility. In-service trainings were held with a total of three sessions
using a PowerPoint presentation style to educate the staff at this facility on the new protocol. A questionnaire was distributed to each employee after the in-service training to evaluate their confidence level in applying the opioid overdose protocol.

A total of 32 employees attended the in-service training and a total of 32 employees responded to the questionnaire for a response rate of 100% and a final sample size of 32 (N=32). The job titles of the employees included nurses, residential aides, counselors and administration staff were captured as a demographic. Nurses represented the highest proportion of the participants (40.6%), followed by residential aides (31.3%), counselors (18.8%), and administration staff (9.4%). Among the 32 employees who responded to the questionnaire, 13 had a medical education background and 19 did not have medical education background resulting in the medical group (n=13) and non-medical group (n=19) respectively.

The confidence level of each employee was measured with a 5-point Likert scale set of questions with a range from 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, and 5=strongly agree. Scores above the midpoint of 3 (neutral) reflect more promising confidence levels, whereas those scores at or below the neutral point indicate less promising confidence in handling an opioid overdose. In evaluating the respondents’ perceptions toward question 1 (Q1), “I am able to identify the signs of an opioid overdose,” 3.1% were neutral, 31.3% agreed, and 65.6% strongly agreed. For question 2 (Q2), “I am able to follow the steps of the opioid overdose treatment protocol,” 28.1% of the respondents agreed and 71.9% strongly agreed. For question 3 (Q3), “I am able to properly administer naloxone intranasally,” 6.3% were neutral, 28.1% agreed, and 65.6% strongly agreed. For question 4 (Q4), “I am able to identify when to give a repeat dose of naloxone,” 12.5% were neutral, 21.9% agreed, and 65.6% strongly agreed. For question 5 (Q5), “Overall I am able to handle an opioid overdose situation,” 28.1% agreed and 68.8% strongly agreed. One person did
not respond to Question 5. Missing data occurs when there is no information for one or more cases in relation to a variable. Cambridge University (2019) stress that missing data up to 5% may not cause any serious problem in the interpretation of the findings. Table 4-3 shows the missing data for all variables in this study. The screening of the data indicates that the amount of missing data for all variables was below the threshold of 5% as recommended by Cambridge University (2019), ranged between 0% and 3%. Thus, no missing data replacement was needed for the variables. Table 1 shows the frequencies and percentages of the responses.

In this analysis, the descriptive statistics of the variables were examined. The mean, minimum, and maximum, measures of central tendency are provided in Table 2. The mean values of Q1 to Q5 were all above 4.5 and close to 5, ranged between 4.53 and 4.72. Thus, the average mean values of these five questions all stand between “agree” and “strongly agree”, tending to be “strongly agree”. The lowest value of Q1, Q3 and Q4 was 3 out of 5, meaning the respondents perceptions towards these three questions were at least “neutral” and there was no one who responded “disagree” with these questions. The minimum value for Q2 and Q5 was 4, meaning the lowest perception toward these two variables was agree and there was not any neutral or disagree perception toward them. The maximum value of Q1 thru Q5 was 5, meaning there is at least one “strongly agree” answer to these questions from the perceptions of the respondents.

The medical staff have licensure and training on how to administer medications, whereas non-medical staff do not. This may create a difference in scores amongst the two groups. The Mann Whitney U test was used to examine the mean rank differences of Q1 thru Q5 between medical (i.e., Nurse) and non-medical (i.e., Residential Aide, Counselor & Administration) staff. Table 4 represents the results of Mann Whitney U test.
As shown in Table 3, the results of Mann-Whitney U test indicated that only the mean rank value of Q4 “I am able to identify when to give a repeat dose of naloxone,” was significantly different between medical and non-medical as the p-value was below the standard significant level of 0.05. In other words, the Mann-Whitney U test indicated that the confidence level for identifying when to give a repeat dose of naloxone was greater for the medical group (Mdn=19.85) than for the non-medical group (Mdn=14.32), U = 80, p=0.047. Therefore, having a medical licensure to administer medications was a significant factor when those without a medical license scores were compared to those who hold the ability to administer medications. Conversely, although the mean rank values of Q1, Q2, Q3 and Q5 for medical group were higher than non-medical group, the differences were not found as statistically significant because of having p-values above the standard alpha level of 0.05. However, there are implications here because for Q3 the p-value was 0.056 which is close to a significant p-value of 0.05. This could indicate that a larger sample size might yield significance between the medical and non-medical groups. Thus, additional training is indicated for the non-licensed staff properly administering naloxone and identifying when the patient may require a repeat dose of naloxone.

**Data Maintenance and Security**

Information collected from participants was used strictly for the purpose of this project and was securely kept in a lock and key cabinet within the project site. Collected data was only accessible to the study personnel. Upon completion of this project, closure of the IRB, and final writing of the manuscript all data will be maintained by the study team for 6 years in accordance with Rutgers University guidelines. Hard copies of consents and aggregate data will be maintained in locked cabinet at Rutgers University for a maximum period of six years.
Discussion

Death by opioid overdose remains a health crisis. Naloxone was approved by the FDA to prevent opioid overdose. Most states including New Jersey have approved for naloxone to be dispensed to individuals without prescription and provide immunity for criminal liability of patients (State of New Jersey Department of Health, 2018). Studies have shown greater success rate of naloxone reversal of opioid toxicity when given immediately prior to EMS arrival (Lynn & Galinkin, 2017). With the potential of an opioid overdose happening on-site at an inpatient drug rehabilitation facility, it is important that staff members can manage an opioid overdose and administer naloxone appropriately before EMS arrival. In response to this epidemic, this DNP project aimed to increase staff members’ confidence in handling an opioid overdose by developing and implementing an evidence-based protocol with didactic training.

The findings of this DNP project support and further clarify the small body of research regarding opioid overdose protocol implementation and staff education within pre-hospital settings. Key findings from the preliminary evaluation of the protocol implementation and staff training indicated that the staff felt confident in identifying the signs of an opioid overdose, following the steps outlined in the protocol, properly administering naloxone intranasally, identifying when to give a repeat dose of naloxone, and handling an opioid overdose situation overall. Results of this study highlight that non-medical staff can manage an opioid overdose, therefore, making it beneficial for both medical and non-medical staff to be trained.

One similarity between this project and other research studies for opioid overdose prevention within community settings was that the opioid overdose and naloxone training yielded above average confidence scores amongst the participants including first responders (Simmons et al., 2016), opioid users (Lott & Rhodes, 2016), pharmacy students (Kwon et al., 2020), family
members of opioid users (Pade et al., 2016), and healthcare workers (Dahlem et al., 2016). Although this study did not include pre-test scores to evaluate if the staff confidence levels increased after implementation of the opioid overdose protocol and training, the post-test highlighted that the staff felt confident in handling an opioid overdose after the provided training. This eliminates the reliance on assumption that the staff at this clinic are able to handle an opioid overdose and gives the employers and supervisors clarity on how confident their staff feel when handling an opioid overdose.

One of the most surprising findings of this study was that there was little significant difference in scores between the medical and non-medical staff except on the concept of how to identify when to give a repeat dose of naloxone. This lack of a significance difference between medical and non-medical participants in regard to identifying the signs of an opioid overdose, following the steps of the opioid overdose treatment protocol, properly administering naloxone intranasally, and being able to handle an opioid overdose situation overall, may be contributed to the fact that both medical and non-medical participants at this clinic are Basic Life Support (BLS) certified. Therefore, each staff member had received prior life support training that could have contributed to their level of confidence even though the medical participants have a professional licensure in diagnosing and treating medical conditions.

A significant difference in scores may have been found in regard to identifying when to give a repeat dose of naloxone, with medical staff scoring higher, because of the fear or concerns about liability amongst the non-medical staff which may serve as a barrier to treatment (Simmons et al., 2016). Non-medical participants who do not have a professional license to diagnose, treat, and administer medications to patients may be hesitant to give an additional dose of medication.
It should be reinforced to them that they are protected from any criminal liability under the New Jersey Good Samaritan Law (State of New Jersey Department of Health, 2018).

**Implications**

**Clinical Practice**

The opioid overdose epidemic is worsening and has become a leading cause of injury-related deaths in the United States (Centers for Disease Control and Prevention, 2018). Nurses are in the frontline of providing patient care and serve as advocates for the betterment of their patients. Nurses can help combat this opioid epidemic by educating other nurses, health care workers, patients, and the patients’ families on how to manage an opioid overdose with the use of naloxone. Evidence-based protocols on opioid overdose can provide a safe baseline within health care facilities to establish how the staff is expected to handle an opioid overdose situation. If an evidence-based protocol is not enforced at a health care facility, nurses should step into their role as patient advocates and recommend policy change within their facility. Many organizations including SAMHSA, Veterans Affairs, and CDC created evidence-based opioid overdose protocols that are made available to healthcare facilities free of charge. These protocols can be used to help healthcare facilities establish an opioid overdose protocol that is suited for their specific facility needs.

Additionally, providers such as nurse practitioners (NPs), medical doctors (MDs), and physician assistants (PAs) who are allowed to prescribe narcotics can improve their prescribing practice. The CDC offers guidelines for prescribing opioids for acute and chronic pain, calculating total daily dose of opioids for safer dosage, and assess risk and addressing harms of opioid use that are made available to providers (Centers for Disease Control and Prevention, 2018). Improving
the way NPs, MDs, and PAs prescribe narcotics can help reduce the risk of patients developing an opioid use disorder.

**Healthcare Policy**

Prior to the implementation of this project, the clinical site did not have a protocol established for the treatment of an opioid overdose. After the implementation of this project and review of the data with the clinical director of this inpatient drug rehab, the proposed policy was approved at this facility. The policy requires all new employees complete the opioid overdose training during their new employee orientation and all current employees will have to attend an opioid overdose refresher training annually to keep current with their skills. The nurses who are in charge of providing training to the new hires will be conducting these trainings. The administrative staff who are responsible for ensuring that all staff are current with all of annual trainings will ensure that the staff have completed their opioid overdose trainings.

At a larger scale, naloxone training should be made into a universal policy such as that of CPR when a person is having a heart attack and is found unresponsive. With the alarming incidence of opioid overdoses reported in the U.S., it may be beneficial to incorporate naloxone training within the BLS certification training. This can help ensure that the naloxone training will reach a greater amount of people to help combat this opioid epidemic and save lives.

**Quality and Safety**

Death by opioid overdose can occur within seconds to minutes. Providing staff with a protocol to follow during an opioid overdose situation can potentially save the lives of their patients. The protocol was transformed into an algorithm with simplified step-by-step guide that can be easily followed during a crisis. These algorithms were placed at the various naloxone
stations throughout the facility to make it easy for staff to access during an opioid overdose emergency.

**Education**

Education is important and health care workers should be given the tools to build a strong foundation in caring for their patients. Substance abuse is so widespread that it should be incorporated into nursing education curriculum. Nurses are taught to be proactive by preventing detrimental health care outcomes. Therefore, they should be provided with naloxone training during their years of education prior to becoming registered by their state to provide care to patients. Opioid overdose can occur across the different specialties within healthcare, so nurses outside of drug rehab settings should be provided with the same knowledge as nurses who directly work with patients with substance use disorders.

**Economic**

This opioid overdose protocol and staff training will be sustained by an onsite employee which makes the cost of this project minimal compared to the amount of lives it could potentially save. Administering naloxone prior to EMS arrival can prevent the detrimental effects from opioid toxicity such as brain damage and coma which can result in an expensive financial impact. The average cost per day for hospital stay was $11,700 in the U.S. in 2016 (Freeman et al., 2018). Early initiation of naloxone to reverse the toxic effects of opioid toxicity can reduce the need for a patient to have to be treated in a hospital setting for an extended period of time which ultimately reduces healthcare costs.

**Future Scholarship**

The protocol and training materials were adopted from well-established evidence-based protocols created by credible institutions including CDC, SAMHSA, and the U.S. Veterans
Affairs. Opioid use disorder may occur within any race, ethnicity, age, gender, and/or geographics. Opioid overdose could occur in various different settings including in residential locations, clinics, schools, churches, and even in public places. Therefore, this project, including the protocol and training materials, has the potential to be generalized to other pre-hospital settings because it addresses how to identify an opioid overdose and explains the plan of care post naloxone administration. This project shown that non-medical laypersons are capable of handling an opioid overdose which makes it possible to use the training materials of this project to educate other nurses, counselors, family, patients, and other laypersons on how to manage an opioid overdose. This project has the potential to be used during BLS and ACLS training to give their participants a better understanding on how to manage an opioid overdose. Future research should consider applying this project to different populations within different settings to further contribute to the opioid overdose body of research.

This project did not incorporate a pre-test evaluation. Future research may want to use pre-test and post-test scores to analyze if the trainings cause an increase in the level of confidence amongst the staff and by what capacity. Additionally, future research may consider incorporating a live demonstration on how to administer naloxone and have the participants demonstrate how to administer naloxone using the naloxone nasal spray. This could be done in conjunction with random mock opioid overdose drills to test the participants’ competency in handling an opioid overdose situation. This project analyzed the level of confidence each participant reported after the protocol implementation and training. However, future research may consider analyzing the participants’ competencies to assess how the training is applied practically.
Summary

The opioid overdose epidemic has taken many lives and remains a public health concern that requires an integrative perspective to address the prevention and treatment of an opioid overdose. The results of this project show how implementation of an evidence-based protocol and training on the use of naloxone can improve staff confidence in dealing with an opioid overdose emergency. The outcome of this project highlights that non-medical workers are also capable of managing an opioid overdose which shifts the total responsibility from medical healthcare workers to non-medical workers as well. Therefore, prevention of death by opioid overdose should go beyond that of healthcare workers and into the communities where people are collectively combating the detrimental effects from opioid abuse.

Healthcare providers and nurses serves as the frontline to this epidemic and can provide the much-needed education about opioid abuse and naloxone to non-medical staff, patients, and the patients’ families. With the worsening state of the opioid epidemic, naloxone training should be taken as seriously as CPR training and policy development needs to be advocated for to make this a public health initiative and allow trainings to reach more people and save more lives.
References


Dahlem, C., Horstman, M., & Williams, B. (2016). Development and implementation of intranasal naloxone opioid overdose response protocol at a homeless health


Table 1

*Frequency & Percentage of Variables*

<table>
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<tr>
<th>Staff Questionnaire</th>
<th>Frequency</th>
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<td>0</td>
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<tr>
<td>Disagree</td>
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<td>0</td>
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<td>65.6</td>
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*Note: n=32, One Missing Value for Q5*
Table 2

*Results of Descriptive Statistics of Variables*

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<th>Variable</th>
<th>Mean</th>
<th>Minimum</th>
<th>Maximum</th>
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<tr>
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<td>4.59</td>
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<td>5</td>
</tr>
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Note: n=32, One Missing Value for Q5
**Table 3**

*Results of Mann Whitney U Test for Q1 to Q5 between Medical & Non-Medical Groups*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sample Size</th>
<th>Mean Rank</th>
<th>Mann-Whitney U</th>
<th>Z</th>
<th>p-value</th>
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<td>Non-Medical</td>
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</table>

* * p < 0.05
Appendix A: Prisma Diagram

1. Literature review screened using search engines Ovid, EBSCO host, Cinahl, Google Scholar, Cochrane, and Rutgers QuickSearch (n=1,318)

2. Literature excluded after screening (n=845)

3. Full-text articles assessed for eligibility (n=473)

4. Full-text articles considered (n=473)
   - Ineligible (n=256)
   - Excluded (n=217), for following reasons:
     - No analysis of the effectiveness of staff education (n=63)
     - No identification of an opioid overdose (n=24)
     - No information about naloxone route of administration (n=57)
     - No information about naloxone proper dose (n=42)
     - No information about naloxone repeat dose (n=11)
     - No information about naloxone precipitated withdrawal (n=16)
     - No information about the safety concerns of transport versus non-transport to a hospital after naloxone administration (n=4)

5. Included articles (n=21)
**Appendix B: Evidence Table**

EBP Question: For medical and non-medical staff in a substance abuse rehabilitation inpatient treatment facility, does the development and implementation of an evidence-based protocol for treatment of opioid overdose and staff education improve their confidence in treating a patient with opioid overdose?

The development of a protocol for treatment of an opioid overdose will address the following clinical questions:

1) What are the signs of an opioid overdose?
2) What is the best route of administration of naloxone in a pre-hospital setting?
3) What is the proper dose of naloxone to reverse the toxic effects of an opioid overdose?
4) When should a repeat dose of naloxone be given?
5) What is the best way to prevent precipitated opioid withdrawal?
6) Should a person be transported to the hospital after the administration of naloxone?

Date: March 20, 2020

<table>
<thead>
<tr>
<th>Article</th>
<th>Author, Date</th>
<th>Evidence Type</th>
<th>Sample, Sample Size, Setting</th>
<th>Study Findings that help answer EBP question</th>
<th>Limitations</th>
<th>Evidence Level &amp; Quality</th>
</tr>
</thead>
</table>
| #1      | Mundin, G., Mcdonald, R., Smith, K., Harris, S., & Strang, J. (2017). | Open-label, randomized, four-way cross-over Latin-square | 12 healthy volunteers aged 20-41 of which 4 were female  
n=10 (1mg i.v.),  
n=11 (8mg i.n., 16mg s.l.)/  
n=12 (16mg i.n.)  
Clinical Pharmacology Unit at [blank] | Although the bioavailability of intranasal naloxone is low (F%=25-28%), the Cmax, or peak serum concentration of IN naloxone at 8mg/0.4ml and 16mg/0.4ml surpassed that of 1mg IV naloxone, and it was achieved within 20mins (Tmax). However, half the peak serum concentration was achieved in 7-8 mins for both the 8mg and 16mg of IN naloxone which was slower than that of the 1mg IV naloxone which is reached within 4 mins. The absolute bioavailability of both the 8mg and 16mg IN naloxone were similar and both only reached greater than or equal to 10% between 4-10 mins. | The sample size was small (n=10-12) which increases the chances of a Type II error.  
Naloxone was tested in healthy individuals and not the target population of opioid drug users.  
The time to administered both the IN and IV naloxone were not | Research Level III, Low quality |
Contributes by revealing that IN naloxone has the bioavailability to reversing the effects of an opioid overdose. Also, because the timing of the peak serum concentration and the absolute bioavailability, the person administering the IN naloxone should wait a few minutes before giving a second dose to prevent any chance of precipitated withdrawal.

The distribution and elimination for IN, IM, and IV naloxone were similar. However, IM and IN naloxone surpassed that of IV over the time span of 20 minutes.

The IM naloxone at a dose of 0.8mg had a higher absorption rate than the IN naloxone. However, the IN naloxone at doses 1.4mg and 2.8mg surpassed the IM peak serum concentration levels (Cmax) at 15 minutes (at 1.4mg) and 10 minutes (at 2.8mg). However, the Cmax difference between the IM and IN doses were not statistically significant.

The observed exposure to naloxone from time 0 to the last measurable concentration in the body (AUC 0-last) were not statistically significant between the IN naloxone 1.4mg and IM 0.8mg. However, there was a significant between IV and IN/IM routes of administration.

The study sample were of healthy people and not the target population of an opioid user. Therefore, the conclusions were based on the pharmacokinetics of naloxone and not necessarily the clinical presentation of reversing the actual effects of reversing an opioid overdose.

| #2 | Skulberg, A., Åsberg, A., Khiabani, H., Røstad, H., Tylleskar, I., & Dale, O. (2019). | Open-label, randomized, four-way cross-over trial | 22 healthy volunteers, 10 women, aged 18-45 (median age=25.8 years) n=22 | Clinical Trials Unit at Oslo, Norway. | The distribution and elimination for IN, IM, and IV naloxone were similar. However, IM and IN naloxone surpassed that of IV over the time span of 20 minutes.

The IM naloxone at a dose of 0.8mg had a higher absorption rate than the IN naloxone. However, the IN naloxone at doses 1.4mg and 2.8mg surpassed the IM peak serum concentration levels (Cmax) at 15 minutes (at 1.4mg) and 10 minutes (at 2.8mg). However, the Cmax difference between the IM and IN doses were not statistically significant.

The observed exposure to naloxone from time 0 to the last measurable concentration in the body (AUC 0-last) were not statistically significant between the IN naloxone 1.4mg and IM 0.8mg. However, there was a significant between IV and IN/IM routes of administration. | Research Level III, Low quality |
The Tmax (time of maximum concentration) were not statistically different between IM 0.8mg and IN 1.4mg. However, the half-life (50% of Cmax) was reached quicker with IM 0.8mg with the average Cmax time being 6.5 minutes for IM 0.8mg and 10.1 minutes for IN 1.4mg.

0.5ng/ml is the suggested minimum concentration for naloxone in the elimination phase for it to be considered effective and both IM 0.4mg and IN 1.4mg were found to stay above that within 2 minutes of administration and lasting for an average of 73-85 minutes. IV 0.4mg had the shortest duration with average lasting time of 45 minutes compared to 88 minutes for IN 1.4mg.

Contributes by revealing that both 0.8mg IM and 1.4 mg IN naloxone have the right concentrations to reverse the effects of an opioid overdose with no statistical difference in the peak concentration levels and the time it takes to reach it. Both IN and IM naloxone is effective and can be a proper route to use in a prehospital setting.

| #3 | Krieter, P., Chiang, N., Gyaw, S., Skolnick, P., Crystal, R., Keegan, F., … Harris, J. (2016). | Randomized cross-over study | Pharmacokinetic Study: n=28, age 18-55 years old, 12 females | Rapid absorption for both IM and IN routes with median Tmax from 20-30 minutes. The IN administration of concentrated naloxone HCL 2-8mg in 0.1-0.2ml solution had pharmacokinetic properties that were comparable to the IM 0.4mg dose. The maximum peak concentration of all IN doses (2mg-8mg) | The study sample were of healthy people and not the target population of an opioid user. Therefore, the conclusions were based on the pharmacokinetics of naloxone and not | Research Level III, Low quality |
| #4 | Mcdonald, R., Lorch, U., Woodward, J., Bosse, B., Dooner, H., Mundin, G., ... Strang, J. (2018). | Open-labeled, randomized cross-over study | 38 healthy volunteers aged 20-54 years old; 11 females Clinical trials facility in Croydon, UK). | Cmax (mean peak serum concentration) for IN naloxone 1mg, 2mg, and 4mgsurpassed that of the IM 0.4mg naloxone. The T50% (plasma concentration greater than 50%) of IN naloxone doses were noted by 10 minutes and the Tmax (time to reach maximum concentration) was 15-30 minutes compared to the IM 0.4mg Tmax of 10 minutes. The bioavailability of the IN naloxone ranged from 47-51% in relation to IM naloxone. This shows that concentrated IN naloxone is comparable to the IM 0.4mg in terms of early exposure, adequate absorption, and maintaining blood levels. IN naloxone is a greater alternative to IM naloxone administration. | necessarily the clinical presentation of reversing the actual effects of an opioid overdose. This study had a small sample size. Therefore, the statistical power for comparison was limited. This study was conducted on healthy people and not the target population of opioid users. | Research Level III, Low quality |
| #5 | Dahlem, C., Horstman, M., & Williams, B. (2016). | Evidence-based protocol | Homeless health clinic Created by in Ann Arbor, Michigan | IN naloxone offers a safe and effective way to reverse opioid overdose and prevents the chances of a needlestick injury. Algorithm for Opioid Overdose: 1) Assess responsiveness. If the patient is responsive, then stay and observe until they are alert. If they are not responsive, | The protocol was implemented in 2014 before the new formulations of the IN naloxone was approved by the FDA. Therefore, they recommended using the intranasal atomizer with syringe to use the | Level V, B, Good quality |
then provide stimulation. If they remain unresponsive after stimulation, call 911.

2) If the patient does not have a pulse, then start CPR with AED; give naloxone and assess breathing; if they are not breathing still within 3 minutes give another dose of naloxone every 3-minutes and continue CPR until they recover. If they have a pulse but is not breathing then proceed with rescue breaths, give naloxone, access breathing, and repeat every 3 minutes if the patient has no response.

3) Monitor until EMS arrives.

The algorithm is composed of the Overdose Education and Naloxone Distribution (OEND) guidelines in conjunction with American Heart Association simplified adult basic life support algorithm and provides a simple step by step guide about what to do when an overdose occurs.

There has been 4 successful overdose reversals since the implementation of this protocol at their homeless clinic.

This protocol will be helpful with the development of a protocol for the project’s clinical site.
| #6 | Substance Abuse and Mental Health Services Administration (2018). | Evidence-based protocol | n/a | SAMHSA recommends: 5 essential steps for first responders:  
1) Check for symptoms of an overdose  
2) Call 911  
3) Administer naloxone: They recommend administering naloxone according to manufacturer instructions. They highlight that more than one dose may be needed due to increased use of fentanyl. Advised to give naloxone every 2-3 mins if patient does not respond.  
4) Provide ventilation support if the person is not breathing by giving rescue breaths (1 breath every 5 seconds) with chest compressions if needed.  
5) Monitor: SAMHSA recommends that anyone who has overdose should be transported to the hospital even if the person becomes conscious and feel better because naloxone is short acting and may result in rebound toxicity. They recommend that the patient be monitored for 4 hours after the last dose of naloxone.  

They also highlight that if you need to leave the person unattended, turn them to their side in case they vomit.  

This guideline highlights pertinent steps to consider when developing the protocol for the project’s implementation. | This guideline does not include any research studies to support their proposed recommendations. | Level V, B, Good quality |
| #7 | Evidence-based guideline | 13 articles were reviewed with 7 articles about administration and the remaining 6 about hospital transport. N=13
Created by The National Association of State Emergency Medical Services (EMS) Officials (NASEMSO), in collaboration with the National Association of EMS Physicians (NAEMSP) and the American College of Emergency Physicians (ACEP) | Route of administration: recommends IN>IM because they are both similar in efficacy, however, IN is easier and safer to administer because it prevents the risk of needlestick injury and is associated with less adverse reactions, specifically agitation and precipitated opioid withdrawal. IN=IV however, IV allow better titration of naloxone which can reduce the chance of precipitated withdrawal; IN is easier to administer. IV>IM because of IV ability to titrate naloxone.
Doses: For IV/IM/IN naloxone they recommend dose of 0.04-2mg. However, with the new formulations of prefilled naloxone is 2-4mg IN or IM. They recommended starting with the lowest dose to prevent precipitated opioid withdrawal. Repeat dose can be given every 2-3 mins if there is no response to the initial dose or if the patient has rebound toxicity.
Transport to hospital: no clear guideline on whether or not an opioid overdose patient should be transported to the hospital after administration of naloxone. | The research studies reviewed for this guideline had high risk for bias, did not study synthetic opioids such as fentanyl, and did not study the new devices of the auto injectable IM naloxone or the highly concentrated IN naloxone. | Level IV, B, Good quality |
Little training is required for the administration of IM. However, IN appears to be the optimal dosage when considering cost, effectiveness, and safety administration.

Other study concluded that IM and IN have equal time response for respiratory depression. However, another article concluded that IM is more effective.

The side effects are observed with all dosage form, but there is less side effect with IN compared to IM due to rapid absorption.

IV would require extensive training making less ideal; however, IN can easily administer by layperson and IM auto-injector requires almost no training.

There is limited randomized control trial regarding different route of naloxone administration in the prehospital setting.

More study is needed in the area of naloxone to identify which dosage is optimal for the treatment prior arriving to the hospital.

The use of relative dichotomous variables such as death or alive reduced some of the inherent bias.

It is possible the patient presented himself at the hospital and additional naloxone was administered.
| #10 | Chou, R., Korthuis, P., Mccarty, D., Coffin, P., Griffin, J., Davis-Oreilly, C., … Daya, M. (2017). | Randomized control trial | Literature review articles in multiple electronic databases: Ovid MEDLINE, PsychINFO, the Cochrane Central Register of Control Trials, and CINAH as well as ClinicalTrial.gov. Also, Food and Drug Administration (FDA). n= 202 full texted articles reviewed | There were 4 deaths due to opioid rebound toxicity among 5443 patients who were not transported to the hospital. High concentration IN naloxone 2 mg/ml seems to have efficacy similar to that of the IM dosage with no difference in side effects. Contributes to the development of an evidence-based protocol; for the treatment of opioid overdose. | It is possible the patient presented the incorrect health information, so their death would not have been included in this analysis. Studies was limited because they studied the older formulation of naloxone. No study evaluated how the stuff background or level of training affected naloxone administration outcome. | Research Level III, C, low quality |
| #11 | Carpenter, J., Murray, B., Atti, S., Moran, T., Yancey, A., & Morgan, B. (2019). | Retrospective chart review | 837 charts were reviewed and 121 were included in the final analysis. The median age is 38 years and 75% were male. N=837 n= 121 conducted at a large urban public trauma and safety net center and its affiliated EMS agency | There was no significant difference in the dose of naloxone required to treat opioid overdose with fentanyl. The finding refutes the notion of high potent opioid like fentanyl requires increase dose of naloxone. | The reason for obtaining urine drug screen is unknown; there was no a protocol rational for obtaining urine drug screen. So, if the inclusion criteria differ from those of the exclusion and that could be a potential source of bias. | Research Level III, C, low quality |
| #12 | Lynn R. & Galinkin JL. (2017). | Systematic review | Forty-two research article from different countries and each research has different size sample. N=42 total of articles reviewed. | The naloxone effect in reverse an opioid overdose is not long lasting. In one study it reversed the sedation of morphine within 2 minutes but the subjects began to feel the effects from the morphine again in 15-30 mins. IM naloxone is used frequently, and the newer auto-retracting needle device has a 15% greater maximum concentration than the former needle and syringe. | There are no studies of naloxone kinetics in fentanyl dose, neither control trial to direct appropriate naloxone dose; so, it is difficult to apply for layperson. | Level III, C, low quality |
The IN naloxone prevents needlestick injury and potential exposure to bloodborne pathogens.

IN naloxone 0.8-2mg has poor bioavailability of 4% compared to the 35% of IM naloxone.

IN naloxone 2mg has a quicker time to peak concentration (5mins) than that of 0.8mg IM naloxone. However, the duration of the serum concentration of IN naloxone was much shorter than IM administration with the duration being 1 hour for IN compared to 4 hours for IM administration. However, the IN naloxone used had poor concentration (2mg/5ml).

With highly concentration IN naloxone 2-8mg, there was a greater maximum serum concentration achieved in a quicker time and longer duration of effect than that of the IM naloxone 0.4mg.

Many reports on IN naloxone being as or even more clinically effective than IV naloxone. One study reported 83% of people responded to an initial dose of IN naloxone 2mg.

A randomized controlled trial resulted with a quicker response with IM naloxone than IN with a difference of 82% in IM and 63% in the IN subjects. However, the IM group experienced more adverse reactions of agitation, 13 % in the IM group compared to only 2% in the IN group. However, the IN formulation in this study was of low concentration (2mg/5ml).
Another study with a higher concentrated IN naloxone (2mg/ml) resulted with similar response time between the IM and IN administrations but IN was associated with the need for more repeat doses.

Finding suggests that trained medical personnel is safe than laypeople, the risk is under dosing naloxone far outweighs the potential risk for opioid withdrawal.

Similar response rate of the IM and IN routes with a dose of 2 mg of naloxone; however, another study quicker response rate and reversal of respiratory depression with the IM route compared to the IN route.

Mahonski, S., Leonard, J., Gatz, J., Seung, H., Haas, E., & Kim, H. K. (2019). Retrospective Review Chart review N=1139. PNK administrations. Reported to the Maryland Poison Center with a mean age of 34.3 years. The study demonstrated that the prepacked naloxone kits (PNKs) remains effective in the opioid overdose intervention. The majority of the overdosed received a single dose of naloxone. There was 12.7% to 5.2% of them received the second and third dose. However, in a different research, it was found no change in the average dose naloxone dose administered.

The research find that high dose of naloxone may be required to reverse the opioid toxicity in people who ingested fentanyl.

It was a retrospective study based on layperson’s reports and observation before and after naloxone admiration. Due to voluntary reporting process, the data may not represent the entire cohort of the cases in the state.

Lack of familiarity in reporting PNK as in 2015 the report was low

Research Level III, B, good quality.
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<tr>
<td>Veterans’ Health Administration (VHA) developed a national Opioid Overdose Education and Naloxone Distribution (OEND) across all VHA medical facilities. n= 142</td>
<td>VHA is one of the first to implement OEND in the United States across the national. Protocol: Responding to an overdose 1) Check for a response 2) If they do not respond, give naloxone and call 911 3) Open airway and give rescue breathing or chest compressions 4) If a person does not start breathing within 2-3 minutes or have rebound toxicity, then administer another dose of naloxone. 5) Place person on their side and observe until EMS arrives. Contributions by providing information, knowledge, policy, and guidelines to develop a naloxone overdose protocol.</td>
<td>Did not specify if any original research studies were used to formulate their protocol. Research Level V, B, Good quality</td>
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<tr>
<td>#15</td>
<td>Central for Disease Control and Prevention. National Institute for Occupational Safety and Health. (2019).</td>
<td>Evidence-based protocol</td>
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<tr>
<td>#16</td>
<td>New Jersey Department of Health Office of Emergency Medical Service (2017).</td>
<td>Evidence-Based Protocol</td>
</tr>
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<td>#17</td>
<td>Kwon, M., Moody, A., Thigpen, J. (2020).</td>
<td>Systemic review</td>
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<td># 18</td>
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<td>Evidence base protocol</td>
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<td># 19</td>
<td>Simmons, J., Rajan, S., Goldsamt, L., &amp; Elliott, L. (2016).</td>
<td>Evidence base protocol</td>
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<td>Winstanley, E. L., Clark, A., Feinberg, J., &amp; Wilder, C. M. (2015).</td>
<td>Cross sectional study design</td>
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<td># 21</td>
<td>Lott, D. C., &amp; Rhodes, J. (2016).</td>
<td>Randomized control trial</td>
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<tr>
<td>#23</td>
<td>Dudley, L. S., Konomos, D., Robbins, V., Qiu, L., Bauter, R., &amp; Merlin, M. A. (2017)</td>
<td>Chart review</td>
</tr>
</tbody>
</table>

n=269  

Setting: Helsinki EMS | Most patients received less or equal 0.4 mg of naloxone either IV, IM or SC. From 84 patients who were overdosed in the scene, 71 were administered naloxone and 8 of them recovered after administering a ventilator and 5 of them recovered without a ventilator.  

Naloxone has been available for the physician and nurses in the inpatient units and now are more available for the first responders and for people without much knowledge about the administration of naloxone such as friends and family members; in the study showed above shows that people’s life can be saved. | Most of the patients were male, it should have been included more females in the study. | Research Level I, Low quality |
Appendix C: Concept Map

Plan, Do, Study, Act (PDSA) cycles for improvement for the development and implementation for an opioid overdose treatment protocol.
Appendix D: Recruitment Flyer

Opioid Overdose Training

Learn how to save a life from opioid overdose by administering Narcan!

Training Dates & Times:
- Tuesday 11/17/2020 at 12pm
- Thursday 11/19/2020 at 5pm
- Saturday 11/21/2020 at 9am

Where: Veritas Recovery Center 4th Floor Conference Room

Contact [Name] (Clinical Director) to reserve

* All employees are welcome to join. No medical experience is needed!

V1 8.28.20
Appendix E: Consent Form

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Implementation of an Opioid Overdose Treatment Protocol
Principal Investigator: Dr. Kathleen Patzusky
Co-Investigators: Edna Hiers, BSN & Feliciana Montalico, BSN

This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You will be given a copy of the signed form to keep. Your alternative to taking part in the research is not to take part in it.

Who is conducting this research study and what is it about?
You are being asked to take part in research being conducted by Edna Hiers & Feliciana Montalico who are Rutgers University doctoral students in the Dept. of Psychiatric-Mental Health Nursing. The purpose of this study is to assess if the development and implementation of an opioid overdose protocol combined with staff training will make the staff feel more confident in their ability to handle an opioid overdose.

What will I be asked to do if I take part?
The questionnaire will take about 10 minutes to complete. We anticipate 54 subjects will take part in the study.

What are the risks and/or discomforts I might experience if I take part in the study?
There is a minimal risk because there is no anticipated discomfort for the potential participants. No personal health information (PHI) will be collected from you that would allow you to be identified. Some questions may make you feel uncomfortable. If that happens, you can skip those questions or withdraw from the study altogether. If you decide to quit at any time before you have finished the questionnaire, your answers will NOT be recorded. In response to the current Covid-19 pandemic, CDC recommends social distancing. New Jersey’s Governor Murphy recommends that all indoor gatherings do not exceed 50 people. Therefore, each educational session will consist of less than 50 participants, including the DNP students who are presenting.

Are there any benefits to me if I choose to take part in this study?
There no direct benefits to you for taking part in this research. You will be contributing to knowledge about how an opioid overdose should be handled by the staff in a drug detox setting.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

How will information about me be kept private or confidential?
Information collected from participants was used strictly for the purpose of this project and are kept securely in a locked key cabinet within the project site. Collected data was only accessible to the study personnel.

What will happen to information I provide in the research after the study is over?
The information collected about you for this research will not be used by or distributed to investigators for other research. Upon completion of the project, closure of the IRB, and final writing of the manuscript all data will be kept in locked cabinet at Rutgers University for a maximum period of six years.
What will happen if I do not want to take part or decide later not to stay in the study? Your participation is voluntary. If you choose to take part now, you may change your mind and withdraw later. In addition, you may skip questions that you are not comfortable answering. You may leave without turning in a completed form or by turning in a blank or incomplete form. However, once you turn in the form, you can no longer withdraw your responses as we will not know which one is yours.

Who can I call if I have questions?
If you have questions about taking part in this study, you can contact the Principal Investigator: Dr. Kathleen Patusky, Rutgers University School of Nursing, by phone or email. You may also contact the co-investigators Edna Hiers, Rutgers University School of Nursing, by phone or email, and Feliciana Montalico, Rutgers University School of Nursing, by phone or email.

If you have questions about your rights as a research subject, you can contact the IRB Director at: Newark Health Sciences IRB (973)-972-3608.

Please keep this consent form if you would like a copy of it for your files.

AGREEMENT TO PARTICIPATE

Subject Consent:
I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (printed): ____________________________________________
Subject Signature: ____________________________________________ Date: __________

Signature of Investigator/Individual Obtaining Consent:
To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed): ________________________
Signature: ________________________ Date: __________
Appendix F: Opioid Overdose Management Protocol

Recovery Opioid Overdose Treatment Protocol

What are opioids?

Opioids are medications used to relieve pain by binding to specific opioid receptors on the nerve cells in the brain, spine, and gastrointestinal tract. They include prescription and illicit manufactured medications such as oxycodone, codeine, methadone, morphine, fentanyl, hydromorphone, hydrocodone, buprenorphine, and heroin.

What is an opioid overdose?

An opioid overdose occurs when a person takes too much opioids. There is not much difference between the right dose and a toxic dose; the difference can be that of one pill, one intravenous injection, or one snort. This cause a great number of opioid receptors that are occupied or stimulated which may lead to loss of consciousness, slow breathing or may stop breathing completely. The risk of an opioid overdose is increased when taking with other medications such as sleep medications, alcohol, anxiety medications, and other opioids. Opioid overdose can lead to medical complications and death within seconds to hours after an opioid overdose.

Who is at risk for an opioid overdose?

Anyone who uses opioids are at risk of an opioid overdose even if the medications are prescribed to them. However, people who have built up a tolerance to the opioids and require higher doses are at an increased risk of an overdose. Additionally, the risk of an overdose is increased when used with other sedating agents such as benzodiazepines and alcohol; as well as in those who are recently released from jail or drug detox or rehabilitation centers because they no longer have a high tolerance.

Five Essential Steps for First Responders When Suspect an Opioid Overdose

Step 1: Evaluate for Signs of an Opioid Overdose and Check for a Response

1) Signs of an opioid overdose
   - The two main signs of an opioid overdose are severe drowsiness or inability to be awakened (unconsciousness) and slow breathing (respiration less than 10 breaths per minute) or stopped breathing.
   - Other signs of an opioid overdose includes: fingernails or lips turning blue or purple, pinpoint pupils, clammy and sweaty skin, and snoring, gurgling, or choking sounds.

2) Check for a response
   - Call the person’s name and if no response, lightly shake the person and firmly rub your knuckles into their sternum (the breastbone in the middle of the chest).
   - Monitor the person by paying attention to their breathing and ability to maintain alertness and responsiveness and try to keep the person awake and alert by providing stimulation.
- If the person does not respond, has slow or shallow breathing (respirations less than 10 breaths per minute), stopped breathing completely, or is unconscious, and an opioid overdose is suspected, call/shout for help immediately.

**Step 2: Call 911**
- An opioid overdose requires immediate attention from someone with medical expertise. Call 911 so that help is on the way while you prepare the naloxone.
- When you call 911 state “someone is unresponsive and not breathing.”
- Be sure to include the address and location and inform that the call is coming from a drug detox and rehab facility.
- Follow the dispatcher’s instructions.

**Step 3: Administer Naloxone**

Naloxone is an antidote approved by the FDA to reverse the toxic effects of an opioid overdose. It is an antagonist medication that has a stronger attraction to the opioid receptor sites than the opioids thus knocking the opioids off the receptors for a short time. This reverses the toxic effects and allows the person to breathe again. Narcan comes in several different formulations and could be administered nasally, intramuscularly, or intravenously. However, research literature suggest that the intranasal route is optimal for prehospital use because it has proven to be effective in reversing opioid overdose, easy and quick to administer, and eliminates the risk of needlestick injury that is associated with the intramuscular and intravenous routes of administration.

**How to administer naloxone nasal spray (Narcan):**
1) Remove Narcan nasal spray from its packaging
2) Hold the Narcan nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.
3) Tilt the person’s head back while providing support to their neck with your hand.
4) Insert the tip of the Narcan nasal spray nozzle into one nostril until your fingers are against the bottom of the person’s nose.
5) Press the plunger firmly with your thumb to give a complete dose of Narcan nasal spray.
6) Remove the Narcan nasal spray from the nostril after giving the dose.

**Step 4: Support the Patient’s Breathing**

Ventilation support is very important with the outcome of an opioid overdose. Ventilation support can be achieved through rescue breaths and compressions.

If the person has a pulse but is breathing abnormally then give rescue breathing by:
1) Making sure the airway is clear.
2) Place one hand on the person’s chin and tilt the head back.
3) While pinching the nose, deliver 2 slow breaths by allowing the chest to completely rise.
4) Deliver 1 breath every 5 seconds for 3 minutes then reassess the patient for a pulse and breathing.
If the person does not have a pulse, perform CPR with chest compressions and attach AED and follow its instructions. Give 30 chest compressions followed by 2 rescue breathing for 3 minutes and then reassess the patient for a pulse and breathing.

Step 5: Monitor the Patient’s Response

Narcan nasal spray generally takes 2-3 minutes after administration for a response. Depending on the amount of opioids used and the presence of fentanyl which has a higher potency, additional doses of Narcan may be needed. Therefore:

- If the patient does not start breathing after 2-3 minutes of Narcan administration, repeat steps 3 and 4.
- If the patient does start breathing but is unresponsive, put the patient on his/her side to keep the airway clear and prevent choking if he/she vomits.
- If the patient start breathing and is responsive, monitor for signs of opioid withdrawal. The signs of an opioid withdrawal include body aches, diarrhea, tachycardia, fever, runny nose, sweating, nausea or vomiting, restlessness, abdominal cramps, irritability dilated pupils, and opioid craving. Although these symptoms are not life-threatening, it can cause the patient to be combative and resist medical treatment. In this case, reassure the client that he or she is safe, and that help is on the way.
- Because naloxone wears off within 30-90 minutes, monitor the patient’s breathing and stay with the patient until EMS arrives. If the patient stops breathing again or breathing slows down to less than 10 breaths per minute, repeat steps 3 and 4.
- All patients who experience an opioid overdose at Veritas Recovery Center must be transported to the hospital via EMS for further evaluation.
Appendix G: Opioid Overdose Management Algorithm

Algorithm for Recovery Opioid Overdose Management Protocol

Assess Responsiveness

- Responsive
  - Stay and Observe Until Alert
  - Provide Stimulation

- No response
  - Not Responsive
    - Call 911
    - Give Naloxone
      - No Pulse
        - CPR/AED
      - Pulse, Not Breathing
        - Rescue Breathing
    - Assess Breathing
      - Breathing
        - Recovery Position & Monitor Until EMS arrives
      - Not Breathing

Signs of an Opioid Overdose
1. Slow respiration (less than 10 breaths per minute)
2. No breathing
3. Unconsciousness
4. Choking or gurgling sounds
5. Not responsive to stimulation
6. Pale or clammy skin
7. Fingernails blue or purple in color
8. Pinpoint pupils
Appendix H: Opioid Overdose Management PowerPoint Training

Management of an Opioid Overdose

Edna Hiers & Feliciana Montalico
Doctor of Nursing Practice Project
Rutgers University School of Nursing

Objectives

- Describe what opioids are, how they work, and how a person develops an addiction
- How to identify a person who is having an opioid overdose
- Describe what naloxone is and how it works in reversing an opioid toxicity
- Recognize when and how to use naloxone properly
- Describe how to manage an opioid overdose

Management of an Opioid Overdose

Opioid Crisis

- According to Centers for Disease Control and Prevention (CDC), from 2017 to 2018 opioid related deaths decreased 5% overall for prescriptive opioids and illicit synthetic opiates in the U.S. However, this data excludes the deaths caused by the use of illicit manufactured fentanyl (IMF).
- IMF is currently being combined with heroin as well as being pressed into fake prescriptive opioid pills.
- IMF is 50-10,000 times more potent than heroin causing a significant increase in deaths.
- Between the year 2017 and 2018, IMF related deaths increased by 11%.
- The opioid related deaths in the U.S. increased 90% due to deaths relating to IMF between the years 2013 to 2017.
- In New Jersey, the mortality rate from opioid overdose increased more than 50% between the years of 2014 to 2017, with the death rate for each year consecutively being 1,253 persons in 2014, 1,454 persons in 2015, 2,056 persons in 2016, and ending with 2,685 persons in 2017

What are opioid?

- Opioids are medications used to relieve pain by binding to specific opioid receptors on the nerve cells in the brain, spine, and gastrointestinal tract.
- They include prescription and illicit manufactured medications such as oxycodone, codeine, methadone, morphine, fentanyl, hydromorphone, hydrocodone, buprenorphine, and heroin.
Management of an Opioid Overdose

What is an opioid overdose?

- An opioid overdose occurs when a person takes too much opioids.
- There is not much difference between the right dose and a toxic dose; the difference can be that of one pill, one intravenous injection, or one snort.
- This cause a great number of opioid receptors that are occupied or stimulated which may lead to loss of consciousness, slow breathing or may stop breathing completely.
- The risk of an opioid overdose is increased when taking with other medications such as sleep medications, alcohol, anxiety medications, and other opioids.
- Opioid overdose can lead to medical complications and death within seconds to hours after an opioid overdose.

Who is at risk of an opioid overdose?

- Anyone who uses opioids are at risk of an opioid overdose even if the medications are prescribed to them.
- However, people who have built up a tolerance to the opioids and require higher doses are at an increased risk of an overdose.
- Additionally, the risk of an overdose is increased when used with other sedating agents such as benzodiazepines and alcohol; as well as in those who are recently released from jail or drug detox or rehabilitation centers because they no longer have a high tolerance.

Management of an Opioid Overdose

Why does this matter?

- At Venitas Recovery Center, clients sometime arrive to the clinic for admission while they are under the influence of opioids.
- There is also a possibility for potential clients to sneak drugs into the treatment facility during admission that may be overlooked during the intake body search.
- These behaviors could result in an overdose on the clinical site.
- Therefore, both medical and non-medical staff members should be properly trained to handle an opioid overdose situation.
- In New Jersey, The Pharmacy Practice Act (N.J.S.A 45:14-67.2) and the Overdose Prevention Act (N.J.S.A 24:65-1) created a standing order proposal to allow pharmacies to dispense naloxone to individuals without a prescription (State of New Jersey Department of Health, 2016).
- Furthermore, the Overdose Prevention Act and the Good Samaritan Law in New Jersey, provides immunity for criminal liability of patients, non-healthcare and healthcare professionals, and pharmacists for dispensing, prescribing, and/or administering naloxone (State of New Jersey Department of Health, 2018).
- Therefore, all employees, including non-medical staff, can be trained to administer naloxone.

How to manage an opioid overdose?

- Step 1: Evaluate for Signs of an Opioid Overdose and Check for a Response
- Step 2: Call 911
- Step 3: Administer Naloxone
- Step 4: Support the Patient’s Breathing
- Step 5: Monitor the Patient’s Response
Management of an Opioid Overdose

Step 1: Evaluate for Signs of an Opioid Overdose and Check for a Response

Signs of an opioid overdose
- The two main signs of an opioid overdose are severe drowsiness or inability to be awakened (unconsciousness) and slow breathing (respiration less than 10 breaths per minute) or stopped breathing.
- Other signs of an opioid overdose include: fingernails or lips turning blue or purple, pinpoint pupils, clammy and sweaty skin, and snoring, gurgling, or choking sounds.

Check for a response
- Call the person’s name and if no response, lightly shake the person and firmly rub your knuckles into their sternum (the breastbone in the middle of the chest).
- Monitor the person by paying attention to their breathing and ability to maintain alertness and responsiveness and try to keep the person awake and alert by providing stimulation.
- If the person does not respond, has slow or shallow breathing (respirations less than 10 breaths per minute), stopped breathing completely, or is unconscious, and an opioid overdose is suspected, call/shout for help immediately.

Step 2: Call 911

- An opioid overdose requires immediate attention from someone with medical expertise. Call 911 so that help is on the way while you prepare the naloxone.
- When you call 911 state “someone is unresponsive and not breathing.”
- Be sure to include the address and location and inform that the call is coming from a drug detox and rehab facility.
- Follow the dispatcher’s instructions.

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- Press the plunger firmly with your thumb to give a complete dose of Narcan nasal spray.
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- Ventilation support is very important with the outcome of an opioid overdose. Ventilation support can be achieved through rescue breaths and compressions.
- If the person has a pulse but is breathing abnormally then give rescue breathing by:
  - Making sure the airway is clear.
  - Place one hand on the person’s chin and tilt the head back.
  - While pinching the nose, deliver 2 slow breaths by allowing the chest to completely rise.
- Deliver 1 breath every 5 seconds for 3 minutes then reassess the patient for a pulse and breathing.
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- Because naloxone wears off within 30-90 minutes, monitor the patient’s breathing and stay with the patient until EMS arrives. If the patient stops breathing again or breathing slows down to less than 10 breaths per minute, repeat steps 3 and 4.
- All patients who experience an opioid overdose at Veritas Recovery Center must be transported to the hospital via EMS for further evaluation.

References


Appendix I: Questionnaire

Dear Participant,

We are conducting research to evaluate the effectiveness of the opioid overdose management training you have just received. Your response in this regard shall help us to complete this research in an efficient way. Thank you for spending your time to participate in this study. All the data you provide will only be used in statistics analysis and be kept confidential.

Based on the training provided, please read the following statements carefully and circle the correct numeric response using the following scale: 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree.

<table>
<thead>
<tr>
<th>#</th>
<th>Question</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>I am able to identify the signs of an opioid overdose.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<tr>
<td>2</td>
<td>I am able to follow the steps of the opioid overdose treatment protocol.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>I am able to properly administer naloxone intranasally.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>I am able to identify when to give a repeat dose of naloxone.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>Overall, I am able to handle an opioid overdose situation.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
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Please indicate your job title: ____________________________
**Appendix J: Project Timeline**

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<tr>
<th>Completion Date</th>
<th>Planning</th>
<th>Pre-implementation</th>
<th>Implementation</th>
<th>Evaluation</th>
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<td>3/3/2020</td>
<td>First planning meeting. Aims and objectives of project proposed to project chair.</td>
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<tr>
<td>3/6/2020</td>
<td>Project introduction</td>
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<tr>
<td>3/10/2020</td>
<td>Proposed project presented to stakeholders. Site approval letter completed.</td>
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<td>3/20/20-4/1/2020</td>
<td>Literature review</td>
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<tr>
<td>4/4/2020</td>
<td>Development of protocol and education presentation</td>
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<tr>
<td>4/6/2020</td>
<td>Meet with clinical director, medical director, and psychiatric DNP to present proposed protocol and educational sessions</td>
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<td>9/15/2020</td>
<td>Submit IRB application</td>
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<td>10/7/2020</td>
<td>Revisions sent to Rutgers' IRB</td>
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<td>10/22/2020</td>
<td>Rutgers’ IRB approval</td>
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<td>11/17/2020, 11/19/2020, 11/21/2020</td>
<td>Conduct educational sessions with staff</td>
<td>Post survey of educational sessions (data collection)</td>
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<td>12/1/2020-2/10/2021</td>
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<td>Analyze the data</td>
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<td>2/15/2021-3/29/2021</td>
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<td>Evaluate and discuss findings and revise the dissertation.</td>
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<tr>
<td>4/2021</td>
<td></td>
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<td>Presentation of final project</td>
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<td>5/2021</td>
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<td>Graduation</td>
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