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Intranasal Naloxone Adminstration Education

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Clinical Leadership Theme

This project focuses on the Clinical Nurse Leader (CNL) elements: Systems Analyst/Risk Anticipator, Outcomes Manager, and Educator. As a system analyst and risk anticipator, the CNL reviews systems to improve the quality of patient care delivery and anticipates and mitigates risks to patient safety. As an Outcomes Manager, the CNL synthesizes data, information and knowledge to evaluate and achieve optimal client outcomes. As an Educator, the CNL uses teaching strategies and current information and technologies to teach healthcare professionals (American Association of Colleges of Nursing, 2007). The specific aim statement is to reduce the number of fatal opioid overdoses in our county by 75 percent within 12 months by providing education for local healthcare providers on intranasal naloxone administration for opioid users or their family, friends, peers, or members of their social network.

Statement of the Problem

The opioid epidemic has spread worldwide, and has killed 69, 000 people annually (World Health Organization, [WHO], 2014). Nationally, over 28,000 people died in 2014 from drug- poisoning; half of these deaths involved a prescription opioid (Centers for Disease Control and Prevention [CDC], 2016). California's Lake County's opioid death rates are four times the California state average. In 2013, the rate of drug -poisoning deaths in Lake County was 45, compared to the State average of 11 (California Department of Public Health, [CDPH], 2016). The Controlled Substance Utilization Review and Evaluation System (CURES), California's Prescription Drug Monitoring Program, data illustrates that in 2013, the rate of opioid prescriptions was 1767 per 1,000 in the county, over three times the state average of 563. It also showed the rate of residents per 1,000 on high doses of over 100 morphine milligram equivalents

was 41.1, or five times greater than the state average of 8.1 (State of California Department of Justice, 2016).

In 2014 in Lake County, 23 deaths were attributed solely to drugs (48 deaths from both alcohol and drugs), and 52 non-fatal hospitalizations, and 50 non-fatal emergency department visits involved opioids (CDPH, 2016). Lake County ranks 50th of 57 in health behaviors, and 56th of 57 in overall county health outcomes (Robert Wood Johnson Foundation, 2016).

According to the *Morbidity and Mortality Weekly Report* (CDC, 2013), in 2010 a total of 40,393 drug-induced deaths occurred in the United States, 74.3 percent of which were unintentional. Prescription drugs have now surpassed illicit drugs as a leading cause of drug-related overdose deaths (CDC, 2013).

The nature of the project derives from the ability of intranasal naloxone to reverse opioid overdose. Opioid overdose, whether from prescribed or illicit use, can result in respiratory depression and death. Naloxone possesses a stronger affinity and ability to bind to opioid receptors to temporarily block the effects of opioids and primarily support respiratory status. The CNL student can be instrumental in developing and distributing educational materials about the administration of intranasal naloxone to assist healthcare providers in informing patients, their peers, families, and members of their social network who might witness an overdose.

Project Overview

The goals and objectives of the CNL project are to provide education to healthcare providers and their supportive staff on the administration of intranasal naloxone. This entails research, participation and collaboration in various stakeholder and action team meetings, development of a county substance use disorder treatment and support services resource guide, the provision of a power-point presentation, demonstration of intranasal administration, and

educational materials to interested providers. The aim statement is to reduce the number of fatal opioid overdoses by 75 percent in Lake county within 12 months by providing education for local healthcare providers on intranasal naloxone administration for opioid users or their family, friends, peers, or members of their social network. This relates to the global aim goal. The CNL aims to improve access and education to intranasal naloxone administration for opioid users or their family, friends, peers, or members of their social network through education provided to healthcare providers or their support staff in clinics in our county.

The actual workflow process begins with providing access (prescription) to intranasal naloxone and educating opioid users and their family, friends, peers, or members of their social network about its administration. The process ends with the opioid user or their friends, family, peers, or members of their social network obtaining intranasal naloxone and the knowledge for its administration, and potentially utilizing it and saving a life. By working on the process, the CNL student expected to improve patient outcomes, improve patient safety, and improve the quality of care. It was important to work on this because the CNL student had identified the need to improve patient outcomes, improve patient safety, and improve the quality of care. Access to intranasal naloxone and education in its use provided to opioid users and their family, friends, peers, or social network can help reverse an opioid overdose, and potentially prevent death.

Rationale

The project originated from a countywide initiative raising the awareness of high rates of opioid misuse and opioid deaths in the County of Lake. The county initiative is known as Safe Rx Lake County (2016), and has been formed through collaboration with Partnership HealthPlan of California (2016) and the California Health Care Foundation (2016). The CNL student, and preceptor, Dr. Karen Tait, Lake County Health Officer, mutually identified a suitable project that

could have beneficial impact in the community. As a public health nurse working in the Lake County health department, it was a complementary opportunity to positively influence community health outcomes.

This was an evidence-based project with a multitude of literature on the topic of prescription and non-prescription opioid misuse, and naloxone. Intramuscular naloxone, as well as its intranasal formulation, has successfully been used in many harm-reduction programs, substance abuse programs, and pre-hospital Emergency Medical Services (EMS) for the reversal of opioid overdose.

Opioid misuse, including prescription opioids, has reached epidemic proportions (CDC, 2016). Naloxone, an opioid reversal agent, can reverse the effects of an opioid overdose of prescription opioids, as well as non-prescription opioids, such as heroin. Through awareness campaigns and prescription practice guideline changes, intranasal naloxone is now available to patients, their family members, peers, or members of their social network even without a prescription through participating pharmacies. The importance of knowledge of its administration is life-saving.

The opioid epidemic is now well recognized throughout the United States. Recent attention has focused on the celebrity Prince, who reportedly died from an overdose of a powerful opioid (Associated Press, 2016). Prince, reportedly struggling with pain issues, had been prescribed an opioid, which resulted in an accidental overdose and death. According to Dr. Barbarajean Magnani, pathologist-in-chief at Tufts Medical Center, "celebrities bring it to our attention, but we see this every day" (Associated Press, 2016, p. 1).

The data is astounding. According to the CDC (2016), seventy-eight Americans die each day from an opioid overdose. The rate of overdose deaths involving opioids quadrupled since

1999. In 2014, over two million Americans were abusing or dependent upon prescription opioids, and there were more deaths attributed to opioid overdose than ever. From 2000 to 2014, nearly half a million people died from drug overdoses; the majority of deaths (more than six out of ten) involved an opioid.

The CNL student's local county is no exception. The county's death rates are four times higher than the State average (California Department of Public Health, 2016). Collectively, the California Healthcare Foundation, Partnership HealthPlan of California, and the local county have developed a coalition to mitigate this serious issue. There are many interventions ranging from new prescribing guidelines (thus significantly reduced prescriptions), increased therapeutic treatment programs, and the Controlled Substance Utilization Review and Evaluation System (CURES), or the California Drug Monitoring Program (State of California Department of Justice, 2016). CURES is a database that displays patient prescription history, prescribing physicians, dispensing information, and refill intervals, and is accessible to both clinicians and pharmacists for monitoring, safe prescribing, and drug diversion prevention. In addition to these aggressive measures, a reversal agent, naloxone, has been proven to be effective against opioid overdose (Mueller, Walley, Calcaterra, Glanz, and Binswanger, 2015).

The CNL student can be effective in assisting to broaden the education and use of the reversal agent within the constraints of a collaborative pilot program. Since this is a novel initiative in the county, healthcare providers may not have been educated on this topic. In addition, the mainstreaming of naloxone prescription may soften the stigma associated with harm reduction programs, such as needle exchange programs. The CNL student also assisted in the development of a resource guide of available substance abuse treatment and support options for dissemination in the county.

The aim statement was to reduce the number of fatal opioid overdoses in the county by 75 percent within 12 months by providing education on intranasal naloxone administration to healthcare providers for opioid users or their family, friends, peers, or members of their social network. The identified threats included lack of control over prescribing and education administration, availability of venues, provider or healthcare organization disinterest, timelines, and political conservatism that may have hindered widespread dissemination of substance abuse and naloxone awareness. To mitigate these potential unintentional threats, the CNL student pursued additional opportunities to provide educational materials through newly available venues. For instance, the Lake County Office of Alcohol and Other Drug Services (AODS) received $30,000 of grant funds for 200 Narcan Nasal Spray kits. The CNL student had planned to provide education in this endeavor, as well. In addition, the CNL student recorded a webinar on intranasal naloxone administration through California Partnership HealthPlan for potential future use for other providers. The project strove to improve patient outcomes, improve patient safety, and improve the quality of care.

Opioid overdoses claim 78 Americans' lives daily in the United States (CDC, 2016). Since naloxone has the ability to reverse overdose, the potential for lives saved is thus very high. The cost of implementing the CNL student project of naloxone education was estimated to be $ 7,900. This encompassed the average salary of a local public health nurse ($35.00 an hour) at 220 total hours, including the cost of computer use, copies, patient education materials, transportation, and utility services such as phone, Internet, and electricity estimated at an additional $200. However, since providers were not charged during this academic project, this cost may be viewed as a savings to provider organizations. Naloxone itself is prescribed, and is not funded by the providers, but by Medi-cal. The mucosal atomization device used in

conjunction with the prescribed naloxone has been supplied free of charge by Partnership HealthPlan of California.

A literature review published in *Population Health Management* found that those who misuse opioids generally also use more healthcare services, such as the emergency department, outpatient physician services, and inpatient hospital admissions (Meyer, Patel, Rattana, Quock, and Mody, 2014). The same review identified that the mean annual excess utilization healthcare costs for opioid misusers with private insurance ranged from $14,054 to $20,546, and those with Medicaid from $5874 to $15,183. A study published in the *Journal of the American Medical Association* identified 135, 971 emergency department visits nationally for opioid overdose in 2010, and inpatient and emergency room expenses totaling $2.3 billion (Yokell, Delgado, Zaller, Wang, McGowan, and Green, 2014). Naloxone distribution was found cost-effective and cost saving, resulting in fewer overdoses and usages of the emergency medical service system (Cofflin and Sullivan, 2013). Cofflin et al. (2016) demonstrated that emergency department visits were reduced with co-prescription of naloxone.

The cost savings of lives, of course, is difficult to quantitatively assess. In this case, cost utility analysis is utilized, and the value and the quality of life are expressed in quality adjusted life years (Penner, 2013). In a meta-analysis by Cofflin and Sullivan (2013), six percent of overdose deaths were prevented with naloxone distribution; one death was prevented for every 227 naloxone kits distributed. Naloxone distribution increased costs by $53, while increasing quality-adjusted life-years by 0.119 for an incremental cost-effectiveness ratio of $438, or cost per quality-adjusted life year (QALY) gained. According to Meyer, Patel, Rattana, Quock, and Mody (2014), the societal burden of opioid overdose results in 830,652 years of potential life lost before age 65.

Literature Review

The PICO question posed was: Does naloxone reduce the number of deaths from opioid overdose in the community? The initial search in the University of San Francisco Gleeson Library Cumulative Index to Nursing and Allied Health Literature (CINAHL) database revealed 66 results of peer-reviewed articles between 2009-2016 when using the words *naloxone* and *community*. When using the words *naloxone, community,* and *death*, the results tightened to 15, the majority of which were pertinent.

Mueller, Walley, Calcaterra, Glanz, and Binswanger (2015) summarized and classified publications on overdose education and naloxone distribution to assess effectiveness, and concluded that naloxone hydrochloride is the standard of care for treatment of opioid induced respiratory depression. It is standard practice in emergency settings for patients with an opioid-induced coma or respiratory depression because of its rapid action as an opioid–receptor antagonist (Compton, Volkow, Throckmorton, and Lurie, 2013). Naloxone has been used for over 40 years in the hospital setting, emergency departments, and pre-hospital Emergency Medical Services (EMS). It has also been used for years in harm reduction programs, such as those lead by the San Francisco Department of Public Health (2016). The evidence for the effectiveness of intramuscular naloxone, and its intranasal form, is abundant. In a prospective, nonrandomized trial of the administration of intranasal naloxone by paramedics to patients with suspected opiate overdoses over a six-month period, intranasal naloxone was shown to have an 83 % effectiveness rate, with potential results projected to be higher in actual practice (Barton et al., 2005). The intranasal route possesses benefits of rapid onset, high plasma bioavailability, direct passage to the central nervous system via the olfactory mucosa bypassing first pass metabolism, and the elimination of needles (Barton et al, 2005). A 2009 randomized control trial

study concluded that intranasal naloxone reversed opioid overdose successfully in 82% of patients, and the intranasal route was as effective as the then more frequently used intramuscular route as a first-line treatment for opioid overdose. Additional benefits of the intranasal route are ease of access and administration and increased safety from reduced exposure risk to blood-borne pathogens such as hepatitis B, hepatitis C, and human-immunodeficiency virus from accidental needle- stick injuries (Kerr, Kelly, Dietze, Jolley, and Barger, 2009). Robinson and Wermeling (2014) concluded that intranasal naloxone is as effective as intravenous administration at reversing the central nervous system-depressing effects of opioids, by comparing respiratory rates and Glascow Coma Scale values before and after naloxone administration.

Opioids have binding sites in the brain, nervous system, and limbic system known as opioid receptors. There are essentially three types of opioid receptors: mu, delta, and kappa. Mu-receptors are responsible for opioid-induced euphoria, analgesia, sedation, and respiratory depression (Adams, Holland, and Urban, 2015). By depressing the respiratory drive, resultant hypoxemia leads to cerebral hypoxia, impaired consciousness, respiratory arrest, cardiac dysthymias, and cardiac arrest (WHO, 2014). Enteen et al. (2010) corroborate that death is due to cardiac arrest following hypoxia from the opioid suppression of the central respiratory drive. Naloxone, an opioid antagonist, possesses has a higher affinity for mu-receptors, and virtually competes with and defeats opioids to bind the mu-receptors. Naloxone replaces the opioid agonist and reverses the biological effects that are caused by opioids, such as respiratory depression, and consequent fatal opioid overdose. Intranasal naloxone’s onset is three to five minutes, and its duration of action ranges from 30- 90 minutes (WHO, 2014).

In 2006, the Boston Public Health Commission started an overdose prevention program and distributed intranasal naloxone kits to community members. After training 385 individuals, 74 successful naloxone overdoes reversals were reported, and intranasal naloxone administration was deemed as effective as intravenous administration (Robinson and Wermeling, 2014).

The incidence of fatal opioid overdose among opioid-dependent individuals is estimated at 0.65 per 100 person years, and non-fatal opioid overdoses are several times more common (WHO, 2014). The estimated mortality rate in overdoses where naloxone was administered by witnesses is one percent, while the estimated mortality rate of opioid overdose where community use of naloxone was not available is two to four percent (WHO, 2014).

Naloxone exhibits no pharmacological effect on an opioid-naïve person, is not a controlled substance, and does not have addictive potential (Harm Reduction Coalition, 2012; Straus, 2013). Naloxone has relatively mild side effects, as those of opioid withdrawal, and while unpleasant, are not life-threatening (Kerr, 2009). The most common side effects are nausea and vomiting, while seizures were reported in 0.45% of overdose reversals (WHO, 2014).

In post-operative reversal of central nervous system and respiratory depression, life-threatening adverse effects such as ventricular arrhythmias, ventricular fibrillation, hypertension, hypotension, tachycardia, pulmonary edema, encephalopathy, coma, and death have been reported (DrugInserts.com, 2013). This is attributed to rapid or larger doses than those used in the community, and potentially underlying cardiovascular conditions, or use of cardiotoxic medications. It is to be used in caution with pregnant women, as it can cause withdrawal of the fetus and mother, and is to be avoided in neonates due to potential abstinence withdrawal syndrome (DrugInserts.com, 2016).

Organizations such as the American Society of Anesthesiologists (2014), the American Medical Association (2016), the Office of National Drug Control Policy (2016), the Substance Abuse and Mental Health Services Administration (2016), Project Prescribe to Prevent (2016), and many others support the use of intranasal naloxone by laypersons in successful opioid overdose reversal. This position statement from the American Society of Addiction Medicine (2014) supports comprehensive training for naloxone administration, increased use of naloxone in opioid overdose, and expanded accessibility to naloxone for those who are likely to witness opioid overdose. In their systemic review of naloxone distribution programs, Clark, Wilder, & Winstanle (2014) concluded that bystanders will successfully use naloxone to reverse opioid overdoses when properly trained through these programs. A systematic review of studies on take-home naloxone to reverse opioid overdose included 21 studies for analysis. One interrupted time-series study, involving 2, 912 opioid users at risk of overdose in 19 communities followed for seven years, demonstrated that education and training intervention complemented by take-home naloxone decreased overdose-related mortality (European Monitoring Centre for Drugs and Drug Addiction, 2015).

A systematic review and descriptive meta-analysis of the international Take-Home Naloxone programs literature study estimates that nine percent of naloxone kits distributed are likely to be used by peers within the first three months for every 100 trained (McAuley, Aucott, and Matheson, 2015). Lim, Bratberg, Davis, Green, and Walley (2016) provide an educational tool that instructs prescribers and pharmacists on the administration of naloxone, in accordance with the priority recommendation of the United States Department of Health and Human Services of expanded use and distribution of naloxone for reducing opioid overdose. The meta-analysis by Giglio, Li, and DiMaggio (2015) demonstrated that bystander naloxone

administration and overdose education programs are associated with increased odds of recovery from overdose.

Since 1996, overdose education and naloxone distribution programs have been successfully distributing naloxone kits and training in their use to laypersons. An evaluation of a program in Massachusetts that trained over 2,900 potential overdose bystanders, reported that opioid overdose death rates were significantly reduced in communities in which the program was implemented as compared to those in which it was not (Walley et al, 2013).

In 2006, the Chicago Recovery Alliance distributed 3,500 intramuscular naloxone doses to opioid users, with 319 reported peer reversals. A twenty percent reduction in opioid deaths, with a ten percent additional reduction for the second and third years, were reported by the Cook County medical examiner (Wermeling, 2010). By August 2011, 22,010 overdose prevention encounters and 2,720 peer opiate-related overdose reversals had been reported (Harm Reduction, 2012).

The San Francisco Drug Overdose Prevention and Education (DOPE) Project has a long-standing history of naloxone distribution and success. The DOPE Project, the first naloxone prescription program established in conjunction with a county health department, the San Francisco Department of Public Health, reported that from 2003 to 2009, 1,942 individuals were trained and prescribed naloxone, 399 naloxone doses were administered, and 89 % opioid overdoses were reversed (Enteen et al., 2010).

The Baltimore Student Harm Reduction Coalition is Maryland ’s first community-based, state-authorized training program for third-party naloxone prescription. During an eight-month pilot period, 250 free naloxone kits were distributed, and three overdose reversals were reported. Trainings were also found effective in increasing self-efficacy in overdose prevention and

response, persisting up to 12 months (Lewis et al., 2016). Bennett & Holloway's (2012) evaluation of the Take- Home- Naloxone- Project in Wales determined that knowledge, confidence, ability, willingness, and successful administration of naloxone improved with education and training, and of 28 administrations of naloxone, 27 overdose reversals were reported.

A review of six overdose education and naloxone distribution programs concluded that trained participants were more likely to recognize overdose, and identify when naloxone administration was indicated, compared with those who had not received training (Cofflin and Sullivan, 2013). Chicago, New York, San Francisco, Baltimore, and New Mexico boast successful naloxone distribution and training programs through their overdose prevention programs (Doe-Simkins, Walley, Epstein, and Moyer, 2009).

One of the major goals of the American Medical Association Task Force is to encourage physicians to co-prescribe naloxone to a patient, or prescribe naloxone to a family member or peer when clinically appropriate. These prescriptions are favored, especially if the patient is on a high opioid dose, has concomitant benzodiazepine prescription, history of substance use disorder, [and possibly Suboxone or Methadone therapy], has an underlying mental health or comorbid medical condition, or might likely assist someone who overdoses (American Medical Association, 2016).

Traditionally, legal concerns may have discouraged providers to participate in overdose education and naloxone prescribing. Some of the issues of expanding overdose education and naloxone prescription programs in the community include medical providers' reluctance to prescribe naloxone. Medical providers may be concerned about legal ramifications, bystanders' ability to accurately recognize an overdose and administer naloxone, or promoting riskier drug

behavior. In a legal review of naloxone prescribing, medical providers who prescribe naloxone consistent with state and federal laws drug prescribing laws realize a low risk for malpractice (Beletsky, 2012). Naloxone can be prescribed by any licensed heathcare provider. However, there are additional laws that offer greater protection and support. California Assembly Bill AB635 (2014) encourages providers to prescribe to those with chronic opioid use, third- party prescribing, standing orders for dispensing by community workers, and layperson possession and administration of naloxone (California Legislative Information, 2014). Pharmacists, too, can prescribe and dispense naloxone, by virtue of California Assembly Bill AB1535 (2015) after undergoing brief training (California Legislative Information, 2015). There is, however, current reluctance in the county on the part of the pharmacists, to do so without a prescription from the physician.

Some individuals with criminal justice involvement or illicit drug use may hesitate to render aid and call 911, out of fear of prosecution (Cofflin & Sullivan, 2013). Good Samaritan Laws, California Assembly Bill AB472 (2012), protect citizens who administer naloxone and seek medical help from civil and criminal liabilities for minor drug and alcohol violations. These laws further support the success of naloxone programs (California Legislative Information, 2012).

Methodology

A fishbone, or cause and effect, diagram was created to illustrate the multifactorial nature of fatal opioid overdose in Lake County. Refer to Appendix A for the cause- and -effect diagram. An analysis was also performed to identify strengths, weaknesses, opportunities, and threats (SWOT) to the CNL student project. Refer to Appendix B for the SWOT analysis. The theoretical framework used in the CNL project was the Institute of Healthcare Improvement's

(IHI) *Model for Improvement*, which focuses on aims, measures, and appropriate changes (Institute for Healthcare Improvement, 2016). The actions taken to implement the project mirror those of the IHI's Plan-Do-Study-Act (PDSA) cycles (IHI, 2016). The planning stage involved numerous meetings with stakeholders, multiple agencies, and Partnership HealthPlan of California, and vast research. The implementation segment of the PDSA cycle involved the arrangement of trainings with providers interested in prescribing intranasal naloxone to patients, and interested in receiving the training for clinical and supportive staff. This entailed collaborating with multiple health organizations across multiple administrative strata, such as the local county Alcohol and Other Drugs Services, Adventist Health, Sutter Health, Mendocino Community Health, Lake County Tribal Health Consortium, and local private clinics, such as Lucerne Community Clinic.

The initial phase was implemented at Lucerne Community Clinic. The second phase was implemented at three clinic sites in Lakeport, Ukiah, and Willits, California within the Mendocino Community Health Clinic network. During the second phase, the CNL student also recorded an intranasal naloxone education webinar for Partnership HealthPlan of California, which has been posted on their *Managing Pain Safely* website. The third phase was implemented at the Lake County Tribal Health Consortium and the Lake County Public Health Department, and a treatment and support resource directory was developed. Refer to Appendix C for a diagram of the PDSA cycles.

The specific actions entailed the provision of training, demonstration, and patient education material for providers and their staff for educating their clients, families, peers, and members of their social network on the administration of naloxone. During meetings at the clinic or provider office, the CNL student provided a power-point presentation of intranasal naloxone

to providers and their supportive staff, demonstrated assembly and simulated administration, and provided educational materials to be used by providers and patients and their families and peers. The study phase of the PDSA consisted of reviewing the questions and comments posed by the audience or noted problems, and adjusting future presentations in the next PDSA cycle. The culminating study phase consisted of evaluating the outcome results.

The goal of the project was to create educational material for the administration of intranasal naloxone for healthcare providers to provide to their patients who are prescribed or suspected of illicit use of opioids, or to their families, friends, peer, or members of their social network. Initially, the CNL student concentrated on providing a power-point presentation, intranasal naloxone administration demonstration and educational materials to a local community clinic, as part of a pilot project lead by Partnership HealthPlan of California. Although the number of actual prescriptions at the community clinic within the first month was low, presumably due to effective opioid dose control and Suboxone treatment, the risk for overdose for this population remained high. As the initiative advanced, the need for additional clinics and providers to provide intranasal naloxone ensued, and the parameters of the project expanded.

A state grant for another formulation of intranasal naloxone, Narcan Nasal Spray, from a different manufacturer, Adapt Pharma, had been approved. The medication had been delivered and the CNL student met with the AODS coordinator to assist in providing educational materials and demonstration for this product. This particular product is accompanied by pre-tooled educational videos and provider information. However, it was determined that AODS required greater infrastructure to legally dispense naloxone in the community, such as a standing order and recognition as an overdose education and naloxone distribution program. The CNL student planned to meet with AODS, Partnership HealthPlan, and the Safe Rx Lake County Coalition on

August 15, 2016 to plan future actions. The CNL student planned to continue the PDSA cycles with other clinics, and the community.

Timeline

The timeline of the implementation of the CNL student project can be viewed in Appendix E. The implementation began with vast research, collaboration with Partnership HealthPlan of California, and preparation and development of an educational power-point presentation and demonstration of intranasal naloxone. International Medication Systems, Ltd., was contacted to obtain naloxone demonstration kits. The presentation was then delivered, along with a demonstration of intranasal naloxone administration and educational materials, at the Lucerne Community Clinic in April 2016. Continued research and efforts to spread the improvement project continued through May and June 2016, as well as attendance of collaborative meetings within various facets of the county initiative. The CNL student met with the Safe Rx Lake County Treatment and Support Resource Action Team, and assisted in developing a resource guide for substance abuse treatment and support services. During this period, the CNL student also attended the Safe Rx Lake County Provider and Law Enforcement Action Team meeting in which new county practice guidelines were reviewed, along with a discussion of intranasal naloxone dissemination and education. During June, various clinics were contacted to assess their interest in prescribing intranasal naloxone through Partnership HealthPlan of California with subsequent education, with efforts continued in July. The CNL student also recorded a webinar on intranasal naloxone administration with Partnership HealthPlan of California, which was posted on their website, *Managing Pain Safely* (Partnership HealthPlan of California, 2016). In July, the CNL student delivered the education to an additional three interested clinics from Mendocino Community Health Clinics in Lakeport,

Ukiah, and Willits, California. During July, the CNL student met with the Lake County Alcohol and Other Drugs Services (AODS) Substance Abuse Coordinator to discuss dissemination tactics for the Narcan Nasal Spray from Adapt Pharma acquired through a state grant. Two hundred complete kits valued at $30, 000 could be disseminated in the community. However, upon review, additional infrastructure measures, such as a standing order and registration as an opioid education and naloxone distribution program, were warranted. A follow-up meeting with Partnership HealthPlan of California, the Safe Rx Lake County Coalition, AODS, and the CNL student will ensue on August 15, 2016 to explore these issues. Another educational opportunity arose to provide the education to Lake County Tribal Health Consortium, and to the public health nurses at Lake County Public Health Department on August 3, 2016.

Expected Results

To evaluate the effectiveness of the project, the collected data focused on the number of fatal drug overdoses, extracted from statistics from the California Department of Public Health, although this generally lags by several years. Other relevant data included the number of opioid-related emergency department visits, and the number of opioid–related hospitalizations, which is also delayed. A real-time measure is the number of naloxone prescriptions and recipient trainings dispensed, which was requested of participating agencies. An important evaluation measure is the county coroner reports of death due to opioid overdose. Upon review of the county coroner death reports from January 2016 to August 2016, two of the six drug-related deaths were affiliated with opioids (Lake County Sheriff's Department, 2016). According to Dr. Karen Tait, Lake County Health Officer, 26 drug-related deaths were attributed to opioids in 2015 (K. Tait, personal communication, August 1, 2016). The ideal of reaching the desired 100 % reduction in

fatal opioid overdose is naturally desired, but one saved life is worth the project effort. A goal of 25 % reduction in opioid overdoses would be anticipated in the first six months, followed by 50 % in nine months, and 75 % in 12 months, or April 2017. This would compute to a total of 20 deaths at six months, 13 deaths at nine months, and six deaths at 12 months, or a reduction of six deaths at six months, 13 deaths at nine months, and 20 deaths at 12 months.

Overall increased awareness of the tragic risks of opioid overdose, substance use disorders, and harm reduction were also expected achievements. In the 2015 *Memorandum to Federal Departments and Agencies,* President Obama aimed to double the number of providers that prescribe naloxone (The White House, 2015). With international, national, state, local, and Clinical Nurse Leader efforts, overall rates of fatal opioid overdose are expected to fall, but it will take some time to realize the results.

Nursing Relevance

The relevance to nursing is the value of improving patient outcomes through system analysis, risk anticipation, health outcomes management, and education. The CNL can raise awareness of substance use disorders, treatment and support resources, and the need for anticipated measures to reverse opioid overdose and prevent unnecessary patient death. Through the CNL competencies, the CNL can help the local and broader global community in reducing the number of deaths due to opioid misuse. The project demonstrated that nurses can lead in their communities and positively impact the health of populations.

“Despite its potential to safely, rapidly, and completely reverse an opioid overdose, the public health impact of this medication has not yet reached its full potential” (Compton, Volkow, Throckmorton, and Lurie, 2013, p. 65). In its resolution, the American Medical Association supports the use of nasal naloxone by trained non-medical personnel, advocates for routine

education of all patients receiving prescription opioids, those at risk, and their families and peers, and advocates for the routine prescription of nasal naloxone to all patients at risk (Drug Policy Alliance, 2016). The Centers for Disease Control and Prevention (2016) advocates for public health departments implementing community-based opioid drug overdose prevention programs, including training, and naloxone provision to potential overdose witnesses to mitigate the opioid crisis (CDC, 2012). According to Doe-Simkins, Walley, Epstein, and Moyer (2009), overdose prevention programs that include the distribution of intranasal naloxone by nonmedical personnel are feasible public health interventions for city public health departments

The monumental passage of Senate Bill SB 524, the *Comprehensive Addiction and Recovery Act of 2016* calls for robust efforts to mitigate the opioid issue, including greater access to naloxone, approving $181 million in funding for states to combat opioid addiction through multiple efforts. States will no longer be dependent on their budgets alone to provide basic public health education and supplies such as naloxone (Community Anti-Drug Coalitions of America, 2016).

As members of the most trusted profession, nurses are in a position to educate patients, and influence laypersons and boost their confidence in administering naloxone. Lead researcher of the San Francisco Public Health Department, Dr. Phillip Cofflin (2016), stated in the recent publication in the *Annals of Internal Medicine*, patients who legally use opioids in their pain management may not realize they are at risk of an overdose. According to the National Development and Research Institute (2015), legal opioid users tend to be “wholly misinformed” about the dangers of overdose, and are not even aware of the signs of overdose. CNLs can provide the necessary education to prevent accidental overdoses to this population. According to Dr. Cofflin, "we're prescribing naloxone for risky drugs, not risky patients” (Neergaard, 2016. p.

1). Dr. Cofflin commented that trainings also offer an opportunity to provide substance use education to minimize stigma and expand the impact of trainings beyond the administration of naloxone (Cofflin et al., 2016).

Reducing disparity and the overall stigma of substance use disorder is also a benefit of this CNL student project. Lake County's population of 65,00 includes 80% White, 17 % Hispanic, 3.2 % African American, American Indians 1.1%, and Asian 0.2 % within a 1,300 square miles radius. The per capita income is $21, 000, and 24.3% live in poverty (CityData.com, 2013). Hispanics and American Indian groups have a higher growth rate of non-medical usage of opioids before the age of 12 as compared to the national rate of 4.2 %; 4.3 % and 6.9 %, respectively (Katzman et al., 2016). According to the Indian Health Services, by 2014, 130 died daily from opioid overdoses in Indian Country (Karol, 2016). By addressing disparity with cultural sensitivity, the CNL can also help reach vulnerable populations in the community.

In a recent observational study published in the *Annals of Internal Medicine,* Cofflin et al. (2016) concluded that naloxone can be successfully co-prescribed in the primary care setting, and is independently associated with a reduction in opioid-related emergency department visits. The study also suggests that training in overdose education opens up dialogue with patients and their families, and may have an effect on patient's substance use behavior.

Evaluation

It is too early to realize the results of the CNL project, and data from reporting agencies such as the California Department of Public Health, lags by several years. The number of fatal opioid overdoses would be the best metric utilized to evaluate effectiveness. In addition, real - time data include the number of naloxone prescriptions and related education. Since the project

initiation, Lucerne Community Clinic has prescribed eight naloxone prescriptions without a reported reversal. Mendocino Community Health Clinic and Lake County Tribal Health Consortium have not yet initiated naloxone prescriptions. The estimated number of healthcare staff members who received intranasal naloxone education is 100.

"Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent. This goal is what matters for patients and unites the interests of all actors in the system" (Porter, 2010, p. 2477). Improving value benefits all involved parties, the healthcare system, and community.

The CNL student project adds value to our community as it can potentially reverse opioid overdoses, and directly save lives. At the point when an individual has stopped breathing during an opioid overdose, he will ultimately die without intervention. With a simple measure such as intranasal naloxone, whether or not accompanied by rescue breathing or cardio-pulmonary resuscitation, the individual may resume breathing and live. Increased access to naloxone potentially reaches people of all age groups, income brackets, ethnicity, education, and includes vulnerable populations such as people who use substances, people with HIV, low- income persons, older persons, disabled persons, minorities, children and youth, and pregnant women. The very essence of public health revolves around improving community and population health, and protecting vulnerable populations.

Unfortunately, the CNL student cannot continue the CNL project, due to the constraints of current employment. However, the project is sustainable. The educational materials have been created and can further be disseminated via electronic route, and the instructions for implementation have been provided. Partnership HealthPlan of California can continue with efforts to spread the change. At this point, the change is not ready to be entirely standardized, as

additional time to test the changes is needed as naloxone is prescribed in the community. However, standardization is anticipated, as naloxone is the standard of care for opioid overdose. It is now important to hold the gains made, maintain aims that were identified, and keep spreading the change to other sites. The components of sustainability include modification of the program after continued spread and analysis, affirmation of a champion (such as Partnership or Safe Rx Lake County), alignment with Partnership's or the Coalition's organizational mission to improve the health of its constituents, and increased perceived benefits of staff and clients through experience with the results of naloxone.

Additionally, support from stakeholders is expected to increase as the project's relevance spreads. The recent legislation to increase the capacity of Suboxone providers from the previous ceiling of 100 to 275 patients is promising in the continued mitigation of the opioid problem. *The Comprehensive Addiction and Recovery Act of 2016* (Community Anti-Drug Coalitions of America, 2016), is a monumental legislation that supports grant programs for the expansion of prevention, education, treatment, and recovery efforts. One of its many measures that include education about naloxone, is expanding its availability to law enforcement agencies and other first responders for opioid overdose reversal. Section 202 authorizes the Department of Health and Human Services to award grants to state, local, and tribal law enforcement agencies for training in the use of naloxone and for the purchase of naloxone. This CNL student project will expand and endure for the benefit of the county, and the greater community.

In 2014, the Harm Reduction Coalition determined that since 1996, it has provided naloxone kits to 152,283 laypersons with 26,463 overdose reported reversals. Providing opioid overdose training and naloxone kits to individuals in the patient's sphere can help reduce opioid overdose mortality (Wheeler, Jones, Gilbert, & Davidson, 2015).

Published material used in this project included educational handouts from the Harm Reduction Coalition, Prescribe to Prevent Project, the San Francisco Department of Public Health, and Partnership HealthPlan of California.

Conclusion

Lake County has already experienced tremendous success through the efforts of Annunziata van Voorene, MCSW, ACSW, and Any Positive Change, a local harm reduction organization. The organization reports 19 opioid reversals with intramuscular naloxone in 2015 alone (A. van Voorene, personal communication, July 31, 2016). It is not a matter of whether naloxone is effective, but how to increase its acceptance and the integration of the reality of substance use disorder and its treatment in Lake County. Through continued efforts of the Safe Rx Lake County Coalition, continued successes may break through the current barriers and bring realistic solutions to real issues. It has been a tremendously rewarding CNL student project, and will hopefully blossom to its true potential. There is nothing more precious than saving a life, even through simple measures. “We can do no great things; only small things with great love” - attributed to Mother Teresa (Mother Teresa of Calcutta.org, 2016).

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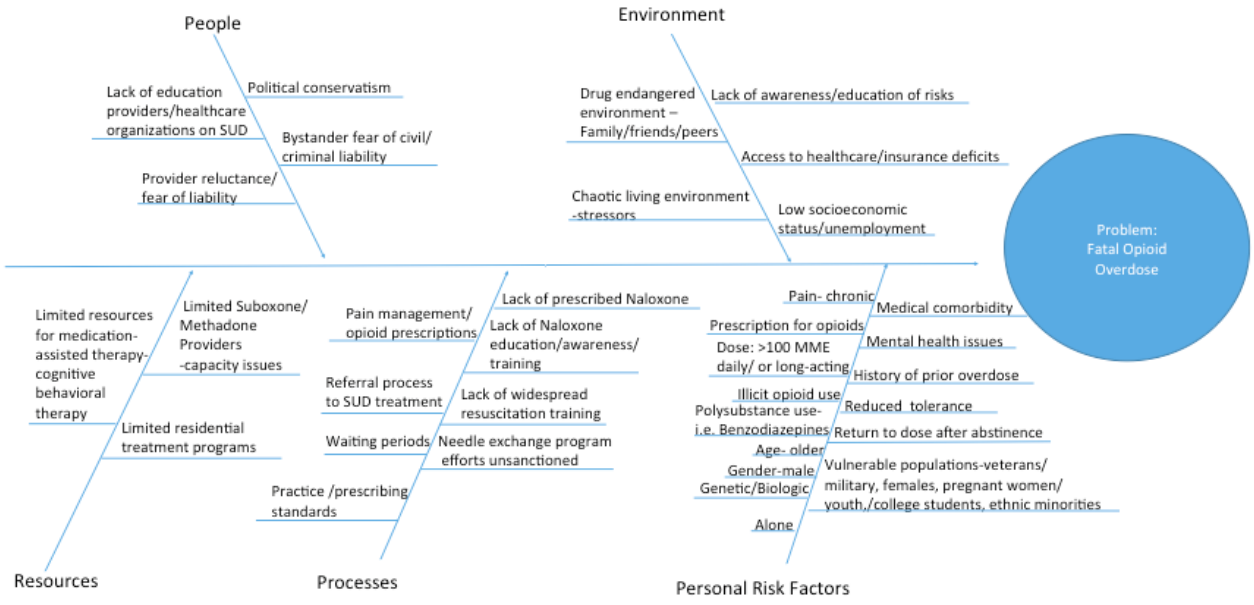
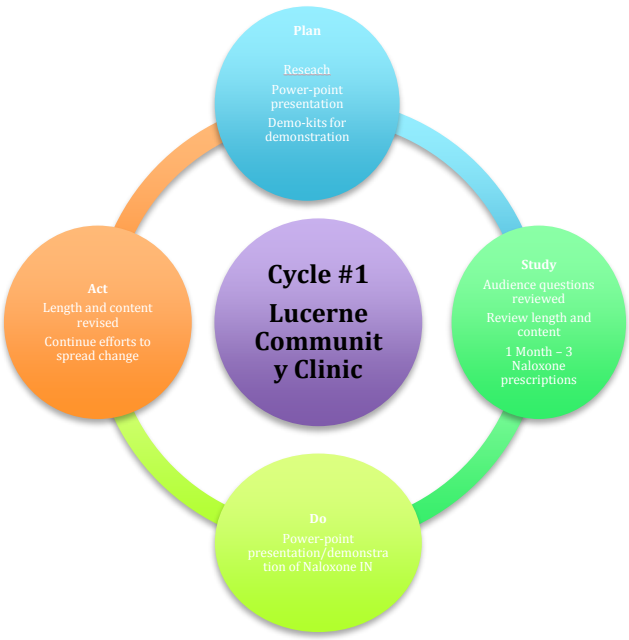
Appendix A

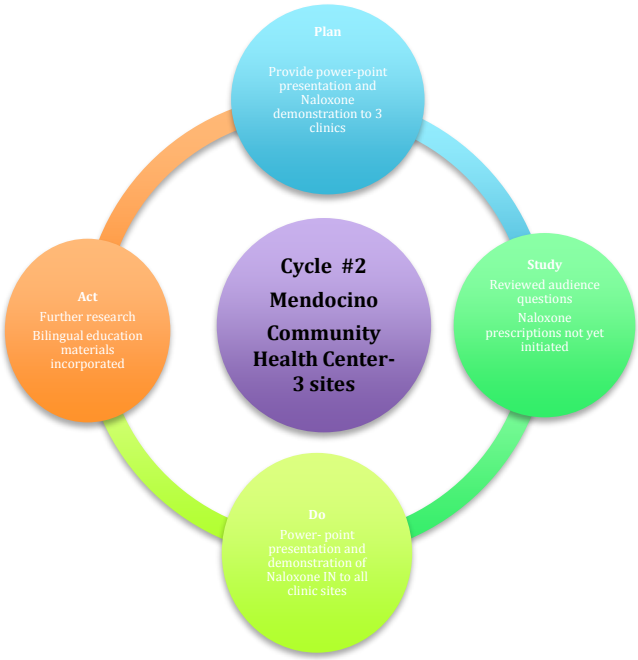
Fishbone Diagram



Appendix B
SWOT Analysis

Appendix C
PDSA Cycles





Appendix D
Process Map
Naloxone Prescription and Education

Appendix E

CNL Project Timeline

April 2016	May 2016	June 2016	July 2016	August 2016
Research, planning with Partnership HealthPlan, delivery of education to Lucerne Community Clinic	Research	Research	Research	
Safe Rx meetings	Safe Rx meetings	Safe Rx meetings		Safe Rx meeting
		Outreach to additional community clinics		
		Recording of webinar with Partnership HealthPlan of California		
		Medi-cal 1115 Waiver stakeholder meetings	Set up meetings with additional clinics	
			Delivery of education to additional clinics- Mendocino Community Health Clinics – 3 sites	Delivery of education to Lake County Tribal Health Consortium
			Meet with AODS to distribute Naloxone/educate	Meet with AODs and Partnership
			Development of Treatment and Support Resource Guide	Completion of resource guide- Safe Rx Treatment and Resource Action Team Meeting
				Evaluation of project