4-26-2018

A Multi-faceted Intervention to Improve Naloxone Co-Prescription Rates Among Primary Care Providers

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A MULTI-FACETED INTERVENTION TO IMPROVE NALOXONE CO-PRESCRIPTION RATES AMONG PRIMARY CARE PROVIDERS

by

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EVIDENCE-BASED PRACTICE PROJECT REPORT

Submitted to the College of Nursing and Health Professions

of Valparaiso University,

Valparaiso, Indiana

in partial fulfillment of the requirements

For the degree of

DOCTOR OF NURSING PRACTICE

2018

Jolane S. Conklin 4/26/18
Student Date

Advisor 4/26/18
Date

DEDICATION

This project is dedicated to family: my husband, Dan; my children, Zack and Kayla; and my parents, Roy and Alana. The journey to get to this point has been arduous, and each one of you has made sacrifices to ensure I accomplished my goals. Thank you for sharing the burden and supporting me during my educational endeavors – we made it happen!

"*Dripping water hollows out stone, not through force but through persistence. "*

- Ovid

ACKNOWLEDGMENTS

I would like to acknowledge and thank Dr. Julie Koch for her unwavering support, patience, and wisdom throughout the course of this project. Without her, I'm sure this project would have "derailed" several times. Her commitment to her students is exemplary and does not go unnoticed.

I would also like to thank Nicole Edson, who began her nursing career with me many years ago and has found herself as my clinical manager. With her support, along with that of our health director (Rosalind Johnston), and our fellow colleagues, this project and my educational goals were seen to fruition. It truly would not have been possible without each of you.

PREFACE

"*We have the self-awareness to be honest with ourselves to say, 'We have been part of the problem, and we have to be a part of the solution."*

-Jonathan Brown, CEO, Indian Stream Health Center

Regarding opioid prescribing and efforts to combat the opioid epidemic

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ABSTRACT

A Multi-Faceted Intervention to Improve Naloxone Co-Prescription Rates Among Primary Care Providers

Jolane S. Conklin, MSN, APRN, FNP-C, ADS

It is estimated that 91 Americans die every day due to opioid overdoses, with at least half of those overdoses involving an opioid prescription (CDC, 2016d). To address this issue, the U.S. Department of Health and Human Services (USDHHS) has initiated an opioid initiative, and the Centers for Disease Control and Prevention (CDC) has released a clinical guideline, both of which include a focus on increasing use of naloxone. Despite these recommendations, providers often fail to co-prescribe naloxone to patients at increased risk of opioid overdose. The purpose of this evidence-based practice (EBP) project was to evaluate the effect of a multi-faceted intervention (including the use of academic detailing sessions, provider reminders, and a clinical champion) to increase naloxone co-prescription rates within an Indian Health Services Tribal Health Department in the Midwestern United States. The Iowa Model of Evidence-based Practice and Kotter's Change Model were used to guide this project, which was supported by 10 pieces of evidence obtained through a systematic search of the literature. Retrospective chart audits were conducted on patients receiving opioid prescriptions of 30 days or greater during the 12-week intervention period and the same time period in 2016. Descriptive statistics were used to compare the frequency of naloxone co-prescriptions pre-intervention (0 of 48 eligible patients; 0%) and post-intervention (10 of 40 eligible patients; 25%). The 25-percentage point increase in co-prescribing was consistent with the supportive evidence and reflected a statistically significant association between the multi-faceted intervention and naloxone co-prescription distribution ($X^2 = 13.538$, $p < .001$). Of the secondary variables of interest, only patient gender was associated with naloxone to a statistically significant level. Results of this EBP project lend support to the recommendation of use of this multifaceted approach as a strategy to increase naloxone co-prescription rates among primary care providers.

CHAPTER 1

INTRODUCTION

Background

The first reference to opioids in our society has been reported to date back to Sumerian culture more than 6000 years ago, when it was noted that cultivation of poppy was the “plant of happiness” (Green, 2017). Throughout the course of history, opioids have taken many names, including laudanum that was used in North America and Europe until the start of the twentieth century (Green, 2017). By the year 1805, opioids began to be known by a name familiar to most in present day: morphine. It was at this point that the active component of opium was discovered and named Morpheus, in honor of the Greek god of dreams (Green, 2017). Now, opioids are present in many formulations and strengths due to advances in pharmaceutical synthetic manufacturing (see Table 1.1 *Common Opioids*).

Opioids affect the central nervous system by binding with mu receptors, which regulate pain and addiction centers within the brain. As the opioids bind to the receptors, physiological responses occur including pain relief, decreased respirations, mood changes, pupil constriction, decreased gastrointestinal tract activity, and stimulation of the receptors that control nausea and vomiting (Calas, Wilkin, & Oliphant, 2016). An overdose of opioids can lead to significant depression of the respiratory center, thus causing cessation of spontaneous respiration which leads to death.

It has been noted that those at higher risk for prescription opioid overdose may include those who are taking higher doses of opioids and those who misuse (skip doses on “good” pain days and double up doses on “bad” pain days), inject, or take in combination with other substances that cause respiratory depression (e.g., benzodiazepines or alcohol) (Calas et al., 2016; Dowell, Hagerich, & Chou, 2016; Duvivier et al., 2017). Additionally, those who have other co-morbidities (e.g., advanced age, depression, lung disease, or liver disease) and those

who have recently had a period of abstinence from opioid use stemming from recent incarceration or rehabilitation may also be at higher risk (Calas et al., 2016; Dowell et al., 2016; Duvivier et al., 2017). Individuals who have difficulty accessing care due to remote locations, lack of transportation, homelessness, or without access to phone services are also considered high risk for opioid overdose (Calas et al., 2016; Dowell et al., 2016; Duvivier et al., 2017).

Naloxone, a medication developed in 1971 as a prescription formulation, and until recently used primarily in hospital settings, is an opioid antagonist that works by binding with the mu receptors in the brain (Calas et al., 2016; Jacobs, 2016). In doing such, opioids are displaced from the mu receptors, thus reversing the effects of central nervous system depression, effectively reversing the physiological symptoms of an opioid overdose; but, naloxone has a half-life of only approximately 30 to 90 minutes, so as the effects wear off, opioids that remain circulating in the blood will again bind to the mu receptors (Calas et al., 2016). Although naloxone's short half-life only buys an opioid overdose victim time for further intervention, it does allow a window of opportunity to access higher level care services. Unique to naloxone, due to its mechanism of action, are no adverse effects to those individuals who would happen to receive a dose in the absence of a true opioid overdose situation (Calas et al., 2016; Duvivier et al., 2017). This potentially life-saving medication has been named as a component in various opioid initiatives, with a push to expand access of naloxone to lay-users who may be at risk for opioid overdose themselves or have known family and friends who may be at risk for opioid overdose (Calas et al., 2016; Centers for Disease Control and Prevention [CDC], 2016a; Duvivier et al., 2017; Mueller, Walley, Calcaterra, Glanz, & Binswanger, 2015).

Statement of the Problem

Data from the Literature Supporting Need for the Project

As unintended overdoses from opioid drugs continue to climb in the United States (U.S.), community members, health care professionals, and government agencies are searching intensely for solutions to combat the escalating epidemic. Those who suffer from addiction and

those that have the potential for overdose due to legally prescribed and obtained medications, as well as their families, are demanding that something be done.

The CDC (2016c) has reported that opioids were involved in 28,647 deaths (61% of all drug overdose deaths) in the U.S. in 2014 and that opioid overdoses have quadrupled since 1999. During this same timeframe, the number of prescriptions written for opioid medications also quadrupled, despite no increased reports of the level of pain in Americans (CDC, 2016c). Additionally, it is estimated that 91 people in the U.S. die every day due to opioid overdoses, with at least half of those overdoses involving an opioid prescription (CDC, 2016d). Furthermore, 1,000 people are treated every day in emergency departments across the country for conditions related to not using opioid prescriptions as directed (CDC, 2016c).

The State of Michigan saw a statistically significant increase in opioid death rates (13.3%) between 2014 and 2015 and had one of the highest overdose death rates in the nation: 20.4 per 100,000 population (CDC, 2016b). In 2015, drug overdose was the leading cause of injury death in Michigan, outpacing motor vehicle accidents, firearm discharge, and suicide (CDC, 2016d). Furthermore, not only has geographic focus been a concern, but so has the status of populations that historically have been known to be at higher risk: Native Americans. Drug-related deaths among Native American Indians and Alaskan Natives increased from 5 per 100,000 population between 1989-1991 to 22.7 per 100,000 population between 2007 and 2009 (Indian Health Services [IHS], 2015). The rate of drug-related deaths among Native Americans was almost twice that of all races in the same time frame (IHS, 2015), and in 2015, unintentional poisoning (drug overdose), was the leading cause of injury death among Native Americans in Michigan (CDC, 2016d).

Prescription opioids, while initially utilized for legitimate purposes, have been shown to lead to higher rates of opioid usage. A recent study found that even one prescription for opioids can be a trigger for abuse (Shah, Hayes, & Martin, 2017). Additionally, the risk of long term opioid use increases sharply when patients are given (a) a long-acting opioid, (b) a 10- to 30-

day supply, (c) more than 700 morphine milligrams cumulative dose, or (d) if they return for a second prescription or refill (Shah et al., 2017).

Recognizing that prescription opioid use has the potential for overdose and can be viewed as a gateway to illicit drug use, both of which have reached epidemic levels, in March 2015, the U.S. Department of Health and Human Services (USDHHS) released their opioid initiative, which highlights three priority areas of focus to address opioid drug and heroin overdose and death: (a) provide training and education resources, (b) increase use of naloxone, and (c) expand the use of medication-assisted treatment (USDHHS, 2016). Following that national initiative, in March 2016, the CDC released a clinical guideline for prescribing opioids for chronic pain to combat the present epidemic (CDC, 2016a). The guideline contains 12 recommendations regarding safe opioid prescribing. Among these, a focus on assessing risk and addressing harms of opioid use exists, namely offering co-prescriptions of naloxone when prescribing opioids to patients at increased risk of overdose (CDC, 2016a).

Data from the Clinical Agency Supporting Need for the Project

Located in Southwest Michigan, the clinical agency was part of a rural tribal health department located on reservation land and partially funded by Indian Health Services (IHS). Facilities also included two other satellite locations, one in an urban area and one located inside a nearby occupational setting. These clinics provide primary care services, dental services, social and behavioral health services, nutrition services, and community health services to all federally recognized tribal members, their family members, and the employees of the organization. As much as possible, all three clinics attempt to provide comparable services and abide by the same policies and procedures.

A recently completed health needs survey of area tribal members confirmed concerns previously identified by health care providers in the clinic:11.9% of tribal members surveyed reported using a prescription drug for experience (i.e., the feeling it caused or to get high), well above the 4.7% average lifetime prevalence of all races (Great Lakes Inter-Tribal Epidemiology

Center, 2016). Additionally, 3.97% of those surveyed reported misuse of prescription drugs within the past 30 days (Great Lakes Inter-Tribal Epidemiology Center, 2016). Furthermore, in reviewing adverse childhood experiences (ACEs), which have been shown to correlate with increased risk of opioid misuse, 24.23% of those surveyed reported living with a problem drinker or alcoholic before the participant turned 18, and 11.03% indicated the same circumstances regarding living with someone who abused illegal street drugs or prescription drugs (Great Lakes Inter-Tribal Epidemiology Center, 2016).

Both the current rates of misuse of prescription medications, as well as the reported level of ACEs, confirmed the significance of the problem to the tribal health department staff, specifically the prescribing providers. As a result, the prescribing providers felt compelled to review previous polices regarding controlled substance prescribing.

The clinical agency did have an existing policy that was developed prior to the employment of the current providers and clinical manager, but the policy did not address several present-day issues (i.e., recently published guidelines for safe prescribing, and inclusion of prescription monitoring database programs). Discussions at group meetings between the Doctor of Nursing Practice (DNP) student facilitator, the clinical manager, the medical director (an internal medicine physician), two physician assistants (PAs), and one staff physician echoed the same themes: (a) the current practice policy was outdated and needed to be reviewed, (b) safe opioid prescribing practices needed to be addressed systematically, and (c) providers did not feel well versed in current guidelines and were uncertain of how to adequately prevent opioid overdose.

During this same timeframe, the local tribal government that provided clinic oversight, expressed their concern in taking a proactive approach to opioid overdose prevention across all tribal lands and properties; the organization implemented a naloxone distribution policy for those at risk for overdose. The combination of provider discussions regarding outdated controlled substance policies, tribal governmental policy changes, and national opioid prescribing guideline

updates prompted Clinic X provider discussion regarding (a) the identification of those at risk for opioid overdose and (b) the ability and appropriateness of prescribing naloxone for overdose death prevention. The providers identified barriers to prescribing naloxone for current clinic patients: proper identification of appropriate candidates, unfamiliarity with current guideline recommendations of co-naloxone prescribing, patients not self-identifying as an overdose risk, and general lack of knowledge regarding the technicalities of writing a naloxone prescription (Clinic X Manager, personal communication, March 1, 2017). One provider anecdotally reported having written a naloxone prescription only once, at the request of the family, while the other providers reported having never written a naloxone prescription (Providers of Clinic X, personal communication, March 1, 2017). Despite the lone provider's indication of prescribing naloxone, evaluation of eligible patients between September 25, 2016 through December 15, 2016, demonstrated 48 patients receiving chronic opioids prescriptions of 30 days or greater; none of which received a naloxone co-prescription.

Purpose of the Evidence-Based Practice Project

Compelling Clinical Question

An agency and community-wide push to become proactive in opioid overdose prevention demonstrate the need for a time-efficient, evidence-based practice (EBP) project which would incorporate a thorough review of current practice standards and guidelines as well as aid in identifying barriers and implementing strategies that would help improve naloxone co-prescription rates among clinic patients who received chronic opioid prescriptions. Thus, the development of the compelling clinical inquiry arose: What are the best strategies for improving provider rates of naloxone co-prescriptions to those receiving chronic opioid medications in a primary care setting?

PICOT Question

Melnyk and Fineout-Overhold (2011) have noted that once there is awareness of a compelling clinical inquiry, then a clinical question can be developed. To guide the development

of this project and facilitate the procurement of the best available evidence, the PICOT (patient population, intervention of interest, comparison intervention or status, outcome and timeframe) format was used. Utilizing this PICOT format led to the development of the question for this project: (P) Among primary care providers in a tribal health clinic, (I) does the introduction of an evidence- based multi-faceted intervention (C) versus the current practice of no tool, (O) improve the co-prescription rates of naloxone to chronic opioid patients (T) within a 12- week period?

Significance of the EBP Project

The goal of this EBP project was to improve naloxone co-prescription rates among clinic providers for the purpose of taking a proactive approach to opioid overdose death prevention. With the release of CDC guidelines in early 2016, providers were given guidance on safe prescribing practices and recommendations which, in the midst of the opioid epidemic plaguing not only the United States, but the world, were desperately needed (Dowell et al., 2016). However, due to time gaps from publication to disseminating and implementing these guidelines fully into today's complicated primary care structure, the benchmark for the level of guideline adherence had not been established.

As the opioid overdose crisis continues to morph, primary care clinicians are poised in a pivotal juncture to both limit the opioids being prescribed and aid in the access to interventions in the event of accidental or intentional overdoses. There is significant literature that indicates primary care providers feel neither confident nor empowered to approach patients with the pretense to simply discuss potential adverse outcomes of opioid substances, much less feel comfortable to discuss naloxone co-prescriptions and actually dispense them (Binswanger et al., 2015; Kerensky & Walley, 2017; Mueller et al., 2015; Wilson, Rodriguez, Carrington, & Fagan, 2017). Although the opioid epidemic is far-reaching, and the answer does not lie with a single intervention, providers must exercise caution in regard to opioid prescribing and their duty, both ethically and legally, to prevent any unintended consequences. It is with that

intention, that this EBP project was developed…with the altruistic goal of preventing the loss of life by focusing on a single aspect of the battle: improvement of naloxone co-prescription rates in the primary care setting.

Table 1.1

Commonly Prescribed Opioids

Generic	Brand Name	Half-life (hours)
Buprenorphine	Buprenex, Butrans	24-60
Codeine	Capital/Codeine, Tylenol with Codeine #3, Tylenol with Codeine #4	4
Fentanyl	Abstral, Actiq, Duragesic, Fentora, Lazanda,Lonsys, Onsolis, Subsys	2-4
Hydrocodone	Lorcet, Lortab, Maxidone, Norco, Reprexain, Stagesic, Verdrocet, Vicodin, Vicoprofen, Xodol, Xylon, Zydonelbudone	3-5
Hydromorphone	Dilaudid	2-3
Meperidine	Demerol, Meperitab	2.5-4
Methadone	Dolophine, Methadose	8-59
Morphine	Astramorph, Duraporph, Infumorph, MSContin	2-4
Oxycodone	Endocet, Endodan, Magnacet, Percocet, Percodan, Primlev, Roxicet, Roxicodone	2-4
Oxymorphone	Opana	7-9

Note: Adapted from Epocrates Plus, (2017).

CHAPTER 2

THEORETICAL FRAMEWORK, EBP MODEL, AND REVIEW OF LITERATURE

Theoretical Framework

Melnyk and Fineout-Overholt (2015) defined evidence-based practice (EBP) as "a paradigm and lifelong problem-solving approach to clinical decision making that involves the conscientious use of the best available evidence with one's own clinical expertise and patient values and preferences to improve outcomes for individuals, groups, communities and systems" (p. 604). Implementing EBP into clinical practice can be challenging due any number of barriers hindering the process. Therefore, utilizing a model to systematically guide the implementation of EBP can be beneficial (Melnyk & Fineout-Overholt, 2015).

To facilitate the translation of evidence into clinical practice within this DNP project, the Iowa Model of Evidence-Based practice was incorporated. The DNP student facilitator used the Iowa Model to integrate current high-quality evidence into clinical practice, with consideration of the targeted population's clinical status and circumstances, their preferences and expertise, available resources, and current beliefs. Aware of the importance for a systematic approach to aid in successful implementation, the DNP student facilitator also incorporated Kotter's Model of Change as the theoretical framework to guide the change processes that were intended to increase naloxone co-prescription rates among primary care providers in the project facility.

Overview of Theoretical Framework

John Kotter's Model of Change, although not widely utilized in nursing until more recent years, has provided a model to effectively introduce change into an organizational environment (Schmidt & Brown, 2015). Kotter proposed an 8-step change model which has been described as a "top down" transformation process, an effective strategy to implement changes in phases while encompassing strategies to overcome barriers and challenges (Schmidt & Brown, 2015). This model was determined to be well suited to this DNP project due to its simplicity and focus

on changing group behavior. The eight steps include (a) establishing a sense of urgency, (b) creating a powerful guiding coalition, (c) developing a vision, (d) communicating the vision, (e) empowering others to act on the vision, (f) planning for and create short-term wins, and (g) institutionalizing new approaches (Borkowski, 2016).

Application of Theoretical Framework to EBP Project

The first step of Kotter's 8-step process involves creating a sense of urgency (Borkowski, 2016). Within this DNP project, a sense of urgency was established as tribal leaders recognized a growing problem with opioid overdoses. A recent survey among the tribal members had highlighted that prescription misuse was occurring at much higher rates than presumed (Great Lakes Inter-Tribal Epidemiology Center, 2016). It became evident that it was only a matter of time before an unintended overdose occurred within the clinic population. Clinic X's health care providers were invited to attend symposiums with local, regional, and national leaders that addressed the significance of rising rates of overdoses within the community and further supported the need for an intervention to urgently address the problem. Although a policy that was developed solely by the clinical manager had been developed, the providers had voiced concerns that, to prevent unintentional harm and ensure they were incorporating current safety and risk mitigation strategies, they needed to have access to the most current opioid prescribing guidelines.

The second step of Kotter's process involves creating a coalition (Schmidt & Brown, 2015). This task was easily completed as various stakeholders including governmental leaders, tribal police, health department administration, and prescribing providers all recognized the significance of the problem. A controlled substance (CS) task force, comprised of the clinical manager and all five providers, was formed to review, and address any gaps within current practice standards and policies.

The third step within Kotter's process involves developing a vision (Schmidt & Brown, 2015). The singular vision of the CS task force was to promote the safe prescribing of high-risk

substances in order to prevent unintentional consequences. However, it was understood that to accomplish this greater vision, the task had to be undertaken in a systematic fashion: reviewing current practices, identifying gaps and variances from recent practice change recommendations, and implementing practice changes to address identified issues.

These previous steps led to the fourth step, communicating the vision (Schmidt & Brown, 2015). Although key stakeholders all recognized the sense of urgency regarding this matter, several felt that available information was not only confusing, but was also, at times, conflicting. The clinical manager and providers were supportive in allowing the DNP student facilitator to take the lead on this task force, finding relevant information and communicating to appropriate stakeholders, both within the health department and throughout the tribal government of the DNP project facility. Regular communication throughout the gap analysis, evidence search, and policy development was essential to maintaining the vision.

Establishing urgency, creating a coalition, developing a vision, and communicating that vision, while being the bulk of the process, do not result in practice and organizational changes. The fifth step in the 8-step process is actually the beginning of intended changes (Schmidt & Brown, 2015). During the fifth stage, empowering others to act on the vision becomes imperative for organizational change (Borkowski, 2016). The ability to remove barriers to proceed with change, as well as use creative thinking and problem solving, becomes imminent to the success of EBP implementation. Within this DNP project, utilization of the first four steps provided a foundation which successfully empowered others and ultimately garnered Clinic X's administrative support to pursue practice changes. Key stakeholders' attendance to the symposiums prompted non-clinical administrative personnel as well as clinical personnel to recognize the magnitude and urgency of addressing this problem. Perceived barriers addressed by staff included technical and administrative barriers related to the current EHR, lack of understanding as to how and when the current policies were developed, fear of creating

a sense of mistrust or insulting current patient populations with potential misplaced stigmas, and a general lack of knowledge regarding current recommended guidelines.

Kotter's sixth step involves planning for and creating short-term wins (Borkowski, 2016). This was achieved through regular reporting by the DNP student facilitator of status and naloxone distribution updates throughout the implementation stage. Providers and the clinical manager expressed a sense of empowerment and satisfaction towards combating the opioid epidemic in the project facility. The sense of accomplishment of contributing to the solution (overdose prevention) rather than contributing to the problem (opioid misuse and overdose) was crucial in maintaining the enthusiasm that would anchor practice changes.

The seventh step in Kotter's change model, consolidating improvements and producing more change (Schmidt & Brown, 2015), is the last step prior to institutionalizing changes. The seventh step, while sequential in the process, occurred concurrently with step six during this DNP project. Small wins in the sixth step fueled motivation to continue to examine other process improvements that could be implemented to support the vision created in step two of the change process.

The eighth and final step in Kotter's change model involves institutionalizing new approaches (Borkowski, 2016). This step is crucial in the process. Without it, practice changes may not be anchored, providers may become unmotivated or lackadaisical; therefore, practice improvements have the potential to return to previous status. To mitigate this potential pitfall, communication and updates were provided at monthly provider meetings and shared periodically at monthly all-staff meetings. Staff who may not have been directly involved in the task force, due to lack of prescribing privileges, were also included to lessen stigma surrounding overdose education and naloxone distribution (OEND) and to provide prescribing providers support in DNP project interventions. To further anchor change, plans were made for the DNP student facilitator to continue to act as the clinical champion after the project intervention period ended. The clinical manager will also remain involved and will be responsible for the

procurement of additional naloxone stock. Updates and necessary modifications will continue to be discussed at monthly provider meetings.

Strengths and Limitations of Theoretical Framework for EBP Project

While Kotter's model has identified creating a sense of urgency as the impetus for change, individuals have often been motivated by an emotional trigger to act. Although the Kotter model has been identified as a team-based model, individuals may be at different levels of priority in terms of urgency, thus creating an imbalance of motivation. However, if individuals have experienced a situation which created an emotional investment in the necessitated change, that experience could spur them to action at a faster pace (Schmidt & Brown, 2015). Within Clinic X, although the DNP student project facilitator was the first to broach the topic of overdose prevention with the other providers, they quickly became emotionally motivated after attending the aforementioned symposia and grasping the breadth of the problem at hand.

Also, as Kotter's model has been identified as a team-based model, it also became evident that it was initially developed to be delivered from a management position (Schmidt & Brown, 2015). Yet, having the right mix of team members has been imperative to success, as a team that is composed of a higher ratio of management staff might foster a sense of intimidation. It has also been deemed important to maintain a balanced and well-round coalition of stakeholders, since a variety of experiences and opinions can provide an environment to create and sustain practice changes (Schmidt & Brown, 2015).

A significant limitation of applying Kotter's change model to this DNP project was the time constraints in which to fully deploy and anchor change within the organization. Since the DNP project was conducted in a relatively brief window of time, it was difficult to spend an ample amount of time on each sequential step. The limited time for implementation had the potential, for those who may have been faced with a heavier workload than usual to implement project driven practice changes, to develop a sense of burden, rather than empowerment.

Therefore, it became essential to pay close attention to step six, creating short term wins (to acknowledge their successes) to continue to propel change.

Evidence-based Practice Model

Melnyk and Fineout-Overholt (2015) stated that “It is not enough to have knowledge of the best evidence to guide clinical practice; that knowledge must be translated into clinical practice to improve patient care and outcomes.” (p. 202). While many health care providers have been highly motivated to integrate EBP into their clinical routines, the processes may be fraught with organizational obstacles. Incorporating a systematic process model to guide the implementation of EBP can be beneficial to anticipate and overcome these barriers.

Overview of EBP Model

The Iowa Model of Evidence-Based Practice to Promote Quality Care has been used successfully within hospitals and other organizations to guide implementation of EBP (Melnyk & Fineout-Overholt, 2015). This process model was originally developed in 1994 by M. Titler and was based on her experiences (Melnyk & Fineout-Overholt, 2015). Based on feedback from its users, the model has undergone revisions, indicating that as our knowledge fund of implementing EBP has expanded, thus too must the model change to incorporate our improved utilization (Titler et al., 2001). The revised model included new terminology and feedback loops, addressed changes in the health care market, and supported the use of other types of evidence when research findings were unavailable to guide practice (Titler et al., 2001).

The first step of the Iowa Model is to identify a problem focus or knowledge focus trigger where an EBP change may be warranted (Melnyk & Fineout-Overholt, 2015). The next step in the process is to determine if the problem is identified as a priority for the organization. This an important step in the process because identifying a problem as a priority to the organization will help garner support to complete the EBP project (Melnyk & Fineout-Overholt, 2015). The following step includes assembling a team of stakeholders which will help to develop, implement, and evaluate practice change (Melnyk & Fineout-Overholt, 2015). Once

the team is assembled, they will need to evaluate and synthesize available literature. At this junction, a decision point is encountered. If it is determined that there is not enough literature available, the team may decide to conduct the needed research themselves or base practice on other types of research such as case reports, expert opinions, scientific principles, or theories. Otherwise, if it is determined that there is enough available literature to proceed, the team will conduct a pilot change within the practice setting. At the conclusion of the pilot, the team will evaluate if the change was appropriate to be adopted into practice or if additional changes need to be made. If it is appropriate, the practice change will be implemented, and the results disseminated (Melnyk & Fineout-Overholt, 2015).

Application of EBP Model to EBP Project

The Iowa Model was chosen for this project because it provided an organized team-based approach to implementing evidence-based practice changes. Initially, a problem-focused trigger was identified: co-prescribing of naloxone was identified as a risk mitigation strategy in recent guideline updates but was not actively being done by prescribing providers within the DNP project facility (CDC, 2016a). It was determined that, due to recent heightened awareness of potential overdose risks within the community, this problem was indeed a priority. As indicated by the step-wise approach of the Iowa Model, a team was assembled to develop, implement, and evaluate an EBP change. The team was comprised of several multi-disciplinary members, including the clinical manager, the DNP student facilitator, and the prescribing providers (two PAs and two physicians). The PICOT question was formed, and a thorough literature search was conducted.

After the literature search was conducted, relevant findings were appraised and synthesized to identify the current best practice to improve provider co-prescriptions rates of naloxone. The pilot intervention change in practice was identified and a detailed plan of the intervention and evaluation strategies was submitted to Valparaiso University's institutional review board (IRB) for approval. As the project facility did not have a formal IRB, team

members reviewed the proposed intervention for any concerns during a regularly scheduled meeting. After all approvals were obtained, the project intervention was implemented into a pilot practice change. Finally, the project intervention was reviewed at the completion of the pilot period and results were analyzed, reviewed, discussed, and anchored into a practice change. Ongoing monitoring and analysis of the current EBP literature and intervention continue to ensure the intervention remains relevant and appropriate.

Strengths and Limitations of EBP Model for EBP Project

The Iowa Model possessed several strengths to guide this project. First, although developed by members of the nursing profession, it provided a simplified approach that has been easily understood by a variety of members within a multi-disciplinary team (Melnyk & Fineout-Overholt, 2015). Second, the Iowa Model provided a systematic, step-wise approach with key decision points on whether to proceed or return to previous steps, thus ensuring best methods were utilized throughout the process. Finally, although this EBP project was led by the DNP student facilitator, the Iowa Model supported a process which incorporated team members to be actively involved, which improved stakeholders' investment within the intervention.

A limitation of utilizing the Iowa Model to guide this EBP project would be the time constraints of the continued process for ongoing analysis and implementation. As this project intervention was conducted on a timeline directed by the educational partnership, there was no opportunity to continue with appropriate revisions to the intervention or further analysis of those revisions. Furthermore, the model did not provide guidance to the team through the data collection and analysis component, which limits its applicability for disseminating project findings to other practitioners who may want to replicate the project themselves. Specific input regarding analysis and data collection could be beneficial for future revisions of the model and applicability to EBP projects.

Literature Search

Sources Examined for Relevant Evidence

An extensive literature search was conducted using multiple database sources including CINAHL, PsychINFO, Joanna Briggs Institute, Cochrane Library, MEDLINE (via EBSCO), ProQuest, and PsychArticles. Due to the rapidly changing literature available regarding this topic, an extensive hand search was also completed in an effort to obtain all current relevant research available. A variety of keywords and medical subject headings (MeSH) were trialed during this search. The final set of terms utilized during the literature search included "naloxone AND prescri* AND opioid* OR opiate* AND primary OR pharm*." A complete list of the search terms and number results found in each database can be found in Table 2.1.

Inclusion criteria for the literature search encompassed a publication date between 2015 and 2017, English language, scholarly or academic journals, and peer-reviewed journals. The narrow, recent publication window was selected since the CDC opioid prescribing guideline (CDC, 2016a), which had been adopted by most, if not all major organizations was introduced in March 2016, thus making many previous studies obsolete or clinically irrelevant. Since the CDC's guideline was particularly relevant to this project, the literature search focused on evidence that was published near or after the time of guideline release.

The literature search yielded 259 articles, of which 65 were duplicates. A review of titles and abstracts resulted in 36 articles being deemed worthy of further review based on inclusion criteria. After reviewing the 36 articles, the DNP student facilitator selected a total of eight articles based on level of evidence and quality of evidence. Additional hand searching resulted in two other articles being included within the final evidence table (Table 2.2).

Articles were included if they pertained to prescribing providers, were in primary care or outpatient clinic settings and had interventions related to naloxone co-prescribing rates. Exclusion criteria included evidence that specifically pertained to (a) hospital settings, (b) community-based distribution programs, (c) emergency medical services naloxone

administration, (d) police naloxone administration, and (e) oncology diagnoses. Evidence was also excluded if the intervention focused only on patient populations, rather than health care providers, or if pregnancy was involved. Articles that included use of pharmacists or pharmacy-based distribution were evaluated individually for relevance and considered for inclusion if they utilized interventions that could either be incorporated into a primary care setting or if they utilized interventions to improve naloxone co-prescribing rates.

Table 2.1

LITERATURE SEARCH RESULTS

DATABASE	SEARCH TERMS	LIMITERS	ARTICLES YIELDED	DUPLICATES	ABSTRACTS RIVEWED	ARTICLES USED
CINAHL	naloxone AND prescri* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, English, Peer-Reviewed	30	0	11	2
PsychINFO	naloxone AND prescri* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, English, Peer-Reviewed	43	9	11	0
Joanna Briggs Institute	naloxone	2015-2017	4	0	0	0
Cochrane	naloxone AND prescri* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, Cochrane Reviews	5	0	0	0
MEDLINE (via EBSCO)	naloxone AND prescri* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, English, Peer-Reviewed	102	47	12	6
ProQuest	naloxone AND prescri* AND opioid* OR opiate* AND primary OR pharm* “naloxone” in abstract	2015-2017, English, Peer-Reviewed	39	9	2	0
PsychArticles	naloxone AND prescri* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, English, Peer-Reviewed	0	0	0	0
Handsearching	naloxone	2015-2017, English	0	0	0	2
TOTAL	**N/A**	**N/A**	**259**	**65**	**36**	**10**

Levels of Evidence

A total of 10 sources of evidence were deemed worthy for inclusion into the supportive literature for this EBP: one randomized controlled trial (RCT), two quasi-experimental, two descriptive studies, three program evaluations, one quality improvement project, and one consensus statement. The ten sources were evaluated using the Johns Hopkins Research Evidence Based Practice Research Appraisal Tool, and an evidence level was assigned, ranging from level I to level V, with level I being the highest level of evidence and level V, being the lowest level respectively (Dearholt & Dang, 2014). The sources in the literature review were further appraised for quality utilizing the Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool or the Non-Research Evidence Appraisal Tool (Dearholt & Dang, 2014).

Using the Johns Hopkins Research Evidence Based Practice Appraisal Tool, research studies receive a level of I, II or III, depending on their design. RCTs or experimental studies receive the highest level of I, while quasi-experimental studies are considered a level II, and non-experimental or qualitative studies are considered a level III (Dearholt & Dang, 2014). Likewise, summaries of multiple research studies are stratified in a similar manner. Systematic reviews, meta-analysis and meta-synthesis studies are appraised with consideration of the studies included within the reviews. For example, if all the studies contained within the review are RCTs, a level I would be given. If studies are a combination of RCTs and quasi-experimental or quasi-experimental only, a level II would be appropriate. A level III rating is given if the studies included with the review are a combination of RCTs, quasi-experimental and non-experimental studies, or non-experimental studies only. If any of the studies contained within the systematic review are qualitative, then a level III is required (Dearholt & Dang, 2014).

The Johns Hopkins Non-Research Evidence Appraisal Tool rates other evidence in much the same fashion. Clinical practice guidelines, consensus or position statements are a level IV, while literature reviews and expert opinions are given a level V ranking. Additionally,

organizational experiences are appraised as a level V if they are quality improvement initiatives, financial evaluations, or program evaluations. Case reports, community standards, clinician experience and consumer preference are also considered a level V (Dearholt & Dang, 2014).

The DNP student facilitator ranked the literature that was included for relevant evidence by the standards explained above. The one RCT (Behar, Rowe, Santos, & Coffin, 2017) was ranked as level I evidence. Two pieces of evidence were considered level II: a retrospective, repeated measures cohort study (Bounthavong et al., 2017) and a quasi-experimental study (Coffin et al., 2016). Two pieces of evidence, both descriptive studies were considered a level III (Behar et al., 2016; Winograd, Davis, Niculete, Oliva, & Martielli, 2017). The bulk of the evidence collected was considered non-research and was leveled as such. One consensus statement was rated as a level IV (Alexander, Frattaroli, & Gielen, 2015), while the remainder of the evidence pieces were ranked as level V: three program evaluations (Devries, Rafie, & Polston, 2017; Oliva et al., 2017; Wilson et al., 2017), and one exploratory pilot project (Delaney, Huff, Mini, Thomas, & Tremaglio, 2016),.

Appraisal of Relevant Evidence

The ten pieces of evidence in the literature reviewed were also appraised for quality, using the Johns Hopkins Research and Non-Research Evidence Appraisal Tools. These tools incorporate the use of quality ratings based on quality appraisal; there are three different quality levels: (A) high quality, (B) good quality, and (C) low quality or major flaws (Dearholt & Dang, 2014).

In relation to pieces of evidence that are appraised with the Johns Hopkins Research Evidence Appraisal Tool, a grade A, high quality, rating is reached if the study is consistent, with generalizable results, sufficient sample size for the study design, adequate control, definitive conclusions, and if there are consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence (Dearholt & Dang, 2014). A grade B, good quality, rating is achieved if there are reasonably consistent results, sufficient sample

size for the study design, some control and fairly definitive conclusions, and reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence (Dearholt & Dang, 2014). A low quality, grade C, is given if there is little evidence with inconsistent results, insufficient sample size for the study design, or if conclusions cannot be drawn (Dearholt & Dang, 2014).

The Johns Hopkins Non-Research Evidence Appraisal Tools are evaluated more specifically to the type of evidence being evaluated but are still given the same quality levels: (A) high quality (B) good quality and (C) low quality or major flaws (Dearholt & Dang, 2014). Level IV evidence (i.e., clinical practice guidelines, consensus, or position statements) are evaluated in regards to (a) material officially sponsored by a professional, public, or private organization or government agency; (b) documentation of a systematic literature search strategy, (c) consistent results with sufficient numbers of well-designed studies, (d) criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions, and (e) national expertise that is clearly evident and has been developed or revised within the past five years. If the previous criteria are met, a high quality (A) rating would be given (Dearholt & Dang, 2014). A good quality (B) rating would be considered if the material meets the criteria above, but only indicates a reasonably thorough and appropriate systematic literature search strategy, reasonably consistent results, and there is evaluation of strengths and imitations of included studies with fairly definitive results (Dearholt & Dang, 2014). A low quality or major flaws rating (C) would be given if the literature (a) was not sponsored by an official organization or agency, (b) included an undefined, poorly defined or limited literature search strategy, (c) had no evaluation of strengths and limitations of included studies, (d) presented insufficient evidence with inconsistent results, (e) lacked the ability to derive conclusions, or (f) had not been revised within the last five years (Dearholt & Dang, 2014).

Level V evidence for organization experience is awarded a high quality (A) rating if there are clear aims and objectives, consistent results across multiple settings, formal quality

improvement or financial evaluation methods used, definitive conclusions, and consistent recommendations with a thorough reference to scientific evidence (Dearholt & Dang, 2014). A good quality (B) rating meets the majority of the high quality (A) criteria but has consistent results in only a single setting and/or reasonably consistent recommendations with some reference to scientific evidence (Dearholt & Dang, 2014). A low quality of major flaw (C) rating is appropriate when there is unclear of missing aims or objectives, inconsistent results, or poorly defined quality improvement/financial analysis method, or when recommendations cannot be made (Dearholt & Dang, 2014).

When Level V evidence (i.e., literature reviews, expert opinions, community standards, clinician experience, and consumer preference) is evaluated, a high quality (A) rating is appropriate if the expert provides clearly evident expertise, draws definitive conclusions, provides scientific rationale, and is recognized as a thought leader in the field. A good quality (B) rating is given if the author's expertise appears to be credible and he or she draws fairly definitive conclusions and provides logical argument for opinions. Finally, a low-quality, major flaws (C) rating is indicated if the author's expertise is not discernable or is dubious or if conclusions cannot be drawn (Dearholt & Dang, 2014).

Level I Evidence

Behar et al. (2017) conducted a good quality (B rating) study that included an academic detailing (AD) intervention to 40 randomly selected opioid prescribing primary care providers (*n* = 40, *N* = 143) in the San Francisco area over a 3-month time frame in 2015. Written materials, including a patient brochure and a provider educational booklet, were developed under the guidance of appropriate experts within the field. The provider educational booklet included information on state and national opioid overdose statistics, patient-level overdose risk facts, rationale for furnishing a naloxone co-prescription to patients receiving long term opioids, naloxone pharmacology, effectiveness and cost effectiveness of naloxone, and indicators for prescribing, as well as guidance on how to educate patients on naloxone and opioid overdoses.

Information regarding state laws and examples of how to prescribe depending on formulation type were also included. A detailing visit reviewed the developed materials and a 1-page instruction sheet for registering for the prescription drug monitoring program, a 1-page opioid morphine milli-equivalent (MME) calculator, and two articles addressing the effectiveness and cost effectiveness of naloxone. The academic detail included a 5- to 60-minute (*m* = 28 minutes) discussion regarding the elements of the handouts. Discussions were not fixed, but instead were tailored to meet the needs and interests of the individual providers. Providers were contacted two to three months after the detailing and again at six to nine months after the intervention to establish if they had, indeed, prescribed naloxone.

Medi-Cal data for each provider was obtained, including the number of naloxone prescriptions that had been filled in the four months before and after the intervention. Among the detailed providers, the number of providers that issued naloxone prescriptions increased from 0 to 3 providers, while the number of naloxone prescriptions filled increased from 0 to 10 prescriptions filled. Behar et al. (2017) reported a statistically significant increase in naloxone prescriptions ($p = 0.10$) compared to those who did not receive the intervention, *IRR* 11.0, 95% CI [1.8, 67.8].

Behar et. al (2017) concluded that academic detailing addressing opioid safety and naloxone prescribing, was not only well-received by primary care providers who received it, but also significantly increased the naloxone co-prescription rates compared to those who did not. The findings supported that naloxone academic detailing can be an effective method to improve naloxone co-prescribing rates among primary care providers. Thus, this study provided evidence to support this DNP project.

Level II Evidence

Bounthavong et al. (2017) conducted a good quality (B rating) study to evaluate the effects of an academic detailing service given to prescribing providers on naloxone co-prescription rates between October 2014 to September 2016 in the Veterans' Affairs. Their

retrospective, repeated measures cohort study evaluated 750 primary care providers who had received at least one academic detailing (AD) service during the study period. Academic Detailers were trained clinical pharmacists who provided individualized, face-to-face interactions to deliver evidenced-based-research, data tools and educational materials in an effort to change prescribing behaviors and promote guideline adherence. Providers may have been aware of OEND programming but were categorized as unexposed until an AD training occurred.

Of the 3313 providers, 22.6% received at least one OEND specific AD visit. While the authors did not include raw data reporting, they did conclude that after one year, the average number of naloxone prescriptions showed a statistically significant increase ($p < .001$) in the exposed group than the unexposed providers with IRR 3.2, 95% CI [2.0, 5.3]. At two years, the average number of naloxone prescriptions continued to demonstrate a statistically significant increase ($p < .001$), again with a IRR 7.4, 95% CI [3.0, 17.9]. Although the authors pointed out that it was likely that an increased awareness of OEND programs grew during this period, naloxone prescribing from baseline to two years in the AD exposed providers still exhibited a 7.1% higher average compared with AD-unexposed providers (95% CI [2.0%, 12.5%]).

Bounthavong et al. (2017) concluded that although AD interventions have been successful in other attempts to align provider compliance to guidelines (e.g., hypertension or judicious use of antibiotics), this was the first study that supported AD for OEND in primary care settings. The findings supported that naloxone academic detailing can be an effective method to improve naloxone co-prescribing rates among primary care providers. Thus, this study provided evidence to support the intervention used within this DNP project.

Coffin et al. (2016) conducted a high quality (A rating) study evaluating the effects of a non-randomized intervention on naloxone co-prescription for primary care patients receiving long-term opioid therapy for pain. This study took place between February 2013 to April 2014 in the San Francisco area, among six safety net clinics which had reported deaths from opioid related overdose between 2010 to 2012.

At each of the sites, an “onsite leader” or champion was selected to deliver a consistent protocol which began with academic detailing for providers. This detailing included rationale and indications for prescribing naloxone, appropriate language to approach patients to reduce stigma, naloxone formulations and pharmacy/payor coverage. Providers and staff were also educated on how to train patients and family members on naloxone use and how to recognize an opioid overdose. Training was provided approximately 30 days prior to the initiation of naloxone co-prescribing. After the initiation of the naloxone co-prescribing program, additional training and at least one follow-up email were also completed.

Of the 1985 patients receiving long term opioids, 38.2% (*n* = 759) were given a naloxone co-prescription during the 2-year study. Naloxone co-prescribing was not implemented at the clinics until the start of the study; therefore, none of the patients had previously received a naloxone prescription. Although more extensive statistical review of data was completed regarding decreases in emergency department visits and daily MME changes, the authors did conclude that naloxone could successfully be prescribed in a primary care setting. Providers who were given an AD session were advised to offer naloxone to all patients receiving opioids; however, many providers still prioritized naloxone co-prescribing to patients with higher established risk factors. Despite this finding, the authors also concluded that providing naloxone through a primary care setting may have ancillary benefits, such as reducing opioid related deaths.

Coffin et al. (2016) concluded that the use of a clinical champion who conducted naloxone academic detailing sessions in the primary care setting could be an effective method to increase naloxone co-prescribing. Thus, this study provided additional evidence to support the intervention and targeted outcomes for this DNP project.

Level III Evidence

Behar et al. (2016) explored the acceptability of naloxone co-prescriptions among primary care providers who were treating patients on long-term opioid therapy for pain. Behar

et al., in collaboration with Coffin et al. (2016), administered surveys electronically four to eleven months after Coffin et al.'s naloxone co-prescribing initiative began. These surveys were distributed to providers in six San Francisco safety net clinics, which via Coffin's et al. (2016) intervention, received at least one AD session prior to the initiation of naloxone co-prescribing practices within those clinics. Nearly 70% of all providers receiving training in the Coffin et al. study (111 of 176) completed the survey. Results indicated that the majority of responding providers (79.3%) had prescribed naloxone since the initiative began, and almost all (99.1%) indicated that they would be "somewhat to very likely" to prescribe naloxone in the future. Providers reported a willingness to prescribe to an expanded number of subgroups, including those on either high dose (>20 MME) or low dose (<20 MME) opioids (97.7% and 59.8%, respectively), the elderly, and those without a history of previous overdose.

This good quality (level A rating) study supported the premise that providers are willing to prescribe naloxone after they receive the AD (the intervention used within Coffin et al., 2016), and the researchers identified areas which need to be further addressed, through additional AD or via other means. Behar et al. (2016) noted that the Coffin et al. intervention was completed before the release of newer CDC guidelines for safe opioid prescribing (CDC, 2016a) and therefore, the Behar et al. (2016) responses were truly reflective of the AD Coffin et al. (2016) provided.

The study findings supported evidence that providers in a primary care setting could increase their willingness to prescribe naloxone after receiving an academic detailing session and, thus, AD could be an effective method to improve naloxone co-prescribing rates among primary care providers. Therefore, this high quality (grade A) study provided additional evidence supporting the creation of a coalition within the team-based approach of the Kotter model used within this DNP project.

Winograd et al. (2017) published a good quality (B rating) study conducted within the Veteran's Health Administration (VHA) that aimed to answer three questions: (a) How

knowledgeable and comfortable are providers regarding the clinical incorporation of OEND? (b) If providers have concerns, what is their nature and magnitude? and (c) Does knowledge or concern vary by practice setting and profession? Surveys were administered to prescribing providers within the VHA system prior to an AD session regarding OEND. Each of these sessions, lasting 25 to 40 minutes, included a brief review of current overdose death rates and trends, overdose risk factors, and preventions methods, naloxone rescue devices, guidance on OEND patient trainings, theoretical and practical barriers as well as strategies for successful implementation.

Forty-five participants including physicians, psychiatrists, residents, and “non-physicians” (nurse practitioners, physician assistants and clinical pharmacists), completed the survey. Prior to the AD session, results indicated that providers were more concerned with potential negative consequences of OEND implementation, and they were less concerned about unsafe opioid prescribing practices.

Winograd et al. (2017) noted that after the OEND training was presented, prescriptions rates rose 331%, while the total prescribers of naloxone increased 323% compared to the 10-month period prior to the OEND training. The researchers stated, “although any relationship between training and increased prescription rates should of course be interpreted with extreme caution in the absence of data linking training attendees to their prescribing patterns, these changes may at least partially reflect the impact of the in-services” (p. 138.).

Winograd et al. (2017) concluded that OEND training appeared to be associated with increasing rates of naloxone prescribing as well as increasing the number of actual prescribers. They further noted that the findings provided evidence for the need of increased OEND implementation efforts among settings where opioids are prescribed, particularly primary care settings. The findings, within this good quality (B rating) study, supported that naloxone academic detailing can be an effective method to improve naloxone co-prescribing rates among primary care providers.

Level IV Evidence

Alexander et al. (2015) provided high quality (grade A) recommendations for an evidence-based approach to combat the prescription opioid epidemic. The authors of this consensus, from the well-known leader in research and evidence-based practice Johns Hopkins, met with experts from a multitude of disciplines for a town-hall style meeting where they reviewed available evidence and developed three guiding principles for actionable recommendations. Applicable to this DNP project, the clinical experts discussed the role of OEND programs in promoting appropriate and safe use of prescription opioids.

Consistent with the strategy developed for this DNP project, the experts recognized that the actionable strategy was to engage health care providers to advance the co-prescription of naloxone. Their recommendations supported the role of a clinical champion for naloxone as an effective method to improve naloxone co-prescribing rates among primary care providers.

Level V Evidence

A good quality (B rating) pilot project, led by Delaney et al. (2016) sought to increase naloxone co-prescription rates among four primary care offices in western Connecticut. This quality improvement (QI) project had two primary objectives: (a) to increase the number of naloxone co-prescriptions written and (b) to explore best practices in developing a co-prescription program in a primary care setting.

The authors first examined baseline rates of naloxone prescriptions by reviewing EHR records. A clinical champion, either a third-year resident or a clinician educator, created a log of all patients that would be eligible for naloxone co-prescriptions. When patients presented to the clinic for scheduled refills from February to April 2015, the eligible patient was approached by the person who maintained the log and offered a pre-determined naloxone co-prescription. If the patient stated he or she was interested, an additional appointment was scheduled for a patient teaching session prior to the prescription being provided.

Baseline data revealed that zero naloxone prescriptions had been written prior to the beginning of the QI project. Following the intervention, among the four clinics, approximately 26% of identified individuals were given a naloxone co-prescription. While the QI project did produce positive outcomes, the authors noted that they encountered several barriers, and as a result, they provided several recommendations for other practices wishing to implement naloxone co-prescribing. Notably, the relevant recommendation to this DNP project included establishing a provider champion at each site (Delaney et al., 2016).

Delaney et al. (2016) concluded that the use of a clinical champion in a primary care setting was an effective way to increase naloxone co-prescriptions. Thus, this study provided evidence to support the intervention for this DNP project, but also provided additional information regarding targeted outcomes and anticipated barriers to implementation.

Consistent with more recent quality improvement initiatives to address the opioid crisis, Devries et al. (2017) (high quality, level A rating) implemented a program to increase OEND within the University of California San Diego Health System. This health system serves as the San Diego County safety net hospital and includes 563 hospital beds and 6 pharmacies, with a total of 636,118 outpatient visits in 2015. Their goal, to increase take-home naloxone with the ultimate goal of preventing fatalities, focused on AD for providers, dissemination of patient education materials, EHR changes to promote naloxone prescriptions, and availability of naloxone in pharmacies. AD was provided via departmental trainings lasting 15 to 60 minutes, posting of bulletins, and email notifications. Training included criteria for prescribing, epidemiology of opioid overdose and health disparities, evidence for naloxone distribution, methods of naloxone administration, EHR steps for prescribing, and related prescribing and liability laws. The training was provided to 252 of 905 eligible physicians, pharmacists, nurses and pharmacy technicians, including 184 of 533 eligible providers with prescriptive authority.

These combined efforts resulted in 245 doses of naloxone being co-prescribed between January and October 2016. This intervention increased the baseline rate of naloxone co-

prescriptions ten-fold from 4.5 per month to an average of 46 per month in the three months following full implementation.

Devries et. al (2017) concluded that academic detailing addressing opioid safety and naloxone prescribing, in conjunction with patient education materials and EHR changes significantly increased the naloxone co-prescription rates. Devries et al. (2017) recommended continued training for providers and the development of a script to assist with difficult patient conversations regarding naloxone use. The findings supported that naloxone academic detailing (which included provider training and reminders) can be an effective method to improve naloxone co-prescribing rates among primary care providers. Thus, this study provided additional evidence regarding length of time for the AD and EHR reminders to support the intervention in this DNP project.

As the first major health system to translate a public health community based OEND approach to a health care system approach, Oliva et al. (2017) (high quality, A rating) examined the effects of a system-wide quality improvement program to launch the development of a national opioid OEND program within all 142 VHA facilities. Their concentration was on developing clinical guidance for issuing naloxone kits as well as developing focal campaign of AD. Their program processes included seven steps, the first being to establish at least one clinical champion at each facility to speed OEND implementation. This clinical champion then worked with leadership to develop an overall OEND roll-out implementation plan. VHA leadership also recommended that the clinical champion determine what material, resources, and protocols were necessary. By doing this, the clinical champions would garner support for overall project success.

As the processes continued, Oliva et al. (2017) reported that VHA efforts varied in the AD of their providers, from individual training of staff by the clinical champion to community partners and train-the-trainer models. It was also deemed important to leverage existing staff

and resources to implement OEND to patient populations by using brochures, mailing flyers, and displaying posters to increase overall awareness of programming.

Between October 2015 to September 2016, VHA AD services completed more than 3900 individualized evidence-based OEND education outreach visits and has had consultation with more than 7000 VHA providers. Although no written baseline data was provided, a graph depiction embedded in the article indicated a sharp quarterly rise in naloxone prescriptions dispensed beginning in the first quarter of 2015, the time indicated as the first documented national AD session. By the end of fiscal year 2016, 5693 VHA providers had written a total of 45,178 naloxone prescriptions for 39,328 patients.

Although much of the original program continues as was originally designed, Oliva et al. (2017) noted that naloxone co-prescribing practices have been amended to include one refill, so patients always have access to naloxone in case of an emergency. Further, they opined that AD can play a critical role in facilitation of OEND implementation. “Medical facilities should consider developing academic detailing programs to maximize the benefits in achieving optimal OEND implementation and sustainability.” (Oliva et al., 2017, p. S176).

Additional lessons learned from this system-wide program address the importance of engaging patients, leaders, and staff across the clinical setting. Oliva et al. (2017) also noted that having a champion with dedicated time to support and facilitate OEND implementation is ideal. This study supported the use of a clinical champion with time to develop and administer patient education materials in addition to the delivery of AD sessions to clinical staff as an effective way to increase naloxone co-prescriptions.

Similar to the work in the VHA system, Wilson et al. (2017) drew upon the best available evidence to design and implement a targeted naloxone co-prescribing program within a large academic family medicine practice in western North Carolina. Their project used a pharmacist, who manually reviewed the EHR and identified those meeting criteria for naloxone co-prescriptions, as the clinical champion. The clinical champion then provided an AD session to

providers which covered four main topics. First, opioid epidemic awareness focused on national and local statistics of the opioid epidemic, a harm reduction approach, the role of naloxone as an opioid overdose reversal agent, and previous successes with community-level distribution of naloxone. The second topic addressed emergency management, including overdose recognition and what to do when an overdose is witnessed. The third focus (naloxone administration) discussed formulations of naloxone, directions for use, onset of action, and when to re-dose. Finally, financial considerations (e.g., insurance coverage of naloxone formulations and billing for clinical encounters when prescribing naloxone) were covered.

Wilson et al.'s (2017) baseline data indicated that 709 of the audited 1297 patients were identified as chronic opioid users; 350 of the chronic users (49.4%) met criteria for naloxone co-prescriptions, but only 3.4% had naloxone on their medication list. The program took four months to develop and implement, achieving full implementation in September of 2016. It is notable that this project evaluation planned assessments at 3-, 6-, 12- and 18-months post-implementation. Thus, although this project was fully implemented on September 2016, Wilson et al. (2017) noted that the manuscript was submitted for publication in August 2016, making it impossible to discuss the impact of these interventions (Wilson et al., 2017).

Although this piece of evidence did not yet have results available thus earning a low quality (C rating), the authors did outline a systematic evidence-based approach for increasing naloxone co-prescriptions within a family practice. Wilson et al. (2017) determined that the use of a clinical champion within the clinical setting, who developed and delivered an AD session, was the most likely to have the desired outcomes. Thus, this piece of evidence provided additional support for the use of a clinical champion and AD sessions as a best practice for increasing naloxone co-prescribing.

Construction of Evidence-based Practice

Synthesis of Critically Appraised Literature

A major focus identified throughout the reviewed literature was that current available research on naloxone co-prescribing and effective interventions to promote co-prescribing is rapidly changing (Alexander et al., 2015; Behar et al., 2016; Behar et al., 2017; Bounthavong et al., 2017; Coffin et al., 2016; Delaney et al., 2016; Devries et al., 2017; Oliva et al., 2017; Wilson et al., 2017; Winograd et al., 2017). Within both the health care and private sectors, an increased awareness of the purpose and availability of naloxone has become apparent. As a result, many health care facilities are facing the issue while operating in crisis mode as they attempt to implement EBP strategies to increase access to naloxone. Thus, there is a need for the dissemination of additional evidence from EBP projects to reinforce best practice.

Although the systematic literature review highlighted the effects of multi-faceted strategies to improve naloxone co-prescribing, the most commonly incorporated elements were the use of AD and clinical champions (Alexander et al., 2015; Coffin et al., 2016; Winograd et al., 2017; Wilson et al., 2017). Not surprisingly, the literature review indicated that providers were more likely to co-prescribe naloxone if their level of knowledge about doing so was increased, and AD sessions were well-documented as an effective means of enhancing practice change (Behar et al., 2016; Behar et al., 2017; Bounthavong et al., 2017; Coffin et al., 2016; Delaney et al., 2016; Devries et al., 2017; Oliva et al., 2017; Wilson et al., 2017; Winograd et al., 2017).

AD sessions carried common themes of rationale and indications for prescribing naloxone, available naloxone formulations, acquisition and payment information as well as strategies to initiate and carry out education to patients (Alexander et al., 2015; Coffin et al., 2016; Winograd et al., 2017; Wilson et al., 2017). Early reviews of several pilot programs using a multi-faceted approach included the use of AD intervention (Behar et al., 2016; Delaney et al., 2016; Devries et al., 2017; Oliva et al., 2017; Wilson et al., 2017). While the facilitators of these

programs acknowledged that many of their results were preliminary, reports of early findings included positive outcomes.

The use of a clinical champion within the practice setting was another commonly included intervention within multifaceted interventions (Alexander et al., 2015; Coffin et al., 2016; Winograd et al., 2017; Wilson et al., 2017). Clinical champions were able to increase the pace at which OEND programs could be successfully implemented into a practice change; the use of a clinical champion was also instrumental for determining or developing an appropriate protocol, identifying or developing training and materials for distribution, and working with leadership to facilitate a smoother roll-out process. Although not all evidence was specific on the clinical educational background of the champion, some supported the use of a pharmacist or another prescribing provider (Wilson et al., 2017).

Additional components of the multifaceted interventions included the use of provider reminders (e.g., alerts within EHR) (Devries et al., 2017; Oliva et al., 2017; Wilson et al., 2017). While other researchers addressed enhancing the accessibility of the physical naloxone prescription (Alexander et al., 2015; Behar et al., 2016; Coffin et al., 2016; Delaney et al., 2016; Devries et al., 2017; Oliva et al., 2017; Wilson et al., 2017).

All the pieces of evidence reviewed acknowledged that the issue at hand, naloxone co-prescriptions, could not be successful with the utilization of a solitary intervention (Alexander et al., 2015; Behar et al., 2016; Behar et al., 2017; Bounthavong et al., 2017; Coffin et al., 2016; Delaney et al., 2016; Devries et al., 2017; Oliva et al., 2017; Wilson et al., 2017; Winograd et al., 2017). Thus, a multifaceted approach was deemed appropriate.

Best Practice Model Recommendation

Utilizing appraised literature was the foundation for this EBP project. The DNP student facilitator presented the evidence synthesis to the CS task force and conferred with the team to determine the best practice recommendations that were applicable to the project facility. The review and synthesis of the best available evidence provided the solid foundation that was

needed to answer the clinical question and develop a PICOT question when using the Iowa model for EBP: Among primary care providers in a tribal health clinic, does the introduction of an multi-faceted intervention, which includes the use of academic detailing and a clinical champion, versus the current practice of no intervention, improve the co-prescription rates of naloxone to chronic opioid patients in a twelve week period?

How the Best Practice Model Will Answer the Clinical Question

Results and evidence for the literature synthesis provided the structure for the development of a multi-faceted OEND intervention. An AD session, which gave step by step instructions for the logistics of dispensing naloxone within the primary care clinic was developed. Clarity regarding who would order and maintain available naloxone stock was attained. A clinical champion was selected (DNP student facilitator) and OEND educational materials were procured for provider AD sessions; patient education brochures for distribution during clinic visits and posters for waiting and exam rooms were made available to spark conversation. AD sessions were held in a group format and additional group follow up and one-on-one sessions were completed when appropriate.

Utilization of the Iowa model incorporates teamwork and collaboration, which was felt to be a fundamental property to the implementation of this EBP project. The Iowa model was especially useful in identifying systems problems and investigating potential interventions which complemented the first three steps of Kotter's change model and mandated input from the task force. The team-based dialogue allowed for open communication to voice concerns and address potential unforeseen barriers to naloxone co-prescribing. The team then determined that the multifaceted approach was warranted but recognized the limited applicability of alerts within the EHR and the potential barriers for the accessibility of the prescription. The barrier of accessibility was overcome by stocking the naloxone within the clinic. Although, the EHR was not used to provide patient alerts, the team worked with the CAC to imbed order sets to

dispense naloxone and provide education in an effort to ease time constraints during clinic visits.

This team-based approach also allowed the facilitation and communication of Kotter's fourth step, understanding of goals. Kotter's fifth step was addressed when an action plan was developed using the best practice suggested by the DNP student facilitator that would lead to a demonstration of improved naloxone co-prescribing as evidenced by an increased number of naloxone prescriptions being distributed.

Citation	Design/Level/ Quality Rating	Setting/Sample	Intervention(s)	Outcomes/Measures	Findings
Alexander, Frattaroli, & Gielen (2015)	• Consensus Statement • Level IV • Grade A	• Community stakeholders • Pharmacy staff • Medical community	• Develop evidence-based consensus statement	• 3 guiding principles developed • 1 relevant to project: promoting appropriate and safe use of prescription opioids	• Engage with providers to advance the co-prescription of naloxone with prescription opioids
Behar et al. (2016)	• Descriptive, correlational, retrospective study • Level III • Grade A	• 6 safety net clinics in San Francisco • 111 Providers	• Naloxone co-prescribing training • Providers received 3 focused follow up sessions (rationale and indications for prescribing naloxone, available naloxone formulations, insurance coverage information and communication strategies around discussing naloxone with patients) • Email reminders sent to providers to remind them about naloxone co-prescribing	• Explore naloxone co-prescribing in primary care setting after trainings	• 79.3% of providers who received the AD session prescribed naloxone (no co-prescribing in place prior to intervention) • 99.1% were likely to very likely prescribe naloxone in the future • 59.8% likely to prescribe to those receiving low doses (< 20 MME daily) • 83.9% likely to prescribe to > 65 years old • 80.7% likely to prescribe to those with no overdose history • 73.6% with no SUD

Citation	Design/Level/ Quality Rating	Setting/Sample	Intervention(s)	Outcomes/Measures	Findings
Behar et al. (2017)	• RCT • Level I • Grade B	• 40 randomly selected opioid prescribing primary care providers in the San Francisco Area	• Providers received detailing regarding naloxone prescribing for 5-60 minutes (*m* = 28 minutes) • Most frequently covered topics included: indications for naloxone, examples of naloxone prescriptions, language to use with patients, and pharmacy outreach	• Changes in rates of naloxone prescriptions, comparison 4 months before and after providers received academic detailing of naloxone prescribing	• Naloxone co-prescriptions filled by patients increased from 0 to 10 among those that had been seen by a provider who received detailing vs. by the providers who did not receive detailing *(IRR* = 11.0; 95% CI [1.8, 67.8], *p* = 0.010)
Bounthavong et al. (2017)	• Retrospective repeated measures cohort study • Level II • Grade B	• VA providers who were actively treating patients in family practice or substance use disorder at time of study	• A total of 750 (22.6%) out of 3,313 providers received at least one OEND-specific AD visit	• Evaluate the impact of academic detailing on naloxone co-prescribing	• Naloxone co-prescribing rate (from baseline to 2 years) was 7.1% greater in the AD exposed providers (95% CI = 2.0%, 12.5%) compared to the AD-unexposed providers

Citation	Design/Level/ Quality Rating	Setting/Sample	Intervention(s)	Outcomes/Measures	Findings
Coffin et al. (2016)	• Quasi-experimental • Level II • Grade A	• 6 safety net clinics in the San Francisco area • 1985 adults receiving long-term opioid therapy for pain	• Onsite leader selected • Clinic staff received training in naloxone prescribing (including rationale and indications for prescribing, language to approach patients, naloxone formulations and pharmacy/payor coverage) • Staff trained how to educate patients about naloxone use and assembly of naloxone device • Follow up training provided • At least one reminder email sent to providers	• Proportions of patients prescribed naloxone, opioid-related emergency visits and prescribe opioid dose based on chart review	• 759 (38.2%) of 1985 eligible patients were co-prescribed naloxone during intervention • No net change in opioid dose over time between those that received naloxone prescription and those who did not (*IRR* = 1.03, 95% CI = 0.91-1.27, *p* = 0.61)
Delaney et al. (2016)	• QI project • Level V • Grade B	• 4 primary care offices in western Connecticut serving as medical home training sites for primary care residents • All patients on chronic opioid therapy screened for eligibility	• 2-month period • Signage placed in check-in areas of patients indicating naloxone was available • QI safety initiative, those eligible for naloxone co-prescriptions identified and approached by residents who were given scripting for encounter	• Rate of naloxone co-prescriptions written	• Training sites increased naloxone co-prescription rates from 0 to 53 of 204 (26%) eligible patients • 3 sites dispensed (*n* = 3, *N* = 64) naloxone prescriptions, where opioids were managed by pain specialists; the 4th site managed opioids by the primary care and dispensed a higher percentage of naloxone (*n* = 50, *N* = 140)

Citation	Design/Level/ Quality Rating	Setting/Sample	Intervention(s)	Outcomes/Measures	Findings
Devries et al. (2017)	• Program Evaluation • Level V • Grade A	• Multisite academic health system in California	• Implement a naloxone distribution program • Staff member were given trainings lasting 15 minutes to 1 hour that covered epidemiology of overdose, evidence for naloxone distribution, methods of naloxone administration, criteria for prescribing, EHR steps for prescribing and related prescribing and liability laws • PowerPoint training was made available to staff who could not attend	• Rate of naloxone co-prescriptions written	• Naloxone prescription rates increased from 4.5 per month to 46 per month following full implementation, indicating a 10-fold increase • Physicians wrote 85.3% (*n* = 209, *N* = 245) • NP wrote 9.8% (*n* = 24, *N* = 245) • PA wrote 3.7% (*n* = 9, *N* = 245) • Pharmacists wrote 1.2% (*n* = 3, *N* = 245)

Citation	Design/Level/ Quality Rating	Setting/Sample	Intervention(s)	Outcomes/Measures	Findings
Oliva et al. (2017)	• Program Evaluation • Level V • Grade A	• VHA medical facilities nationwide (*N* = 142)	• Implement OEND nationwide	• Pharmacy development of naloxone rescue kits • Developing clinical guidance for issuing kits • Supporting OEND as a focal campaign of AD	• VHA dispensed 45,178 naloxone prescriptions in 2016 by 5693 prescribers to 39,328 patients • Initial VHA pilots varied in their training process, ranging from individual training by clinical champion to training of staff by community partners and train-the-trainer models. • Recommendations included: • Have a champion with dedicated time to support and facilitate OEND implementation. • Establish at least one clinical champion at each facility to help speed OEND implementation. • Clinical champion should work with leadership to develop OEND implementation plan • Consider using AD

Citation	Design/Level/ Quality Rating	Setting/Sample	Intervention(s)	Outcomes/Measures	Findings
Wilson, Rodriguez, Carrington, & Fagan. (2017)	• Program Evaluation • Level V • Grade C	• Large academic family medicine practice in North Carolina • *n* = 350 (*N* = 709) patients met CDC criteria for naloxone prescribing • *n* = 12 had naloxone on their medication list prior to implementation	• Develop a targeted naloxone co-prescribing program in a primary care practice through use of a clinical champion • Sequential concurrent three phase rollout: • Phase one: Pharmacists (clinical champion) embedded in practice provided academic detailing 1. Opioid epidemic awareness 2. Emergency management 3. Naloxone administration 4. Financial considerations • Phase two: Logistical barriers to prescribing naloxone were addressed • Phase three: Barriers related to patient engagement addressed	• Improve naloxone co-prescriptions rates	• Program in progress • Article was received for submission August 31, 2016, program was fully implemented September 2016. Authors address that next steps include determining how many patients identified actually received naloxone prescription. Assessments planned at six, twelve and eighteen months.

Citation	Design/Level/ Quality Rating	Setting/Sample	Intervention(s)	Outcomes/Measures	Findings
Winograd, Davis, Niculete, Oliva, & Martielli. (2017)	• Descriptive study • Level III • Grade B	• Convenience sample of prescribers within the Veterans Affairs health system • *n* = 45, *N* = 54	• Non-interventional • Surveys completed by prescribing providers to obtain baseline knowledge and concerns prior to attending OEND education training	• Determine how knowledgeable and comfortable are providers regarding the clinical incorporation of OEND • Determine if providers have concerns, what is their nature and magnitude? • Determine if knowledge or concern vary by practice setting and profession.	• Concerns of iatrogenic effects of OEND were rated higher than concerns about impressions of unsafe prescribing practices ($t(42) = 3.06$, $p < .01$) • Endorsement of lack of knowledge/familiarity/comfort ($t(42) = 3.91$, $p < .001$)

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

Naloxone co-prescriptions are recommended as a risk mitigation strategy in opioid prescribing, yet there is still a nationwide struggle to gain acceptability of universal prescribing in primary care settings (CDC, 2016a). Despite recommendations by governing bodies and agencies targeting the opioid epidemic, there remains a wide gap between naloxone co-prescriptions practices and provider adherence to guidelines (CDC, 2016a; IHS, 2015; USDHHS, 2016)

Participants and Setting

The focus of this DNP project was to implement a multifaceted intervention, which included an academic detailing program, provider reminders, and the utilization of a clinical champion, to improve rates of naloxone co-prescribing within a primary care setting. The project was initiated among an Indian Health Service Tribal Health Department with one satellite locations in a rural setting and one an urban setting; these facilities will furthermore be referred to as Clinic X. A third satellite location, within an occupational setting, was not included in the project data as that facility typically did not see a patient population which received chronic opioids, and the DNP student facilitator was also the primary provider at that location. Thus, excluding patients seen at this venue removed the potential selection bias that may have skewed outcome data in this EBP project.

While in separate geographic locations, the clinics had attempted to standardize practice across the settings and utilize evidence-based medicine whenever possible. Although clinic providers typically remained stationed at one location, all were cross-trained to work in any of the settings. Many of the support staff and other departments worked among all the clinics on a routine basis.

Within the Indian Health Services Tribal Health Department, the governing tribal council had deemed the opioid epidemic a priority and implemented a policy to assist with the distribution of naloxone to at-risk tribal members and clinic utilizers. Despite this, the tribal health department providers had vocalized concerns at regularly scheduled staff meetings regarding current best-practice evidence for both opioid prescribing and naloxone distribution. A recently revised mission statement which focused on quality, integrated patient centered-care prompted the review of current prescribing practices to determine if what was presently utilized was in fact, current best practice.

Offering a wide variety of primary care services including pain management, the clinics were well-appointed to determine if a multi-faceted approach would increase naloxone co-prescriptions to patients who were prescribed long-term (30 days or longer) opioid medications. The clinics were staffed by providers of a variety of health care disciplines, with prescribing providers including one full-time PA in the rural location, one full-time PA in the urban location, one NP (DNP student facilitator) in the occupational setting and two physicians: one working full-time and rotating through each clinic location and the medical director who works one day per week, rotating clinical sites. The medical director provided oversight to the advanced practice clinicians and assisted with complex patient management, including those who were prescribed controlled substances. Aligning well with the Iowa model, in a team format, all providers verbally gave support to proceed with a project that would assist with furthering the goal of safe opioid prescribing and management.

Pre-Implementation Data

Clinic X provided services to 48 eligible patients receiving chronic opioid prescriptions (30 days or longer) between September 25th, 2016 through December 15th, 2017. None of these patients were found to have received a naloxone prescription during this period. Nearly two-thirds of these patients were females (66.7%, *n* = 32) and the remaining 16 patients being

males (33.3%). The slight majority of patient were seen in the urban clinic (58.3%, *n* = 28), while the rural clinic provided services to the other 41.7% (*n* = 20).

Outcomes

This EBP project examined how a multifaceted intervention, utilizing a clinical champion who provided an academic detailing session and intermittent formal and informal follow-up (provider reminders) to the prescribing providers could influence naloxone co-prescriptions. Additionally, during the primary formal academic detailing session, printed materials were distributed. The printed materials served two purposed: (a) references for prescribing providers and (a) educational tools to be distributed to patients during clinic encounters. The primary outcome of the EBP project was to measure the rates of naloxone co-prescriptions written to eligible clinic utilizers by primary care providers within the health care clinics during a 12-week period. Literature supported the use of a clinical champion to advocate for the use of naloxone co-prescriptions and provide the academic detailing session (Behar et al., 2016; Behar et al., 2017; Bounthavong et al., 2017; Coffin et al., 2016; Delaney et al., 2016; Devries et al., 2017; Oliva et al., 2017; Wilson et al., 2017; Winograd et al., 2017). Twelve weeks of pre-implementation data were collected via retrospective chart review, for those patients who had received opioid prescriptions of 30 days or greater, from the corresponding period the year prior. Evaluating data from the same period the previous year helped to eliminate seasonal fluctuations of clinic usage and to prevent any prescribing practice changes that providers may have self-initiated during the planning stages of this DNP project. This data was then compared to prescribing patterns twelve weeks during the implementation phase, a length chosen purposefully to align with recommendations from the CDC that patients receiving chronic opioids be re-evaluated every three months (CDC, 2016a). This time frame provided the best scenario for being able to capture all eligible chronic opioid users during the intervention period. For comparison of naloxone co-prescription rates collected during the pre-implementation phase

and implementation phase, chi-square analysis was utilized. Based on evidence demonstrated from Delaney et al. (2016), a benchmark outcome of a 25% increase in naloxone co-prescribing rates would indicate project success. Additionally, secondary analyses investigated relationships between patient demographics, provider adoption of co-prescribing, daily MME prescribed, concurrent benzodiazepine use, clinic location, and whether a clinic visit occurred for any reason during the data collection period.

Planning and Intervention

The implementation of the practice change and data collection was conducted over twelve weeks, from September 25, 2017 to December 15, 2017. Consistent with Kotter's eight-step change theory, support from the clinical agency and key stakeholders was obtained early in the planning stages. The clinical manager and prescribing providers contributed to the plan and provided verbal encouragement to the DNP student facilitator. As planning proceeded, the project was divided into three phases. The first phase being the pre-implementation phase where the DNP student facilitator collected data, procured educational materials, and developed the academic detailing session. The second phase consisted of the implementation of the intervention, which included the presentation of the formal academic detailing session and clinical champion involvement. The third and final phase consisted of post-intervention data collection and analysis.

Following the approval of the IRB board from Valparaiso University, implementation and coordinating data collection began September 25, 2017. A large portion of the preparatory work was completed by the DNP student facilitator via unpaid hours that also satisfied DNP program course requirements. Development of the instrument design for data collection (Appendix A), a one-hour academic detailing session PowerPoint (Appendix B), provider naloxone prescribing guide (Appendix C), and patient naloxone educational pamphlet design (Appendix D), as well as procurement of educational posters (Appendix E) and adding the naloxone into the EHR for documentation of distribution in the clinic were all completed prior to implementation.

Additionally, with the assistance of the Clinical Applications Coordinator (CAC), an employee of the agency who assists providers and other clinic staff to optimize the utilization of the EHR and create, run, and distribution various reports in her normal job duties, baseline data of all current chronic opioid patients was obtained and reviewed for accuracy, which was later distributed to the appropriate ordering provider during the formal academic detailing session. Consistent with Kotter's short-term wins, the clinical champion provided project updates and status of naloxone distribution at regularly scheduled monthly provider meetings, planned email update at the mid-way point and other informal individual contacts via phone, email, video conference and face-to-face interactions. The DNP student facilitator made efforts to ensure informal contacts occurred equally among prescribing providers so that naloxone adoption rates would not be influenced.

During the implementation phase, the providers, the registered nurse (RN) clinical manager, and the clinical support staff; consisting of two full time RNs and two full time medical assistants (MA), were provided the academic detailing session regarding naloxone co-prescriptions during two separate sessions on September 25th and September 26th, 2017. Although originally planned to take place in a single session, so all members of the CS task force could be present, a scheduling conflict arose, and the session was therefore repeated the following day to capture those previously unable to attend. The 1-hour session, conducted in the health department conference room at the rural location with simultaneous video-conferencing to the urban location, consisted of a PowerPoint presentation adapted from educational materials previously developed by PrescribeToPrevent, a nationally recognized organization that published toolkits regarding opioid safety and overdose prevention resources for prescribers and pharmacists (PrescribeToPrevent, 2015). The publications were widely available on the internet and were free for use. During this session, the following topics were addressed: (a) relevant opioid overdose statistics, (b) naloxone pharmacology, (c) current naloxone co-prescribing recommendations, (d) current organizational naloxone policy (which included stocking naloxone onsite and dispensing the medication prescribed the day of the

office visit versus returning for the for the education component), (e) proper naloxone administration (via a 7-minute video [an organizational policy requirement for patients being distributed naloxone]), and (f) procedures for EHR documentation. A packet containing a copy of the PowerPoint slides (Appendix B), the current CDC prescribing clinician pocket reference (Appendix F), naloxone product comparison sheet (Appendix G), a fact sheet from the manufacturer of the naloxone product purchased for distribution (Appendix H), and a quick start guide for the same naloxone product (Appendix I) were provided to all participants. Additionally, each prescribing provider received an individualized report compiled by the CAC that listed all patients who had received an opioid, benzodiazepine, or naloxone prescription in the 90 days preceding the academic detailing session.

The providers were advised to begin utilizing universal naloxone co-prescribing practices immediately and were encouraged to use the CAC provided list of their patients as a reference to capture those patients during any clinic visit that occurred during the intervention period, whether for an opioid related reason or for another reason, such as acute illness. The DNP student facilitator was available throughout the implementation period for support or additional academic detailing as needed, which arose only as simple clarification questions regarding the distribution process, not the pharmacology or rationale for naloxone co-prescribing. Consistent with Kotter's short-term wins, a follow up email was sent by the clinical champion at the 6-week mark to remind providers of the ongoing intervention and to inform providers of interim data, including the number of prescribed naloxone dispensed thus far; this reminder intended to provide further motivation and prevent stagnation of the EBP project intervention. The intervention was also discussed at the monthly provider meetings, providing another opportunity to discuss short-term wins (such as distribution success) and any provider concerns and barriers were addressed at that time.

Clinical support staff, who also attended the academic detailing session, were responsible for the management of a naloxone distribution log as per organizational policy

(maintained in an electronic fob access formulary at each location). Access was only available to providers, clinical support staff, and the clinical manager. Support staff were also responsible for maintaining the supply of naloxone and reordering if stock became low. Replacement stock generally arrived one business day after the order was placed.

Posters obtained from PrescribeToPrevent.org (2015) (Appendix E) were placed in targeted vantage point locations of the waiting area, restrooms, and exam rooms. Additional information regarding the availability of naloxone at the clinic was included in an educational article written by the DNP student facilitator, published in the quarterly health publication, fall edition (Appendix J). This publication was mailed to the homes of all current registered patients of the clinic and additional copies were widely available throughout the clinics in the waiting areas and exam rooms. The original intention for these materials were for patient education; however, during the EBP project, they also served as visual reminders to the prescribing providers.

During the post-implementation phase, the DNP student facilitator calculated the outcomes measures, including the primary objective: naloxone co-prescription rate differences between the pre-intervention period and the intervention period. Since the pre-intervention group was known not to have dispensed any naloxone co-prescriptions, secondary statistics were calculated solely on the intervention group. To determine if relationships existed in the intervention group, demographics (including age, gender, daily MME, concurrent prescription of benzodiazepines clinic location and provider discipline) were evaluated.

Data

Collection

At the completion of the 12-week implementation period, a chart audit was conducted to determine the percentage of eligible patients prescribed naloxone. This was done with the assistance of the CAC, who, within her usual job duties, generated reports from the Resource and Patient Management System EHR used by the clinics. Reports regarding co-prescriptions

of naloxone as well as current opioid prescriptions written were then verified by the DNP student facilitator for accuracy and cross-referenced with the naloxone distribution log maintained by the clinical support staff to ensure complete data capture. Based on the reports generated by the CAC, 48 EHR records were audited pre-implementation and 40 EHR records were audited from the implementation period. Demographics regarding mean age, gender, primary diagnosis, tribal affiliation, concurrent benzodiazepine prescriptions, and daily MME of opioid dosing were also collected to evaluate if there were any differences in the proportion of naloxone co-prescriptions written based on these characteristics. Additionally, whether the patient had a clinic visit during the intervention period, which clinic dispensed the naloxone, which provider dispensed, and whether the dispensed naloxone was recorded in the EHR correctly were further evaluated.

Informal bi-weekly review of the naloxone distribution log afforded the opportunity for continuous evaluation of study implementation. This was provided by either a verbal report from the clinical support staff in each clinic or a visual review by the DNP student facilitator.

Management and Analysis

SPSS Version 22 was utilized for data analysis. Parametric statistics were conducted to test that providing academic detailing sessions via a clinical champion was associated with an increased rate of naloxone co-prescriptions dispensed within a primary care clinic setting. In an effort to determine if further relationships existed in the intervention group, additional parametric and non-parametric testing was completed to evaluate statistical differences.

Protection of Human Subjects

The student facilitator successfully completed the National Institutes of Health (NIH) protection of human rights training on February 28th, 2017 (Appendix K). To protect human rights and maintain compliance with HIPAA laws, identifying information (e.g., patient name and medical record number) was kept within the clinical setting and security was maintained in a locked cabinet, accessible only by the DNP student facilitator. The naloxone distribution log, as

per organization policy was securely maintained in an electronic fob access formulary which itself was located inside the providers' office. Electronic fob access was available only to the providers, clinical support staff, and clinical manager. The office space itself was locked when not occupied by a provider. During chart audits, EHR records accessible to the DNP student facilitator through authorization of her employment status, were conducted in the facilitator's closed office when other staff members were not present, to ensure that protection of data was maintained. No identifying data of individual patients was disclosed during the final report, as project data was reported in the aggregate form only. The student facilitator will maintain the records in this secure fashion for three years, at which time data will be destroyed by shredding.

CHAPTER 4

FINDINGS

This EBP project was designed to determine the effect of a multi-faceted intervention on the naloxone co-prescription rates among primary care providers, who prescribed chronic opioids to patients for 30 days or greater, in a tribal health clinic. The PICOT question posed was: *Among primary care providers in a tribal health clinic, does the introduction of an evidence-based multi-faceted intervention versus the current practice of no tool, improve the co-prescription rates of naloxone to chronic opioid patients within a 12-week period?* The project was conducted in two Indian Health Service clinics in Southwest Michigan, one rurally located, the other within an urban setting. While each location had a primary, full-time advanced practice clinician, both of which were PAs, two additional providers, a full-time staff physician and a part-time physician medical director, rotated to all the clinics operated by the tribal government. All providers had been cross-trained to work at each location. The multi-faceted intervention consisted of provider education provided during a one-hour discussion and PowerPoint academic detailing session, the utilization of a clinical champion (DNP student facilitator), and posters placed strategically throughout the clinic (waiting room, exam rooms and bathrooms), which served the dual purpose of visual reminders to the providers and provided education to the patients.

Data collected from a retrospective chart review during a 12-week intervention period was compared to the correlating 12-week time period the previous calendar year and manually entered into the *Statistical Package for the Social Services* (SPSS) for statistical analysis. Testing was performed to answer the following primary question:

Question one: What are the naloxone co-prescription rates and are they significantly different between the two project periods?

Statistical analyses also evaluated secondary questions:

Question two: Does patient age influence the likelihood of dispensing a naloxone co-prescription?

Question three: Does patient gender influence the likelihood of dispensing a naloxone co-prescription?

Question four: Does the amount of daily MME influence the likelihood of dispensing a naloxone co-prescription?

Question five: Does the concurrent prescription of benzodiazepines influence the likelihood of dispensing a naloxone co-prescription?

Question six: Does the clinic location influence the likelihood of dispensing a naloxone co-prescription?

Question seven: Does the provider discipline (PA or physician) influence the likelihood of dispensing a naloxone co-prescription?

Participants

Physician one had over 20 years of clinical experience and had been working with the tribal clinic for approximately four years. This part-time physician serves as the medical director of the clinics, rotating between sites on a weekly basis. Physician two had over 25 years of clinical experience and worked full time, alternating between the rural and urban clinics. Physician two had been employed by the tribe for the past three years, but on a part-time basis until the past year. PA one had nearly 30 years of clinical experience and had been employed by the tribal clinic for approximately six years, working from the rural location. The final provider, PA two, was the most recent to join the staff, having approximately three years of clinical experience and working for the tribal clinic in the urban location for the past two years.

Clinic patients were eligible to receive a naloxone co-prescription from the provider during the EBP project if they were a federally recognized tribal member, spouse of a tribal member, or otherwise eligible to be seen at either clinic location as an employee of the Tribal Government. Additionally, eligible patients were ages 18 and above, non-pregnant, and

receiving an opioid prescription (of any MME equivalents) of 30 days or greater during the EBP project.

Consistent with Kotter's model and the team-based approach, patients were considered eligible for inclusion regardless of a medical visit occurring during the 12-week intervention. Since the clinics offer services across several healthcare modalities, eligible patients may have been physically present at the clinic during the intervention either accessing another service or presenting to pick up a physical prescription for the opioid medication. Therefore, team members had opportunities unique to this setting to offer naloxone co-prescriptions outside of a traditional medical clinic visit.

Size and Characteristics

Pre-Intervention Group Characteristics. A retrospective chart audit of patients' medical records was conducted to collect baseline data. Data was compiled from 48 medical records of patients who received a 30-day or greater prescription of opioids in the 12-week period dating September 25th, 2016 to December 15th, 2016. The chart audit consisted of patients ranging in ages from 26 to 72 years. The mean age was 50.0 years (*SD* = 10.46). Of the group, 33.3% (*n* = 16) were male and 66.7% (*n* = 32) were female. The majority of the patients, 56.3% were of 'other tribal affiliation" (*n* = 27), members of the tribal affiliation which funds the clinics constituted 41.7% (*n* = 27) of the audited charts; patients in the remainder 2.1% of audited charts were categorized as "non-tribal affiliation" (*n* = 1). During the 12-week audit period, 75% (*n* = 36) of the patients did have a clinic visit occur, while the remainder did not. The majority of eligible patients were patients of the urban location, 58.3% (*n* = 28); while the remaining patients, 41.7% (*n* = 20) were patients at the rural location. Prescribing provider discipline was equally split among patients with PAs and physicians, each writing 50% (*n* = 24) of the opioid prescriptions in the audit period. The mean daily MME was 24.6 (*SD* = 18.37) with a range of 5 to 95 MME. Additionally, 8 (16.7%) of the patients received a benzodiazepine prescription in addition to their opioid prescription (see Table 4.1).

Intervention Group Characteristics. Data was collected from a total of 40 patients who obtained an opioid prescription of 30 days or greater during the 12-week intervention period that occurred between September 25th through December 15th, 2017. The patients were similar in age to the pre-intervention group, ranging from 29 to 70 years old with a mean age of 49.9 years (*SD* = 10.44). The intervention group, however, did have a higher percentage of females, 72.5% (*n* = 29) than the previous group. Accordingly, the percentage of male patients was less (27.5%, *n* = 11). Membership of the tribe which funds the clinic was 37.5% (*n* = 15), non-tribal affiliated patients accounted for 10% (*n* = 4) of the opioid prescriptions, and the majority of the patients receiving opioids were of other tribal affiliations (52.5%, *n* = 21). The overwhelming majority of the patients, 37 (92.5%) did have a visit during the intervention time frame, while only the remaining three did not (7.5%). As noted with the pre-intervention group, the urban located clinic was the source of the majority of the patients receiving an opioid prescription 65% (*n* = 26), while the remaining 35% (*n* = 14) were patients at the rurally located clinic. A physician was the prescribing provider for 55% (*n* = 22) of patients receiving an opioid during the intervention period, while 45% (*n* = 18) of the patients were prescribed by the PAs. Daily MME among opioids prescribed ranged from 2.5 to 172.5, with a mean of 24.16 (*SD* = 30.96). Only 22.5% (*n* = 9) patients in the group received a concurrent benzodiazepine prescription, while the remaining 77.5% (*n* = 31) did not (see Table 4.1).

Changes in Outcomes

Statistical Testing and Significance

Using SPSS Version 22 for analysis, parametric tests were run to compare the naloxone co-prescription rates between the two groups: pre-intervention (*N* = 48) and intervention (*N* = 40). Statistical significance for all data was established as $p < .05$. A chi-square test of independence was calculated to analyze the association between the use of a multi-faceted intervention and naloxone co-prescription rates. Secondary variables of interest were

calculated within the post-intervention group utilizing chi-square analyses and independent samples *t* testing.

Findings

Primary outcome.

Question one: What are the naloxone co-prescription rates and are they significantly different between the two project periods? During the pre-intervention group, there were no naloxone co-prescriptions distributed (0 of 48 eligible patients) while 10 of the 40 eligible patients within intervention group (25%; $X^2 = 13.538$, $p < .001$) had naloxone distributed (see Figure 4.1). Additionally, all 10 of the patients who received the naloxone co-prescription, did have a clinic visit occur during the intervention period. A further demographic breakdown of those who received naloxone and those who did not is available in Table 4.2.

Secondary outcomes.

Secondary descriptive statistics were calculated within the post-intervention group to evaluate if further relationships existed. Parametric and non-parametric tests were utilized as appropriate. None of the secondary variables of interest, except patient gender, were found to affect naloxone distribution.

Question two: Does patient age influence the likelihood of dispensing a naloxone co-prescription? An independent-samples *t* test comparing the mean ages of patients which received naloxone co-prescriptions against those who did not. The mean age of people who received naloxone ($M = 50.5$) was not significantly different from the mean age of those who did not. ($M = 49.7$; $t = 0.207$, $p = .837$).

Question three: Does patient gender influence the likelihood of dispensing a naloxone co-prescription? In the intervention group, 11 male patients and 29 female patients were eligible to receive a naloxone co-prescription (see Figure 4.2). However, none of the eligible males received one, while 10 (34.4%) of the 29 eligible females did ($X^2 = 5.057$, $p = .025$).

Question four: Does the amount of daily MME influence the likelihood of dispensing a naloxone co-prescription? Review of the data indicated that there was a wide range in the daily MME patients who had been co-prescribed naloxone, ranging from 10 to 172.5 daily MME. Patients in the intervention group who did not receive a naloxone co-prescription had daily MME ranging from 2.5 to 95. The mean daily MME of the patients who received naloxone co-prescriptions (M = 39.68) did not significantly differ from eligible patients who were not prescribed naloxone (M = 22.99; t = 1.500, p = .142).

Question five: Does the concurrent prescription of benzodiazepines influence the likelihood of dispensing a naloxone co-prescription? Within the intervention group, nine of the 40 patients (22.5%) had a concurrent benzodiazepine prescription, one of the additional risk factors for opioid overdose potential. Of the 10 patients who received a naloxone co-prescription, 30% (3 patients) were concurrently receiving a benzodiazepine prescription. No statistically significant relationship was found (X^2 = .430, p = .512).

Question six: Does the clinic location influence the likelihood of dispensing a naloxone co-prescription? Since each of the clinics served a unique population due to the contrasting urban and rural populations, naloxone co-prescriptions between locations was also evaluated. The rural clinic serviced 35% (n = 14) of the eligible patients while the urban clinic serviced the remaining 65% (n = 26). As mentioned previously, naloxone co-prescriptions were dispensed ten of the total eligible 40 patients. Of the ten, two (20%) were the rural patients and eight (80%) were the urban patients. Although the urban setting had a 4:1 ratio over the rural setting, clinic location did not appear to be a statistically significant factor in naloxone co-prescription rates (X^2 = 1.319, p = .251).

Question seven: Does the provider discipline (PA or physician) influence the likelihood of dispensing a naloxone co-prescription? Finally, comparisons between disciplines was conducted. While each of the PAs were stationed primarily at one clinic, both the full-time and part-time physician rotated among the clinics. Interestingly, the physicians prescribed the

majority, 70% (*n* = 7) of the naloxone co-prescriptions, while the PAs prescribed 30% (*n* = 3). However, the physicians also saw a slight majority, 55% (*n* = 22), of the eligible patients in the intervention phase. Provider discipline did not appear to be a factor in naloxone co-prescription rates (X^2 = 1.212, *p* = .271). A further breakdown of provider dispensing patterns in located is Table 4.3.

Table 4.1

Group Characteristics

	Pre-Intervention		Intervention	
Gender	*Frequency*	*Percentage*	*Frequency*	*Percentage*
Male	16	33.3%	11	27.5%
Female	32	66.7%	29	72.5%
Tribal Affiliation				
Funding Tribe	20	41.7%	15	37.5%
Other Tribe	27	56.3%	21	52.5%
Non-Tribal	1	2.1%	4	10.0%
Clinic Location				
Rural	20	41.7%	14	35.0%
Urban	28	58.3%	26	65.0%
Clinic Visit During Audit Period				
Yes	36	75.0%	37	92.5%
No	12	25.0%	3	7.5%
Concurrent Benzodiazepine Prescription				
Yes	8	16.7%	9	22.5%
No	40	83.3%	31	77.5%

Table 4.2

Intervention Group Characteristics

	Naloxone		No Naloxone	
Gender	*Frequency*	*Percentage*	*Frequency*	*Percentage*
Male	0	0%	11	36.7%
Female	10	100%	19	63.3%
Tribal Affiliation				
Funding Tribe	1	10%	14	46.7%
Other Tribe	9	90%	12	40%
Non-Tribal	0	0%	4	13.3%
Clinic Location				
Rural	2	20%	12	40%
Urban	8	80%	18	60%
Clinic Visit During Audit Period				
Yes	10	100%	27	90%
No	0	0%	3	10%
Concurrent Benzodiazepine Prescription				
Yes	3	30%	16	20%
No	7	70%	24	80%

Table 4.3

Naloxone Co-Prescriptions Dispensed by Provider Type

	Physician 1	Physician 2	PA 1	PA 2
Naloxone Prescribed - Yes	1	6	2	1
Naloxone Prescribed - No	1	14	11	4
Clinic Location (Rural/Urban)	0/2	1/19	13/0	0/5
Total Eligible Patients	2	20	13	5
Adoption/Co-Prescribing % Per Provider	50%	30%	18.18%	20%
Adoption/Co-Prescribing % Within the Organization	5%	50%	32.5%	12.5%

Figure 4.1

Improvement in Naloxone Co-Prescription Rates

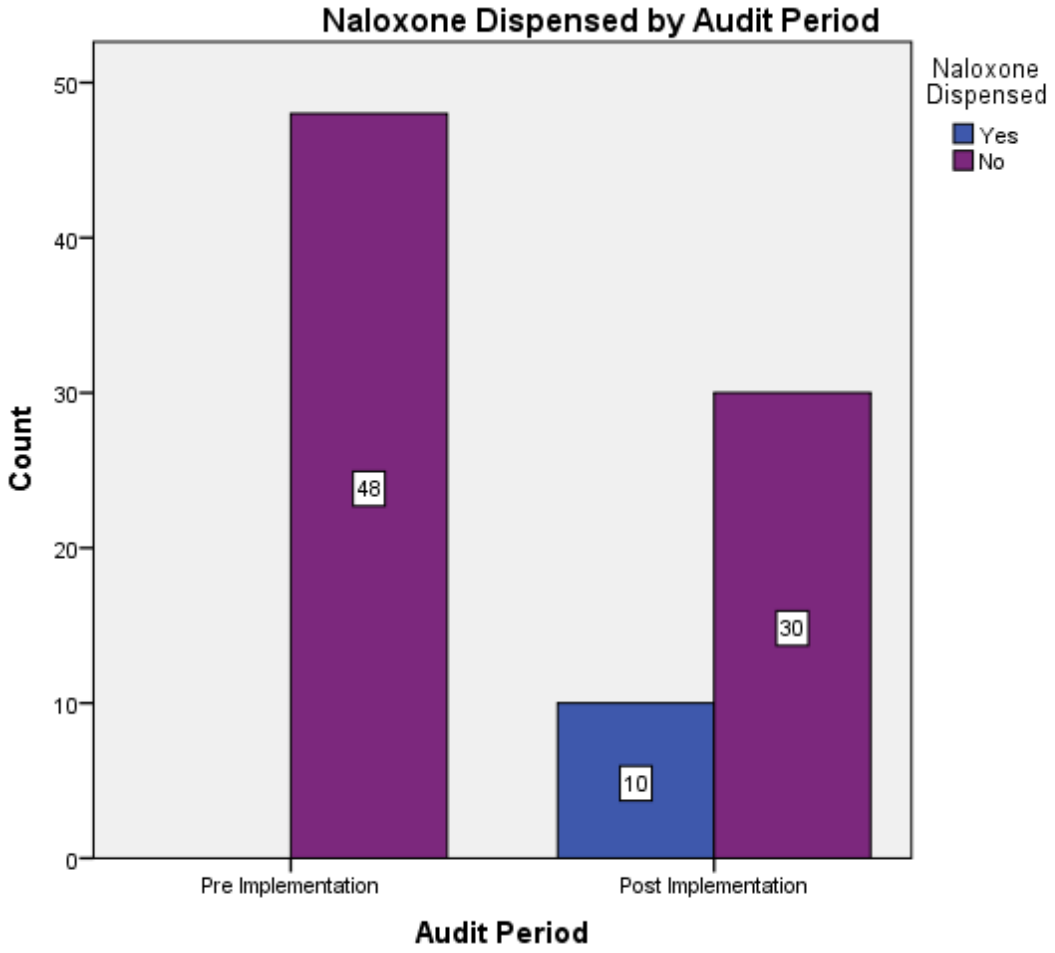
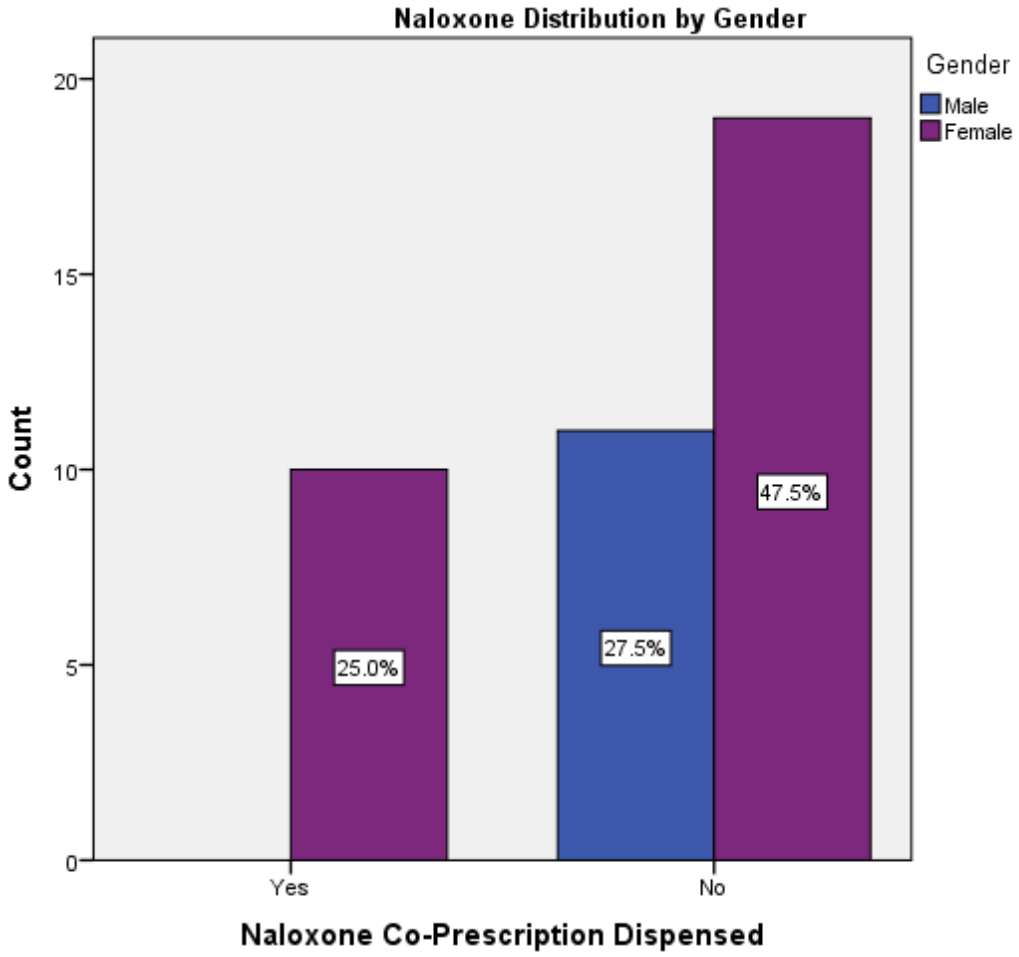


Figure 4.2

Naloxone Distribution by Gender



CHAPTER 5

DISCUSSION

This EBP project was designed to answer the PICOT question: "*Among primary care providers in a tribal health clinic, does the introduction of an evidence-based multi-faceted intervention versus the current practice of no tool, improve the co-prescription rates of naloxone to chronic opioid patients within a 12-week period?"* This project, which was implemented at two clinics located in the Midwest within an Indian Health Services Health Department, sought to determine if a multi-faceted intervention, which included an academic detailing session, the use of a clinical champion and visual reminders, influenced the behavior of providers to increase naloxone co-prescription rates. An explanation of project findings, along with examination of key factors that contributed to success and project limitations, will be discussed in this chapter. Additionally, evaluation of theoretical and EBP framework utilized to guide this project and implications for future projects of this nature will also be detailed.

Explanation of Findings

Although the naloxone distribution policy from which this project was initially conceived, was part a larger organizational policy, logistical implementation and acceptance was left up to the individual departments of the organization. The evaluation plan for this EBP project was directed to answer the primary outcome question, but also was intentionally designed to evaluate secondary outcomes in an effort to guide future naloxone co-prescription practices.

Question one: *What are the naloxone co-prescription rates and are they significantly different between the two project periods?* As the primary outcome for this project, the majority of focus was placed on this particular query. Initially, zero naloxone prescriptions had been distributed in the pre-intervention stage (n = 0, N = 48). The pre-intervention period data was procured via a retrospective chart audit of eligible patients who obtained an opioid prescription of 30 days or greater during the time period of September 25th, 2016 to December 15th, 2016.

This data was then manually reviewed to ensure accuracy and quantified using an audit sheet developed by the DNP student facilitator. The audit processes were repeated for the 12-week period that followed the prescribing providers' AD session and distribution of educational materials by the clinical champion (September 25th to December 15th, 2017). Initially, the timing of the project was scheduled to coincide with the purchase and delivery of naloxone stock and availability of providers to attend the AD session; however, a delay in the naloxone stock delivery, caused the product to be unavailable for physical distribution within the clinic setting for the first 10 days of the project intervention period. Thus, providers initially had to write a prescription to be filled by the patient elsewhere. Of the 40 possible eligible patients receiving an opioid prescription of 30 days or greater during the intervention period, 25% (n = 10) were given a naloxone prescription, a statistically significant increase (X^2 = 13.538, p <.001). The increased percentage of co-prescriptions written for eligible patients was congruent with the supportive evidence reviewed for this EBP project (Behar et al., 2017; Bounthavong et al., 2017; Coffin et al., 2016; Delaney et al., 2016; Devries et al., 2017).

Additional secondary outcomes were evaluated based solely on data from the implementation period since no naloxone co-prescriptions had been given pre-implementation. To evaluate if any further relationships existed, additional parametric and non-parametric testing was completed to determine statistical significance.

Question two: *Does patient age influence the likelihood of dispensing a naloxone co-prescription?* Previous literature indicated that providers were more likely to prescribe naloxone to patients who were older (Behar et al., 2016). However, within this EBP project, the age of those who received naloxone (M = 50.5) was similar to those who did not (M = 49.7); therefore, a statistical relationship relating to age was not established (t = 0.207, p = .837).

Question three: Does patient gender influence the likelihood of dispensing a naloxone co-prescription? While male patients represented 27.5% of those eligible for the co-prescription, none received the naloxone. Females accounted for the remaining 72.5% of the

population and were the recipients of 100% of the naloxone distributed during the project. Although none of the supportive evidence reviewed for this project indicated gender bias in co-prescribing, the difference in co-prescribing among gender within this project did achieve statistical significance (X^2 = 5.057, p = .025).

Question four: *Does the amount of daily MME influence the likelihood of dispensing a naloxone co-prescription?* Behar (2016) discussed that prescribing providers were to utilize naloxone co-prescriptions among either subgroup of patients prescribed high (> 20 MME) or low dose (< 20 MME). Among the patients seen during the intervention period, there was a wide range in the daily MME amount (2.5 to 172.5, M = 24.16, SD = 30.96). Contrasting Behar's findings, those that received naloxone, did have a higher MME amount (M = 39.68) than those who did not (M = 22.99), the difference among these groups could be attributed to the small population size and the inclusion of one outlier who had a daily MME of 172.5 (one of the naloxone recipients). This postulation was further supported when statistical significance was not established regarding prescribing patterns related to daily MME (t = 1.500, p = .142).

Question five: *Does the concurrent prescription of benzodiazepines influence the likelihood of dispensing a naloxone co-prescription?* Guidelines indicate that concurrent use of benzodiazepines are a risk factor for increased opioid overdose potential, and this was an issue that was discussed during the AD session conducted by the clinical champion (Alexander et al., 2015; CDC, 2016a; Duvivier et al., 2017; USDHHS, 2016). When the providers were provided their individual list of patients currently receiving opioid prescriptions, concurrent benzodiazepine prescriptions included. Although 30% (n = 3) of the 10 patients receiving a naloxone co-prescription were found to be also on a benzodiazepine prescription, overall 22.5% (n = 9) of those seen during the implementation period (N = 40) were concurrently receiving a benzodiazepine. This did not indicate statistical significance in regard to naloxone co-prescribing practices (X^2 = .430, p = .512).

Question six: *Does the clinic location influence the likelihood of dispensing a naloxone co-prescription?* Early community distribution programs for naloxone have focused on urban populations, and current literature appears to maintain much of the same focus (Behar et al., 2016; Behar et al., 2017; Binswanger et al., 2015; Bounthavong et al., 2017; Coffin et al., 2016; Delaney et al., 2016; Devries et al., 2017; Mueller et al., 2015; Wilson et al., 2017; Winograd et al., 2017). However, the CDC (2016b & 2016c) has indicated that both rural and urban populations are affected by opioid overdose and are in need of intervention. Naloxone co-prescriptions were dispensed to 10 of the total eligible 40 patients. Of those 10, two (20%) were rural patients and eight (80%) were urban patients. While the urban setting in this EBP project dispensed naloxone prescriptions at a 4:1 ratio over the rural setting, this difference was not statistically significant ($X^2 = 1.319$, $p = .251$).

Question seven: *Does the provider discipline (PA or physician) influence the likelihood of dispensing a naloxone co-prescription?* While the DNP student facilitator was the EBP project leader and clinical champion, she was also the only nurse practitioner within the practice, stationed at a third location of the organization, which due to its focus on acute care visits, did not typically see patients who would meet project inclusion criteria. Therefore, the DNP student facilitator postulated that the other advanced practice clinicians (PAs) may be more open to adoption of the naloxone co-prescribing intervention since they had an educational attainment level similar to the clinical champion. It was also postulated that since both of the PAs were stationed full time in a single clinic, they would take more ownership of eligible patients and thus have higher naloxone co-prescribing adoption levels when compared with the full time MD and part-time MD who rotated between each of the clinics. However, during the intervention period, physicians saw 55% of the eligible patients ($n = 22$, $N = 40$) and prescribed 70% of the naloxone ($n = 7$, $N = 10$). Ultimately, this correlation also did not achieve statistical significance ($X^2 = 1.212$, $p = .271$).

Evaluation of Applicability of Theoretical and EBP Frameworks

To guide this project systematically, both a theoretical framework (Kotter's Model of Change) and an EBP framework (the Iowa Model of Evidence-Based Practice to Promote Quality Care) were utilized. The applicability of both will be discussed further below.

Theoretical Framework

The Model of Change, developed by John Kotter has provided a linear approach to behavioral change in an organization (Melnyk & Fineout-Overholt, 2015). While the project facility was smaller in size than others in similar projects (Behar et al., 2016; Behar et al., 2017; Bounthavong et al., 2017; Coffin et al., 2016; Delaney et al., 2016; Devries et al., 2017; Oliva et al., 2017; Wilson et al., 2017), numerous organizational obstacles still needed to be addressed to ensure project success; thus, Kotter's model was well suited to this EBP project.

Kotter's first step, establishing a sense of urgency, was instrumental for obtaining the support and cooperation of those involved with the change process. Much of this step was initiated prior to the development of this EBP project. Due to a heightened awareness created by national media coverage, the recent tribal health survey, and the ability to attend various seminars and webinars by both management and clinical staff, support for the project was garnered. Organizational leaders were aware of the opioid epidemic and thus had drafted a policy for naloxone distribution, but clinically this had not been implemented due to lack of process and procedures. The top-down approach of recognition and acknowledgement of the clinical problem was the catalyst for this project.

The second step was to create a powerful guiding coalition. With the support of upper level organizational leadership and health department management, a clinical team was assembled to determine how to best implement the naloxone distribution policy and ensure safe opioid prescribing practices. While initially this team included the prescribing providers and RN clinical manager, it was later expanded to include members of behavioral health and other clinical support staff. Working on projects in a team-based format was familiar to the invested

parties and was further supported by utilizing Kotter's model. As the timing of these initial first steps coincided with the DNP student facilitator's educational plan for an EBP project, it became an obvious and unanimous decision for the DNP student facilitator to lead the group and direct the project. Further support of the project was realized when management, recognizing the sense of urgency, (a) allowed team members to block schedules to attend meetings, (b) supported the DNP student facilitator's use of available work resources (i.e., computer, internet, printer, and copier), and (c) permitted the DNP student facilitator to work on the project during periods of decreased patient down time.

Consistent with Kotter's third step of developing a vision, the assembled clinical team determined that they would like to pilot an evidenced-based method to distribute naloxone to current clinic patients as another positive step in their efforts to enhance safe opioid prescribing practices. As organizational leadership had already developed and approved a general policy that supported naloxone distribution to anyone who accessed clinic services, the team needed to further refine that vision and develop a strategy which would garner widespread support. Thus, after review of literature and synthesis of available evidence, it was envisioned that all clinic patients who received opioid prescriptions of 30 days or greater would be co-prescribed naloxone.

While the prescribing providers and RN clinical manager had been supportive of the project from inception, it was recognized that discussion of opioid overdose prevention strategies could be an uncomfortable topic for others; therefore, it was imperative to develop a clear strategy to complete Kotter's fourth step: communicating the vision. Team members sought to include ways to decrease barriers and misconceptions regarding the distribution of naloxone for potential administration by lay persons. To address the issue among clinic staff, some with medical knowledge and some without, a brief naloxone detailing session was provided by the DNP student facilitator during a health staff meeting. The session afforded an opportunity to communicate the vision of the project and aided in eliminating preconceived

negative ideas or thoughts regarding naloxone. Questions were welcomed and addressed in the group setting and a further opportunity to address any other questions or concerns in private was also provided. This academic detailing was duplicated at a more in-depth session for behavioral health staff who, coincidentally, began distributing naloxone to their own at-risk clients during the same time period. To communicate the vision of naloxone distribution and eliminate potential misconceptions of naloxone, further communication to patients and clients was conducted via written and pictorial methods, as well as one-on-one discussions. To achieve this, a brief article, written in layman's terminology, was authored by the DNP student facilitator, and included within the quarterly health publication that was distributed to all patients and clients who accessed the health department (Appendix J). Additionally, 8.5" x 11" posters from prescribetoprevent.org (Appendix E) were obtained, printed, and placed in the waiting areas, the backs of restroom doors, and in examination rooms.

Kotter's fifth step has focused on empowering others to act on the vision. To accomplish this, the team decided that including clinical staff in the AD session and giving them access to the naloxone stock would be beneficial. While the intended outcome of this EBP project was to improve naloxone co-prescribing rates among those receiving opioid prescriptions of 30 days or greater, the ultimate goal was increase naloxone acceptance and availability among the tribal community. It was felt that giving other staff members, clinical or not, knowledge of the processes so that they were able to inform others would work towards these larger goals while supporting the prescribing providers' more immediate and measurable goals of this project.

The sixth step in Kotter's model, planning for and creating short-term wins, was achieved in a number of ways. Throughout the project, administrative support was readily given, thus facilitating the staff's acceptance of the change process. Allowing staff and the DNP student facilitator time to work on the project as a team propelled this intervention forward. The major win, however, was when organizational leadership approved a direct purchase agreement and funding for the naloxone to be physically stocked within the clinic. While this additional support

was not initially anticipated, the DNP student facilitator became aware of this initiative during the planning stages and incorporated the distribution of stocked naloxone into the implementation phase. The acquisition of physical naloxone stock eliminated multiple barriers; patients would be able to receive naloxone without worry of cost, availability, or acquisition. For staff, this early win was helpful in the anchoring change process, as it created a pathway that would ease and simplify the procedure of naloxone distribution. Further short-term wins were celebrated by the occasional delivery of snacks brought by the DNP student facilitator and left in the break areas for all staff to enjoy, written with a visual message of "Nalox (save some) one: Thanks for all you do!" This reinforcing strategy also created an opportunity for staff not directly involved with the project to have conversations regarding naloxone, further contributing to sustained organizational change and acceptance. Other short-term wins that were directed more specifically towards the prescribing providers were regular updates at monthly provider meetings regarding the progress of distribution, such as when the first naloxone had been dispensed. As was supported in the literature, (Behar et al., 2016; Coffin et al., 2016), a planned, formalized email was sent at the midway point of the implementation to the prescribing providers which communicated distribution progress to that point thanking them for their participation, celebrating the progress to date and providing a reminder to continue with naloxone co-prescribing practices.

Although Kotter's model was designed to be linear in nature, the seventh step (consolidating achievements and producing more change) was recognized both during the implementation stage and following implementation as data were evaluated. While during the sixth stage, progress was being communicated for short term wins, this was simultaneously contributing to the formalized step in the model. At the conclusion of the implementation stage, all data, results and achievements were translated into a narrative format which describes the overall effect of the practice change. Furthermore, the results of the EBP project contribute to anchoring practice change by recognition of future barriers and additional adaptations needed.

The changes were further anchored during the process of transitioning to a new EHR system, when the team constructed built in templates for ease of documentation. Additionally, realizing the distribution process was successful and being utilized by several departments from a single naloxone stock, funds for the 2018 fiscal year were procured to continue to provide the supply. Finally, while outside the time constraints of this intervention period, it has been noted during informal reviews of current naloxone distribution logs that other patients with a documented chronic opioid medication, have since received naloxone. Most notable is that several of these patients are male. This is indicative that naloxone co-prescribing practices are continuing to be adopted by providers and accepted by patients.

The eighth and final step in Kotter's Change Model is institutionalizing new approaches. Again, while linear in design, this final step was considered throughout the project in an effort to not just change naloxone co-prescribing practices for chronic opioid patients, but to change the naloxone perception and availability for all who utilize the clinic. The team recognized that this process change was a new approach to safe opioid prescribing and may be uncomfortable for staff and patients to discuss and accept. Through this EBP project, patients and staff became more accustomed to naloxone distribution and created a new culture of acceptance and standard of practice, thus creating a sustainable and viable practice change. To continue sustainability and anchor organizational change, further efforts have been made to ensure naloxone stock continues to be accessible to those who utilize it and the DNP student facilitator continues to act as clinical champion. Additional measures to ease documentation and alert providers of eligible patients are being built into the new EHR, which will further anchor co-prescribing practices. Recognizing that measures to combat the opioid epidemic, whether from prescribed medications or illicit substances, are rapidly changing, the health department director and clinical manager continue to support ongoing efforts to stay abreast of the latest trends. Recently, they have approached the DNP student facilitator, requesting that she attend the May

2018 National Tribal Public Health Summit and Tribal Health Opioid Consultation, as a representative of the Clinic X Tribe.

EBP Framework

EBP is model of care driven by evidence-based research, clinical expertise and patient preference (Schmidt & Brown, 2015). Using these elements, the utilization of EBP improves the quality and outcomes of patient care. The use of EBP models assists in translating evidence into clinical practice and provides a systematic approach to navigating complex healthcare systems and disciplines.

The Iowa Model was chosen for this project as it provides stepwise, team-based approach to initiating change. The Iowa Model includes (a) identifying a problem-focused or knowledge-focused trigger, (b) determining if the problem is identified as a priority for the organization, (c) assembling a team, (d) reviewing and synthesizing the available literature, and (e) conducting a pilot change (Titler et al., 2001).

Several of the steps with the Iowa Model correlated with Kotter's 8-Step Process of Leading Change; thus complementing each other in theory and framework. The Iowa Model was a good fit because it provided the necessary guidance to initiate the change process. The five steps of the process were easy to follow and provided the doctoral student guidance and support for initiating change in a practice that was not engrained with EBP. As the organization had already made clear that the issue of naloxone distribution was a priority, the first step, identifying a problem-focused trigger, was easily recognized. Thus, the creation of the team, led by the doctoral student, was undertaken, and a review of the literature embarked upon. The Iowa Model directed the team and the DNP student facilitator (in her role of team leader) to assemble and evaluate evidence that was used to guide implementation of the EBP project.

Upon determining there was sufficient evidence available to proceed with a pilot practice change, the Iowa Model further guided the DNP student facilitator and team to collect baseline data, determine outcomes and begin implementation. The pilot change was determined to be

successful based on the increase in naloxone co-prescriptions distributed during the intervention period. Additional review to further improve the EBP practice change has been discussed in efforts to improve on the current process, with a new outcome objective of increasing the naloxone co-prescription rate to 75% of all eligible chronic opioid users. The team initially formed for this project will remain in place and be utilized to translate other EBP projects into clinical practice changes.

Strengths and Limitations of the EBP Project

Strengths

This EBP project had numerous strengths. The one considered to have the most impactful effect on the project was the collaboration and cooperation of the leadership and prescribing providers. The support and desire of the leadership to see this project facilitated and directed was instrumental in the undertaking and success. The utilization of synthesized literature to implement evidence-based practice changes was a strength to garner support from leadership sources. In this project, the health department director and organizational leadership did not have a clinical background; their area of expertise was business management. Knowing this, the DNP student facilitator utilized data in terms of significance, costs, and potential long-term savings to further anchor support for the long-term sustainability of this practice change. Additionally, the collaboration of the prescribing providers, who themselves, while resistant to changes as most individuals are, recognized that this was an issue which needed to be addressed. The attention and time devoted by all vested parties proved to be a key consideration, further aligning with Kotter's Model of Change and the Iowa Model directive to determine if an issue is a priority to the organization.

A second strength to this project was the procurement of physical stock and availability of naloxone. While this was not planned for initially, it was helpful and eliminated barriers previously noted in similar projects (Behar et al., 2017; Behar et al., 2016; Coffin et al., 2016; Delaney et al., 2016). It also answered one of the questions initially posed by providers, who

queried, “even if we write the prescriptions, how do we know they (patients) are filling them?” The procurement of this stock and initiation of this project also provided an avenue for other disciplines within the clinic to begin discussions with clients and facilitated the development of a procedure that enabled staff to dispense kits to those individuals who were felt to benefit from the receipt of naloxone, whether for themselves or an at-risk family member.

Additionally, this project provided a basis on which to open communication lines between organizational leadership, the health department, tribal police department and the tribal affiliated casino security, and emergency medical technician (EMT) staff. Discussion and implementation of this project, designed to focus on naloxone co-prescribing, sparked further undertakings to increase naloxone awareness, increase community distribution, and decrease the negative stigma often associated with naloxone utilization. Through these communications, the tribal council of the organization has approved future funding for naloxone purchasing, the tribal police have secured their own stock, and the casino EMTs have had naloxone training and carry it in their medical bags. The tribal police department has also agreed to the installation of a secured “Red Med Box” in which unused medications, including opioids, can be safely disposed. This box had previously sat in the basement of the health department unused and essentially forgotten, until discussion directly stemming from this project occurred.

Finally, the use of the DNP student facilitator in the role of the clinical champion was viewed as a strength. While the facilitator was completing the final portion of her doctoral studies, she was also a practicing NP employed within the organization. This first-hand knowledge was beneficial to the implementation process and navigation of the organizational structure unique to tribal entities. The utilization of a prescribing provider colleague in this role allowed the AD sessions and subsequent contacts with the providers to be tailored to meet the individual personalities and needs, thus creating further acceptance of a practice change. Time devoted to leading the change, armed with current knowledge of standard practice within the

organization, the barriers that may be encountered as well as the expertise and focus for completion, proved to be instrumental in the successful implementation of this EBP project.

Limitations

While the project had multiple strengths, it certainly was not without limitations. The major obstacle in the EBP project was the sample size. Having only four prescribing providers and a small pool of eligible patients (pre-intervention: *N* = 48, intervention: *N* = 40) from which to conduct analyses made it difficult to determine if these results would be replicable on a larger scale, although they were similar to 25% adoption rates reported in the literature (Devries et al., 2017), and if the percentage change would be statistically significant if the larger population size provided adequate power to determine the intervention effect. While the clinical champion was a nurse practitioner, the providers in the intervention only represented two of the three major disciplines often seen in primary care, which limits the ability to confidently translate the results of this EBP project across all education backgrounds. Devries et al. (2017) noted that physicians (85.3%) were found to be more likely to prescribe naloxone than NPs (9.8%) and PAs (3.7%), a finding that was replicated similarly in this project (physician prescribing accounted for 70% of the naloxone co-prescriptions). Consideration of different academic backgrounds and/or multiple clinical champions may be indicated for future projects of this design.

Another limitation to this project was being conducted in an organization that while well-versed in grants, QI projects and data collection, was not familiar with formal EBP processes. Although IRB approval was obtained from the university IRB, the project facility did not have a formal IRB in place. This was an organization that typically had dissemination through tribal or governmental channels and was not familiar with the IRB processes which were deemed necessary by the university to ensure protection of subjects for dissemination of findings. When the DNP project facilitator approached management and the health department director early in the process to review the planned intervention and explain the needed approvals, management

determined that the university IRB approval would be sufficient. A week prior to the planned intervention start, the health director of the organization began to reconsider whether the university IRB would be adequate or if a further review process was indicated. The university IRB packet and approval were given to the health director for review; and, the director determined that the processes included within the university IRB application were thorough enough to meet the needs of the tribal organization and permission was obtained to proceed with the proposed intervention. While ultimately, no delay in the proposed start date occurred, the timing of the additional review by organizational leadership did result in additional concerns about being able to carry out the academic detailing sessions as scheduled and determining whether the project would be conducted at all.

An issue which did delay full implementation status, but ultimately did not appear to hinder the project outcomes was the availability of the physical naloxone stock. The project was carefully timed to encompass every three month visit recommendations from the CDC (2016a), while avoiding the decreased patient volume due to multiple closures related to the approaching holiday season. As mentioned previously, the availability of the naloxone stock was not part of the original planned intervention. However, this beneficial procurement was approved and therefore, incorporated into project. Due to the time constraints of implementation start dates and availability of the providers, it was deemed prudent to proceed with the scheduled AD sessions even though the naloxone stock had not arrived at the project facility. The prescribing providers were instructed to write for a prescription of naloxone, which the patient could then fill at an off-site pharmacy of their choosing during the interim. Stock arrived ten days after the AD sessions and was distributed the following day to both project sites by the DNP student facilitator. Although the DNP student facilitator recognizes that not all clinic facilities attempting to replicate this EBP project, will be able to supply naloxone directly to the patients, presumably due to the cost factor, it is noted that no naloxone prescriptions were written when the naloxone stock was unavailable.

Another confounding factor that occurred during this project period was the simultaneous implementation of naloxone distribution by the behavioral health staff, potentially providing naloxone to mutual patients of the clinic and thus, removing them from data capture. Although the intention of the project had been made clear to all management staff early in the process, limited opportunities for communication specifically with the behavioral health manager hindered collaboration between the departments. This resulted in a separate, parallel intervention occurring concurrently with the health clinic intervention. While the DNP student facilitator was able to provide a brief AD session to the behavioral health clinicians, it was not specifically tailored to their educational background and was limited regarding time allotment. Additionally, all naloxone was distributed from stock maintained in the clinic via locked access. Although tracking forms and a process was implemented to track what patients had received naloxone, this was not seen to fruition with the behavioral health staff. This resulted in a potential loss of data capture if behavioral health distributed to a shared patient without full documentation on the tracking logs.

The project facility has faced many challenges with their current EHR and although the clinical champion worked with the CAC on several initiatives to ease documentation and educational components regarding naloxone co-prescriptions, this was done with the awareness that the project facility was changing to a new EHR in the coming fiscal year. While specific education was given during the provider AD session regarding the process for documentation, it was found that only one of the naloxone distributions was completed in the EHR and the rest were tracked solely via the paper distribution log maintained with the naloxone stock. It remains unclear if the resistance to documentation in the EHR lies with the cumbersome way it must occur, provider resistance to process change or whether the effort to do so was lacking knowing that a new documentation system would be implemented in the near future.

Although initially planned to occur more frequently, the clinical champion was limited in face to face contact. Although the providers were accustomed to practicing in separate clinics,

there had previously been opportunities for at least monthly in person contact and further video conferencing contacts. Due to a change in the way monthly health staff meetings were conducted and the inability to video conference related to equipment issues, the clinical champion's ability to have in-person contact was limited. Phone and email contacts were increased to counteract this issue, however the effect, whether positive or negative, this may have had on the overall intervention cannot be determined.

Additional limitations that are notable include the rate of patient acceptance. While this project focused on provider adherence to co-prescribing practices, there was no method established to determine naloxone acceptance by the patient. Further, there was no formal tracking method to determine if any of the 40 eligible patients in the project had already received naloxone from other sources such as community distribution programs. Finally, although the 12-week time frame was chosen to mimic CDC (2016a) recommendations of a re-evaluation visit, it was also fashioned in that manner to meet the time constraints of the DNP student facilitators academic schedule. Therefore, it is quite feasible that a longer time frame would provide increased access to the 40 eligible patients receiving opioids (30 days or greater) and result in higher naloxone co-prescribing rates.

Implications for the Future

Practice

In response to increasing prevalence and focus on the opioid epidemic, several national agencies (i.e., the CDC, USDHHS, VHA and IHS) have published guidelines focused on promoting safe opioid prescribing. Each of these respective guidelines have identified naloxone co-prescribing as measure to ensure safe prescribing practices, yet the authoring groups have given little direction on how to accomplish this task.

As clinicians continue to incorporate practice changes to address evolving opioid issues, this EBP project demonstrates that advanced practice nurses are well situated to search, evaluate, and appraise rapidly evolving research and develop a systematic approach to

translate current evidence into daily practice. This project further represents that even when acting as the lone advanced practice nurse among a multi-disciplinary practice setting, doctoral prepared nurses are well-positioned to champion the implementation of evidence-based practice changes. This project can easily be replicated to other tribal health facilities and primary care settings.

Theory

Change is difficult for many individuals and facilities to embrace. Therefore, a systematic approach that provides a roadmap to incorporate current evidence and guidance for overcoming obstacles that may be encountered along the way is crucial when implementing changes to parties that may be resistant to doing so. Kotter's Change Model and the Iowa Model both provided the necessary framework for this project to proceed successfully. Both this theoretical and EBP framework will continue to be beneficial as the DNP project facilitator disseminates the results of this project, thus anchoring change in practice and lending support to future use of these models when implementing additional EBP practice changes.

Research

Future research should include larger sample sizes and multiple clinical facilities to determine generalization of findings across various settings. Additionally, this EBP project was conducted over a 12-week implementation time frame and further longitudinal studies are needed to determine if knowledge garnered from the AD session is sustained or if additional follow up AD sessions are indicated. Further, the clinical champion in this project was not available to make face-to-face contact on a frequent basis, therefore additional studies should evaluate the effectiveness of an off-site versus physically on-site champion and its subsequent effect on naloxone co-prescribing rates.

While this project facility was able to distribute naloxone at no cost to the patient, this may be cost prohibitive to other facilities and therefore, not replicable. Additional studies should be conducted to determine what role, if any, the immediate access plays on provider adoption

and patient acceptance rates. Finally, this project unfortunately was not designed to evaluate patient acceptance rates if naloxone was offered. Thus, future research and QI projects should be designed to evaluate those patients who decline naloxone co-prescribing, the barriers for acceptance and methodology to decrease those barriers as well as tracking patients who accept the prescription and whether or not they ultimately obtain the naloxone.

Education

Although patient education was not a targeted objective of this EBP project, it did occur as an unmeasured component through printed materials and provider – patient discussion. The AD sessions developed and tailored for the individual prescribing providers were adapted several times to target additional staff members, who may or may not possess clinical terminology within their positions. Hence, the DNP facilitator was well situated to morph between clinical language and lay terminology to meet the needs of the intended audience.

Additionally, this project further opened communication lines for future education and naloxone distribution, potentially to individuals who did not meet inclusion criteria of this project. While the prescribing providers, who were the target of this intervention, were supportive and receptive to naloxone discussions, it became apparent that not all staff members possessed the same level of comfort and at times were visibly uncomfortable when the conversation was broached. Future educational efforts should incorporate increased awareness of the participants' comfort level regarding naloxone and its use in opioid overdose prevention in order to best facilitate receptiveness.

Conclusion

This EBP project answered the query posed by the initial PICOT question: Among primary care providers in a tribal health clinic, does the introduction of an evidence- based multi-faceted intervention versus the current practice of no tool, improve the co-prescription rates of naloxone to chronic opioid patients within a 12- week period? The answer was a resounding yes. The project further demonstrated that doctoral prepared advanced practice nurses are well

situated and adequately educated to act as change agents by the ability to develop, implement and evaluate clinical practice changes. This a crucial component for improving quality of care and patient outcomes through the incorporation of evidence-based practices. Additionally, this project demonstrated that DNP led practice changes can have a positive, unintentional ripple effect towards larger collaborative organizational changes.

Safe opioid prescribing, and naloxone co-prescribing are a rapidly increasing healthcare concern which affects people of all genders, ethnicities, ages, geographic locations and socioeconomical status. Even as this EBP project associated with the DNP student facilitator coursework comes to a close, the CDC (2018) is releasing new, alarming statistics that the Midwestern region saw opioid overdose rates increase 70% from July 2016 to September 2017, the point at which this EBP project intervention began. Experts continue to call for coordinated efforts among providers to judiciously prescribe opioids and increase naloxone distribution (CDC, 2018). While this EBP project included small numbers of patients, the findings did indicate a viable and effective evidenced-based intervention for primary care providers to contribute to safe opioid prescribing and OEND efforts. Failure to incorporate evidenced-based practice into efforts to squelch the ever-shifting horizon of the opioid epidemic could result in devastating consequences to those directly affected and their loved ones left behind.

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BIOGRAPHICAL MATERIAL

Jolane began her nursing career in 1998 as a licensed practical nurse. Furthering her studies, she graduated with an associate's degree in 2000 from Glen Oaks Community College. While in school, she began working as an Emergency Department (ED) technician and discovered her passion to work with underserved populations. Jolane spent several years working in community EDs in both Indiana and Michigan, serving as a staff nurse, preceptor, and charge nurse as well as teaching ACLS and PALS classes. She also worked as an acute care float on various units which helped prepare her for her role as a fixed wing air transport nurse.

Jolane returned to school and pursued her BSN, graduating from Goshen College in 2006. In 2010, she achieved her professional goal and became a certified family nurse practitioner when she earned her master's degree, also from Goshen College. Her passion to work in underserved populations led her to seek employment within the state correctional system where she provided primary care services to the prison population. Jolane is currently employed through the Indian Health Services Health Department, where she is able to provide a variety of care services to Native American populations. Aware that the nursing profession is changing and in need of those who can advocate for underserved and introduce evidence-based practice into clinical care settings, Jolane once again returned to school to pursue her doctoral degree, which she anticipates receiving in spring 2018 from Valparaiso University. She is a National Health Care Scholars Corp alumni and certified Acudetox Specialist who maintains membership with Sigma Theta Tau (Nu Omicron Chapter and Zeta Epsilon Chapter), American Association of Nurse Practitioners, American Nurses Association, Michigan Council of Nurse Practitioners, Associate member of the American College of Environmental and Occupational Medicine, and The National Registry of Certified Medical Examiners for the Federal Motor Carrier Safety Administration.

ACRONYM LIST

ACE: Adverse Childhood Experience

AD: Academic Detailing

CAC: Clinical Applications Coordinator

CDC: Centers for Disease Control and Prevention

CS: Controlled Substance

DNP: Doctor of Nursing Practice

EBP: Evidence-Based Project

EHR: Electronic Health Record

EMT: Emergency Medical Technician

HIPAA: Health Insurance Portability and Accountability Act

IHS: Indian Health Services

IRB: Institution Review Board

MA: Medical Assistant

MME: Morphine Milliequivalents

MeSH: Medical Subject Heading

NIH: National Institutes of Health

OEND: Overdose Education and Naloxone Distribution

PA: Physician Assistant

PICOT: Problem, Intervention, Comparison, Outcome, Time

QI: Quality Improvement

RCT: Randomized Controlled Trial

RN: Registered Nurse

US: United States

USDHHS: United States Department of Health and Human Services

VHA: Veteran's Health Administration

APPENDIX A

CHART AUDIT

PERIOD: PRE POST
MRN# _____

GENDER Male Female

AGE: _____

TRIBAL AFFILIATION:
XXX TRIBAL OTHER TRIBAL SEC. 813

NALOXONE DISPENSED? Yes No

DOCUMENTED IN EHR? Yes No N/A

CLINIC HOME: XX XX

PROVIDER: XXX XXX XXX
XXX XXX XXX

Qualifying Med?_____

Daily MME?_____

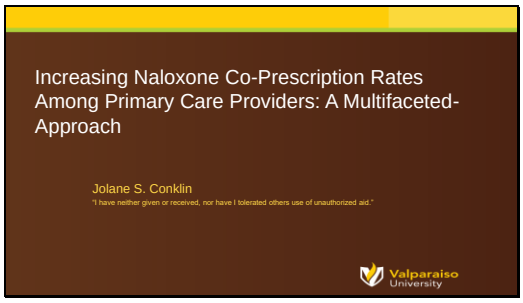
Concurrent Benzo Rx? Yes No

Clinic Visit During Audit Period? Yes No

Primary Dx?_____

APPENDIX B

Slide 1



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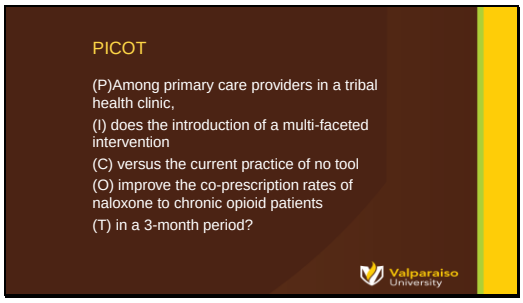

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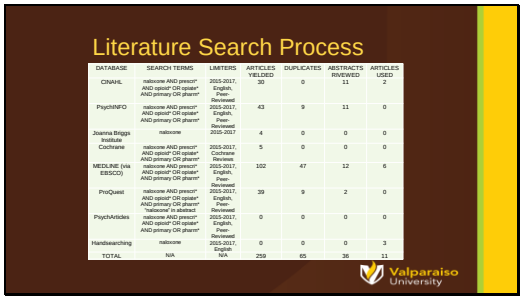


DATABASE	SEARCH TERMS	LIMITERS	ARTICLES YIELDED	DUPLICATES	ABSTRACTS RIVIEWED	ARTICLES USED
CINAHL	naloxone AND prescr* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, English, Peer-Reviewed	30	0	11	2
PsychINFO	naloxone AND prescr* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, English, Peer-Reviewed	43	9	11	0
Joanna Briggs Institute	naloxone	2015-2017	4	0	0	0
Cochrane	naloxone AND prescr* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, Reviews	5	0	0	0
MEDLINE (via EBSCO)	naloxone AND prescr* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, English, Peer-Reviewed	102	47	12	6
ProQuest	naloxone AND prescr* AND opioid* OR opiate* AND primary OR pharm* "naloxone" in abstract	2015-2017, English, Peer-Reviewed	39	9	2	0
PsychArticles	naloxone AND prescr* AND opioid* OR opiate* AND primary OR pharm*	2015-2017, English, Peer-Reviewed	0	0	0	0
Handsearching	naloxone	2015-2017, English	0	0	0	3
TOTAL	N/A	N/A	259	65	36	11

Slide 4

Synthesis of Evidence

Common Themes:

- MAJOR:
  - Academic Detailing
  - Clinical Champion
  - Current Research Rapidly Changing
- MINOR:
  - EHR Alerts
  - Accessibility of physical naloxone prescription

Valparaiso University

Slide 5

Objectives:

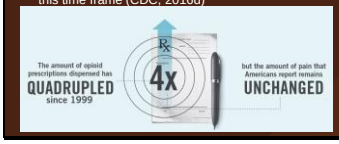
- Providers/Participants will increase:
  - Knowledge base regarding naloxone
  - Comfort level of naloxone co-prescribing
  - Safer prescribing practices
- Expected Project Outcome:
  - Increase in the rate of naloxone co-prescriptions

Valparaiso University

Slide 6

Background Information

- Opioids involved in 61% of all drug overdose deaths in 2014 (CDC, 2016c)
- Opioid overdoses have quadrupled since 1999 (CDC, 2016c)
- Opioid prescriptions have also quadrupled during this time frame (CDC, 2016d)



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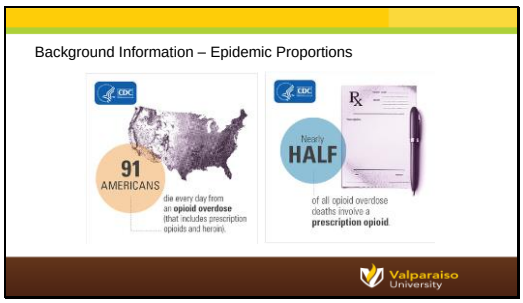

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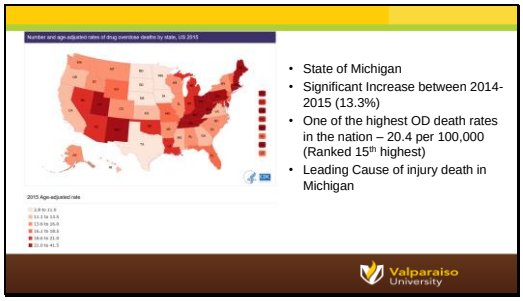

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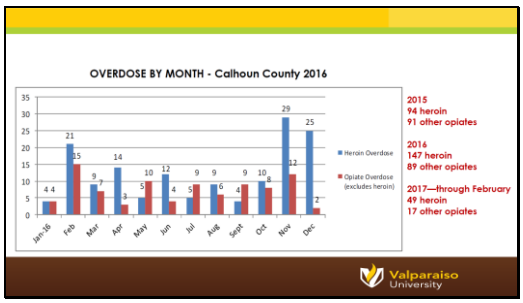

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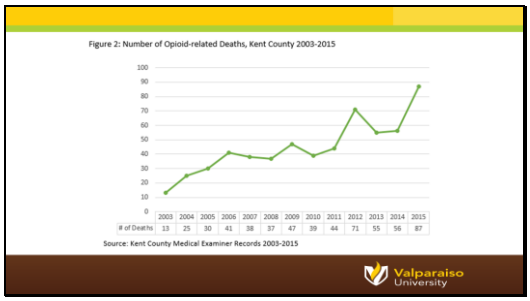
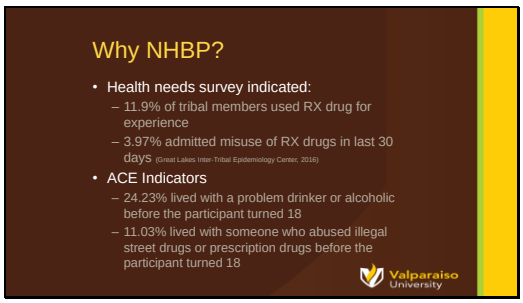


Slide 12

Slide 13



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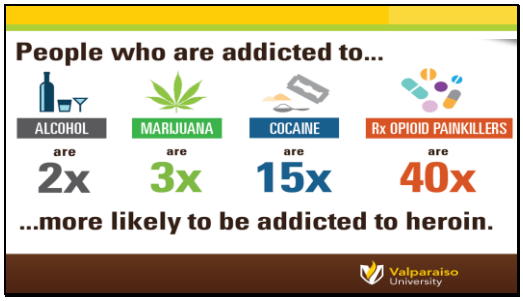

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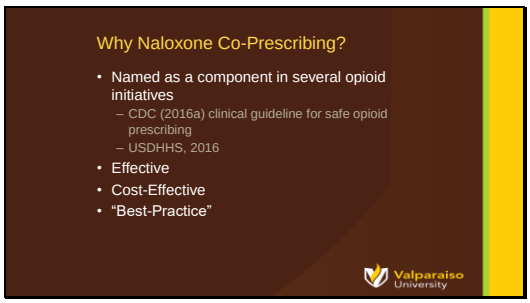

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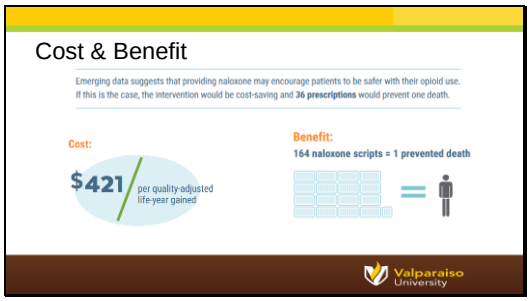

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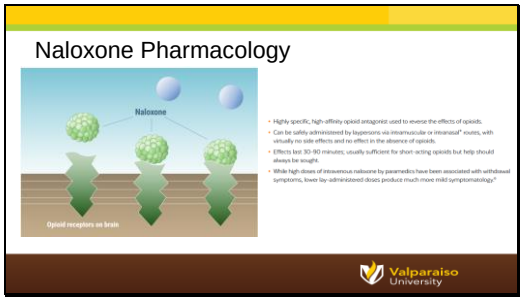

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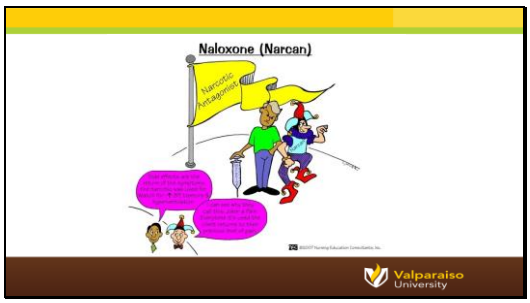

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IHS Naloxone Co-prescribing

Indian Health Service
The Federal Health Program for American Indians and Alaska Natives

- Recently rotated to a new opioid
- Prescribed **morphine equivalent daily (MED) dose of 50mg or more**
- On long acting opioids particularly if in conjunction with short-acting opioids
- Poly-opioid use
- Prescribed opioids greater than 30 days
- Over the age of 65 years
- Households with people at risk of overdose such as children or someone with a substance abuse disorder
- Patients who have difficulty accessing emergency medical services (distance, remoteness, lack of transportation, homelessness, and/or without phone services)
- Recent mandated substance use treatment, incarceration, or period of abstinence with history of drug abuse
- Concurrent prescription or over-the-counter medications
  - Benzodiazepines
  - Antipsychotics
  - Antiepileptics
  - Muscle relaxers
  - Hypnotics
  - Antihistamines
- UNIVERSAL CO-PRESCRIBING????

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Arguments for Universal Co-Prescribing

The American Medical Association has endorsed the distribution of naloxone to anyone at risk for having or witnessing an opioid overdose.[1]

CONSIDER OFFERING A NALOXONE PRESCRIPTION TO:

- All patients prescribed long-term opioids
- Anyone otherwise at risk of experiencing or witnessing an opioid overdose

WHY PRESCRIBE TO ALL PATIENTS ON LONG-TERM OPIOIDS?

It is difficult to predict which patients who take prescription opioids are at risk for overdose.

Many patients do not feel they are at risk for overdose. Prescribing to all patients on opioids will help patients understand naloxone is being prescribed for risky drugs, not risky patients.

About 40% of overdose deaths result from diverted medications.[1] Whether intentional or unintentional, diverted opioids are a serious risk. Co-prescribing naloxone increases the chance that the antidote will remain with the medication.

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Opioid Safety Language

- Avoid word "overdose"
  - Negative connotations
  - Prescription opioid users may not relate
- Instead use:
  - "Accidental overdose"
  - "Bad Reaction"
  - "Opioid Safety"
  - Use Epipen analogy

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Other Distribution Notes

- Nasal formulation
  - Keep in pack
  - Store between 59-77 degrees
  - Protect from light
- May provide patient with "Quick Start Guide" (Included in NHBP policy)
- Opioid Safety pamphlet
- Have patient tell someone where the keep it!

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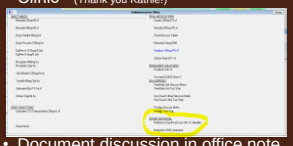
Documentation

- Able to pick from "Administered in Clinic" (Thank you Kathie!)



- Document discussion in office note
- Follow NHBP policy

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Current NHBP Policy

- Copy included in packet
- Allows for “3rd Party Prescribing”
- Staff mandated to have annual training
- Naloxone stored in formulary (or will be)
- Adapt pharma training video
- Training completion form
- Log of distributed naloxone kits

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Adapt Pharma Video

- http://adaptpharma.com/news-events/press-kit/
- Also accessible through “Narcan Now” app
- How would staff like this available for easier access?
  - Email link?
  - Install Shortcut to each computer?
  - Have IT add link to intranet?
  - Other ideas?

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Michigan Law Updates

- Signed into law on Wednesday, Dec. 28, 2016.
- Public Act 383 of 2016.
- **Authority**
  - This standing order is issued pursuant to Michigan law which allows the Chief Medical Executive (CME) to issue a standing order that does not identify particular patients at the time it is issued, for the purpose of a pharmacist dispensing the opioid antagonist naloxone. MCL 333.17701 *et seq*.,
- **Authorization**
  - This standing order may be used by pharmacists to generate a prescription for Eligible Individuals to obtain naloxone from a pharmacy. This order is authorization for pharmacists to dispense naloxone and devices for its administration SOLELY in the FDA-approved naloxone formulations and devices prescribed herein.
- Link to info regarding law: http://www.michigan.gov/documents/budget/Emergency_Rules_Opioid_Antagonists_572010_7.pdf
- http://www.legislature.mi.gov/(S(kxxcot1o5lsyf45ro11bge4c))/mileg.aspx?page=GetObject&objectname=2016-HB-5326

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What Next?

- 12 week intervention
- Clinical Champion support
- MAPS reports for each provider
- Article in Fall Health Publication
- Other Resources in Packets
- Info posters in rooms
  - Information for patients
  - Visual Reminder for clinic staff

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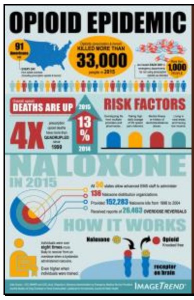

Questions??

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APPENDIX C

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

Naloxone
for opioid safety

A provider's guide to prescribing naloxone to patients who use opioids

Overdose is the leading cause of injury-related death in the U.S.

100 PEOPLE DIE FROM DRUG OVERDOSE EVERYDAY IN THE UNITED STATES.

FIGURE 1. DEATH BY LEADING CAUSE OF INJURY (PER 100,000)[1]

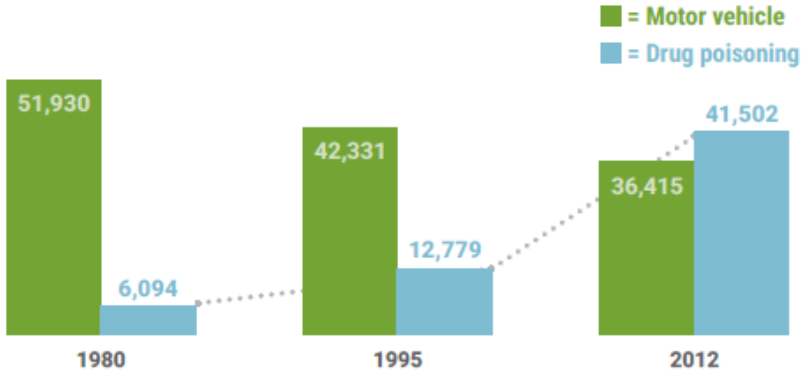
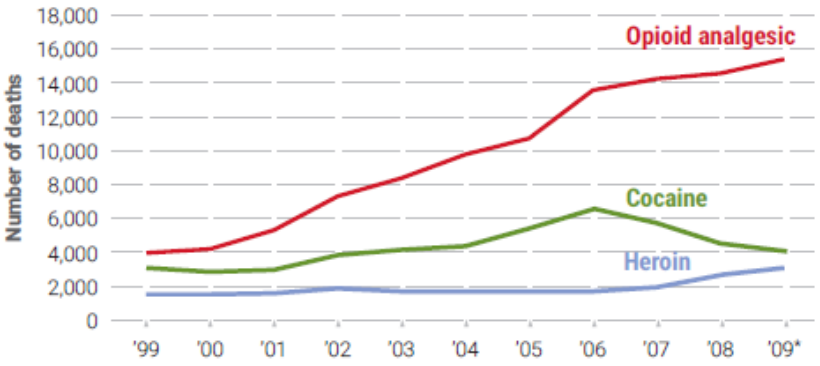


FIGURE 2. OVERDOSE DEATH BY DRUG TYPE[2]



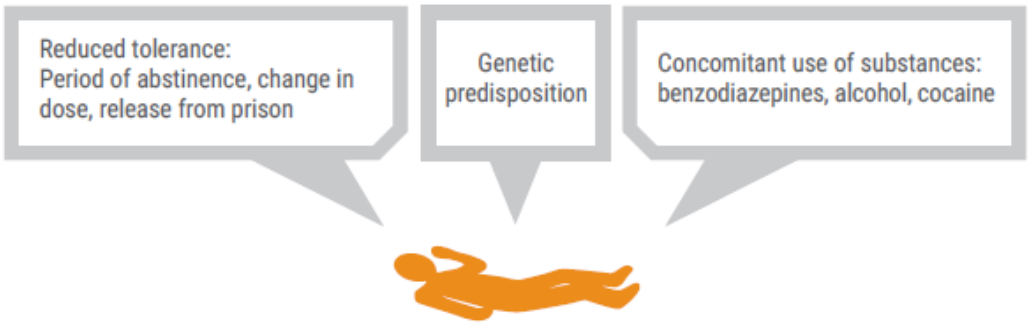
Opioid analgesics accounted for over 16,000 deaths in 2010.

* The reported 2009 numbers are underestimates. Some overdose deaths were not included in the total for 2009 because of delayed reporting of the final cause of death.

Accidental opioid overdose is preventable

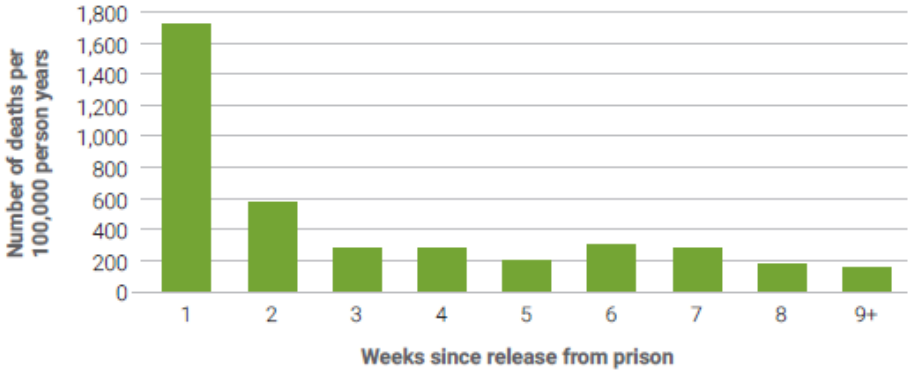
The main risk of death from an opioid overdose is prior overdose. A patient who has previously overdosed is 6 times more likely to overdose in the subsequent year.[3]

OTHER FACTORS THAT INCREASE RISK OF OVERDOSE:



The majority of opioid overdose deaths involve at least one other drug, including benzodiazepines, cocaine or alcohol.[4]

FIGURE 3. OVERDOSE MORTALITY RATE BY WEEK SINCE PRISON RELEASE:
An example of overdose risk if opioids are discontinued and restarted[5]

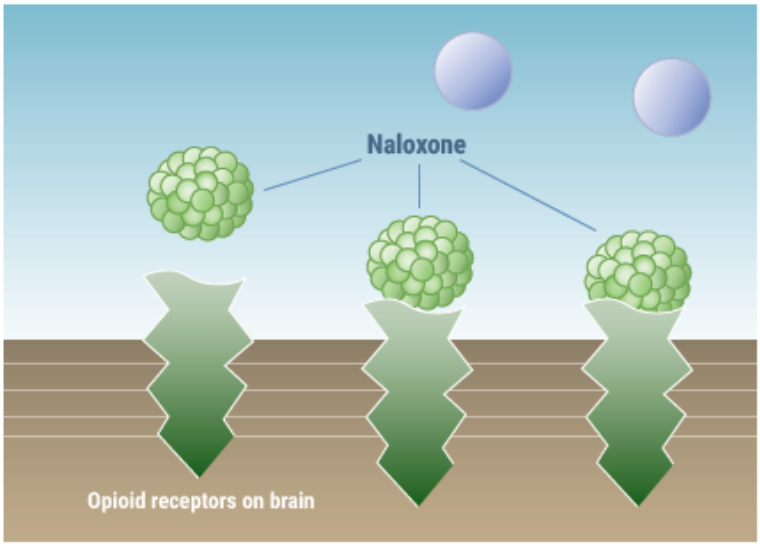


When a patient reduces or stops opioid use, there is an increased risk of overdose death if opioid use increases again.

Naloxone

- Highly specific, high-affinity opioid antagonist used to reverse the effects of opioids.
- Can be safely administered by laypersons via intramuscular or intranasal* routes, with virtually no side effects and no effect in the absence of opioids.
- Effects last 30-90 minutes; usually sufficient for short-acting opioids but help should always be sought.
- While high doses of intravenous naloxone by paramedics have been associated with withdrawal symptoms, lower lay-administered doses produce much more mild symptomatology.[6]

FIGURE 4. NALOXONE MECHANISM OF ACTION[7]



Naloxone has a higher affinity to the opioid receptors than opioids like heroin or oxycodone, so it knocks other opioids off the receptors for 30-90 minutes. This reverses the overdose and allows the person to breathe.

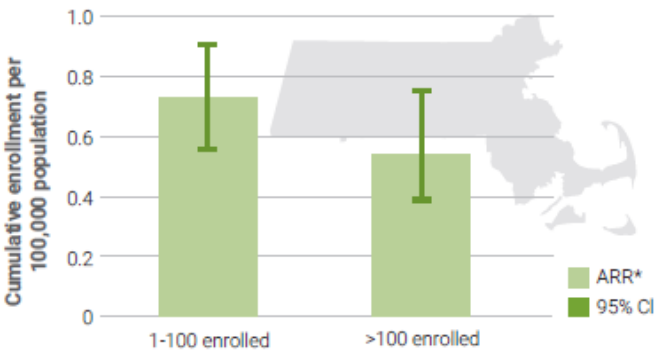
The American Medical Association has endorsed the distribution of naloxone to anyone at risk for having or witnessing an opioid overdose.[8]

There are 240 sites across 18 states that prescribe or distribute naloxone. Since 1996, naloxone has been distributed to over 53,000 people and more than 10,000 overdose reversals have been reported.[9]

* Intranasal is off-label but is supported by the American Medical Association and has become the preferred route for many emergency responders.[10, 11, 12]

Naloxone is effective

FIGURE 5. FATAL OPIOID OVERDOSE RATES BY NALOXONE IMPLEMENTATION IN MASSACHUSETTS[10]



In California, counties with naloxone programs had an overall slower rate in the growth in opioid overdose death compared to counties without naloxone programs.[13]

* Adjusted Rate Ratios (ARR) adjusted for population age <18, male; race/ethnicity; below poverty level; medically supervised inpatient withdrawal, methadone and buprenorphine treatment; prescriptions to doctor shoppers, year

...and cost-effective[14]

A manuscript in the *Annals of Internal Medicine* indicated that providing naloxone to heroin users is robustly cost-effective and possibly cost-saving. Investigators believe similar results apply to other opioid users.

Cost:

$421 per quality-adjusted life-year gained

Benefit:

164 naloxone scripts = 1 prevented death

Emerging data suggests that providing naloxone may encourage patients to be safer with their opioid use. If this is the case, the intervention would be cost-saving and **36 prescriptions** would prevent one death.

Indications for naloxone prescription

CONSIDER OFFERING A NALOXONE PRESCRIPTION TO:

- All patients prescribed long-term opioids
- Anyone otherwise at risk of experiencing or witnessing an opioid overdose

WHY PRESCRIBE TO ALL PATIENTS ON LONG-TERM OPIOIDS?

It is difficult to predict which patients who take prescription opioids are at risk for overdose.
Many patients do not feel they are at risk for overdose. Prescribing to all patients on opioids will help patients understand naloxone is being prescribed for risky drugs, not risky patients.
About 40% of overdose deaths result from diverted medications.[15] Whether intentional or unintentional, diverted opioids are a serious risk. Co-prescribing naloxone increases the chance that the antidote will remain with the medication.

Potential behavioral impact

Being offered a naloxone prescription may lead to safer opioid use.

U.S. army base Fort Bragg in North Carolina averaged 8 overdoses per month. After initiating naloxone distribution, the overdose rate dropped to zero—with no reported naloxone use.[16]

> *"[W]hen I prescribe naloxone...there's that realization of how important this is and how serious this is in their eyes."* —US army Fort Bragg primary care provider

Selected San Francisco Health Network clinics began co-prescribing naloxone to patients on opioids in 2013.

> *"I had never really thought about [overdose] before...it was more so an eye opener for me to just look at my medications and actually start reading [about] the side effects, you know, and how long should I take them...I looked at different options, especially at my age."*
> —San Francisco patient[17]

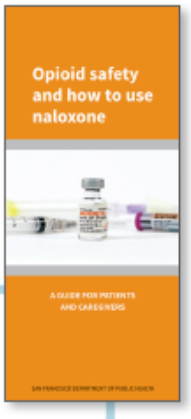
Offering a naloxone prescription can increase communication, trust and openness between patients and providers.

> *"By being able to offer something concrete to protect patients from the danger of overdose, I am given an opening to discuss the potential harms of opioids in a non-judgmental way."*
> —San Francisco primary care provider[18]

How to educate patients on naloxone

Clinic staff can educate patients about naloxone. Education generally includes:

- When to administer naloxone
- How to administer naloxone (including demonstration)
- Informing patients to alert others about the medication, how to use it and where it's kept, as it is generally not self-administered



Brochures remind patients and caregivers how to manage an overdose. Example brochures can be found at **www.prescribetoprevent.org**.

OPIOID SAFETY LANGUAGE

The word "overdose" has negative connotations and prescription opioid users may not relate to it.

Patients prescribed opioids (including high-risk persons with a history of overdose) reported their risk of "overdose" was 2 out of 10.[19]

Instead of using the word "overdose," consider using language like "accidental overdose," "bad reaction" or "opioid safety." You may also consider saying:

"Opioids can sometimes slow or even stop your breathing."

"Naloxone is the antidote to opioids—to be [sprayed in the nose/injected] if there is a bad reaction where you can't be woken up."

"Naloxone is for opioid medications like an epinephrine pen is for someone with an allergy."

State law encourages naloxone prescribing

Naloxone is NOT a controlled substance. **Any licensed healthcare provider can prescribe naloxone.** California State law provides additional protections to encourage naloxone prescribing and distribution:

PROVIDER AND PATIENT PROTECTIONS (CA AB635 effective 1/1/14)

- **Providers are encouraged to prescribe naloxone** to patients receiving a chronic opioid prescription.
- **Naloxone prescriptions also can be written directly to third party individuals** (caregivers, family members, friends, etc.) who are in a position to witness and assist a person at risk of an opioid overdose.
- **A licensed healthcare prescriber can issue a standing order** for the dispensing of naloxone by healthcare or community workers to individuals at risk of experiencing or witnessing an overdose.
- **Lay persons can possess and administer naloxone** to others during an overdose situation.

GOOD SAMARITAN PROTECTION (CA AB472 effective 9/17/12)

- **Witnesses of an overdose who seek medical help are provided legal protection** from arrest and prosecution for minor drug and alcohol violations.

PHARMACIST PROVISION OF NALOXONE (CA AB1535 effective 1/1/15*)

- **Pharmacists are allowed to directly prescribe and dispense naloxone** to patients at risk of experiencing or witnessing an opioid overdose.

* Pending pharmacy and medical board agreement on regulations.

Examples of how to prescribe naloxone

INJECTABLE

- Naloxone 0.4mg/1ml IM if overdose. Call 911. Repeat if necessary. #2
- IM syringes (3ml 25g 1" syringes are recommended) #2

INTRANASAL (OFF-LABEL)

- Naloxone 2mg/2ml prefilled syringe, spray ½ into each nostril if overdose. Call 911. Repeat if necessary. #2
- MAD (Mucosal Atomization Device) nasal adapter

Atomizer access is complicated. Select pharmacies now carry the atomizer, but most still have trouble accessing it. Insurers may require a TAR for reimbursement.

AUTO-INJECTOR

- Naloxone auto-injector 0.4mg #1 two pack, use PRN for suspected opioid overdose

SBIRT CODES COVER TRAINING (per 15 min intervals)

MediCare: G0396
MediCal: H0050
Commercial: CPT99408

Please copy or scan and send to your local pharmacist.

Pharmacy access

All pharmacies can fill naloxone prescriptions, but naloxone is new for many pharmacists so some may not know how. If a pharmacist is unsure how to fill a naloxone prescription, the information outlined on this page may be helpful.

ORDERING:

- Injectable: **Hospira** NDC#00409-1215-01; **Mylan** NDC#67457-292-00
- Intranasal: NDC#76329-3369-01
- MAD (atomizer) nasal devices produced by Teleflex*
- Auto-injector: NDC#60842-030-01

BILLING:

- Naloxone is covered by MediCal (as a "carve-out" **so submit directly to FFS MediCal**—do NOT send a PA to the HMO plan), and many other plans
- The MAD does not have an NDC, therefore cannot be billed through usual pharmacy billing routes. Pharmacies may be willing to cover the cost of the MAD or patients may be requested to pay for the cost of the MAD, which is around $5 per atomizer.

COUNSELING:

- Instruct patients to administer if non-responsive from opioid use and how to assemble for administration.
- Include family/caregivers in patient counseling or instruct patients to train others.

SIDE EFFECTS: Anxiety, sweating, nausea/vomiting or shaking. Talk to your doctor if these occur. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.

*** Contact Michelle Geier, PharmD, with questions or concerns related to pharmacies, at (415) 503-4755 or michelle.geier@sfdph.org**

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

Resources

Medical Board of California: Guidelines for Prescribing Controlled Substances for Pain: **www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf**

California Society of Addiction Medicine: Naloxone resources for providers, naloxone legal status, webinars and trainings: **www.csam-asam.org/naloxone-resources**

Prescribe to Prevent: Clinic-based prescribing information and guidelines: **www.prescribetoprevent.org**

Reach for Me: Film and resource materials for advocates, families and providers: **www.reach4me.org**

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About this publication

This publication was produced by the San Francisco Department of Public Health. Support was provided by the National Resource Center for Academic Detailing (NaRCAD). No pharmaceutical company resources were used in the development of these materials and authors (Phillip Coffin MD, Assistant Clinical Professor of HIV/AIDS at University of California San Francisco, and Emily Behar MS) deny any financial conflicts of interest.

The recommendations contained in this brochure are general and informational only; specific clinical decisions should be made by providers on an individual case basis.

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

NaRCAD National Resource Center for Academic Detailing

Suggested citation: San Francisco Department of Public Health. *Naloxone for opioid safety: a provider's guide to prescribing naloxone to patients who use opioids.* January 2015.

Design and layout: Amy Braddock

APPENDIX D

What is an opioid overdose?

Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can't handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone...

Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Morphine	MSContin, Kadian, Embeda, Avinza
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Fentanyl	Duragesic, Actiq
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit **www.prescribetoprevent.org**

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

2016

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

In case of overdose:

1 Check reponsiveness

Look for any of the following:

- No reponse even if you shake them or say their name
- Breathing slows or stops
- Lips and fingernails turn blue or gray
- Skin gets pale or clammy

2 Call 911 and give naloxone

If no reaction in 3 minutes, give second naloxone dose

3 Do rescue breathing and/or chest compressions

Follow 911 dispatcher instructions

>> STAY WITH PERSON UNTIL HELP ARRIVES.

How to give naloxone:

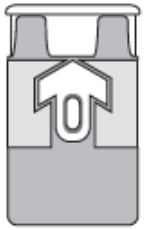
There are 4 common naloxone products. Follow the instructions for the type you have.

Nasal spray

This nasal spray needs no assembly and can be sprayed up one nostril by pushing the plunger.

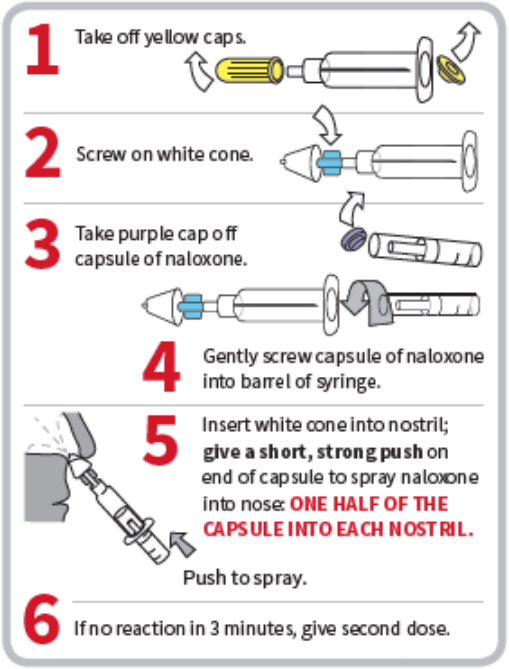
Auto-injector

The naloxone auto-injector needs no assembly and can be injected into the outer thigh, even through clothing. It contains a speaker that provides step-by-step instructions.



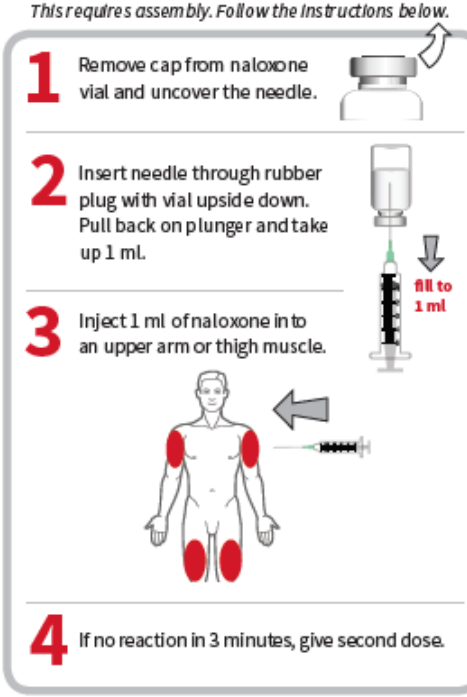
Nasal spray with assembly

This requires assembly. Follow the instructions below.

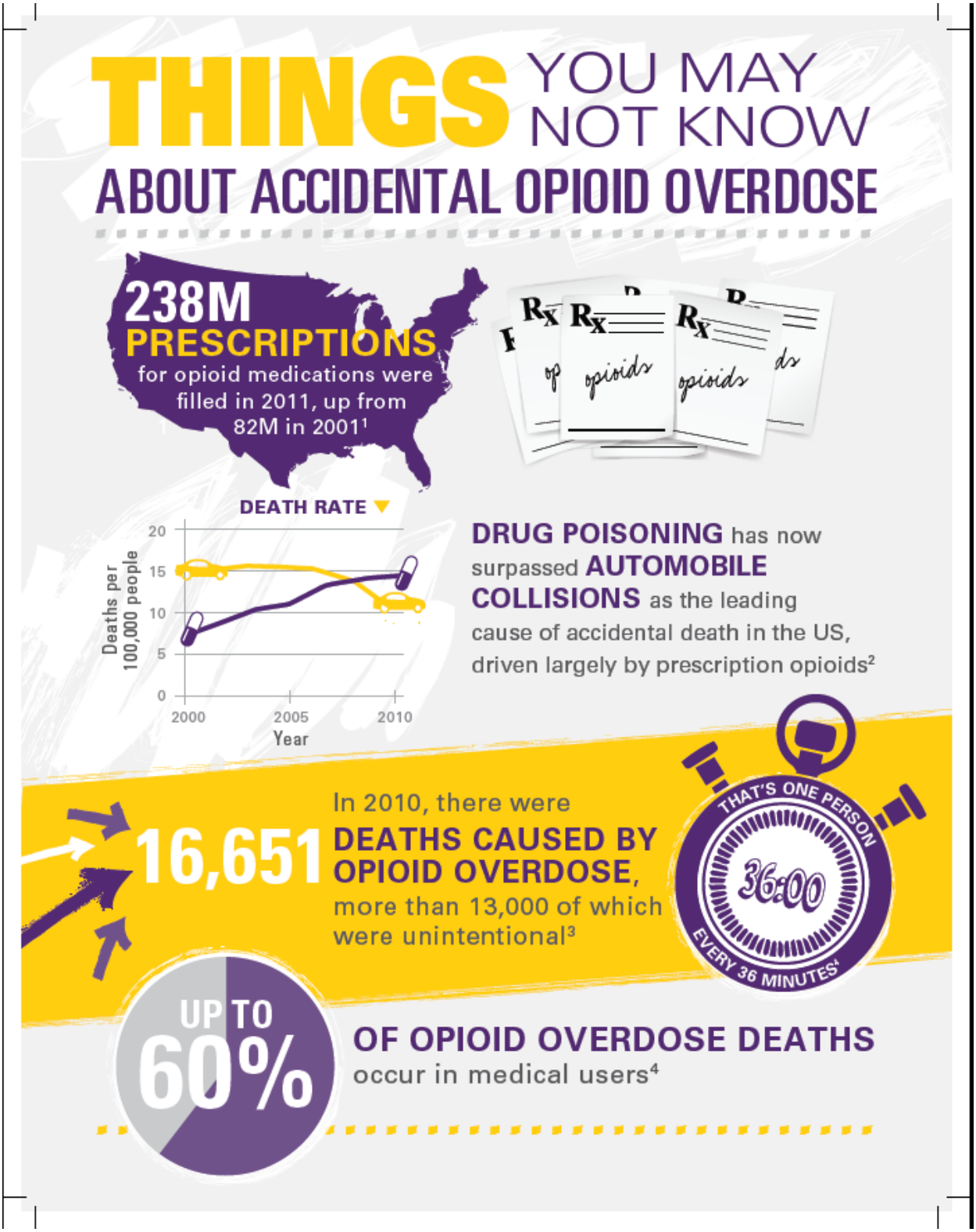


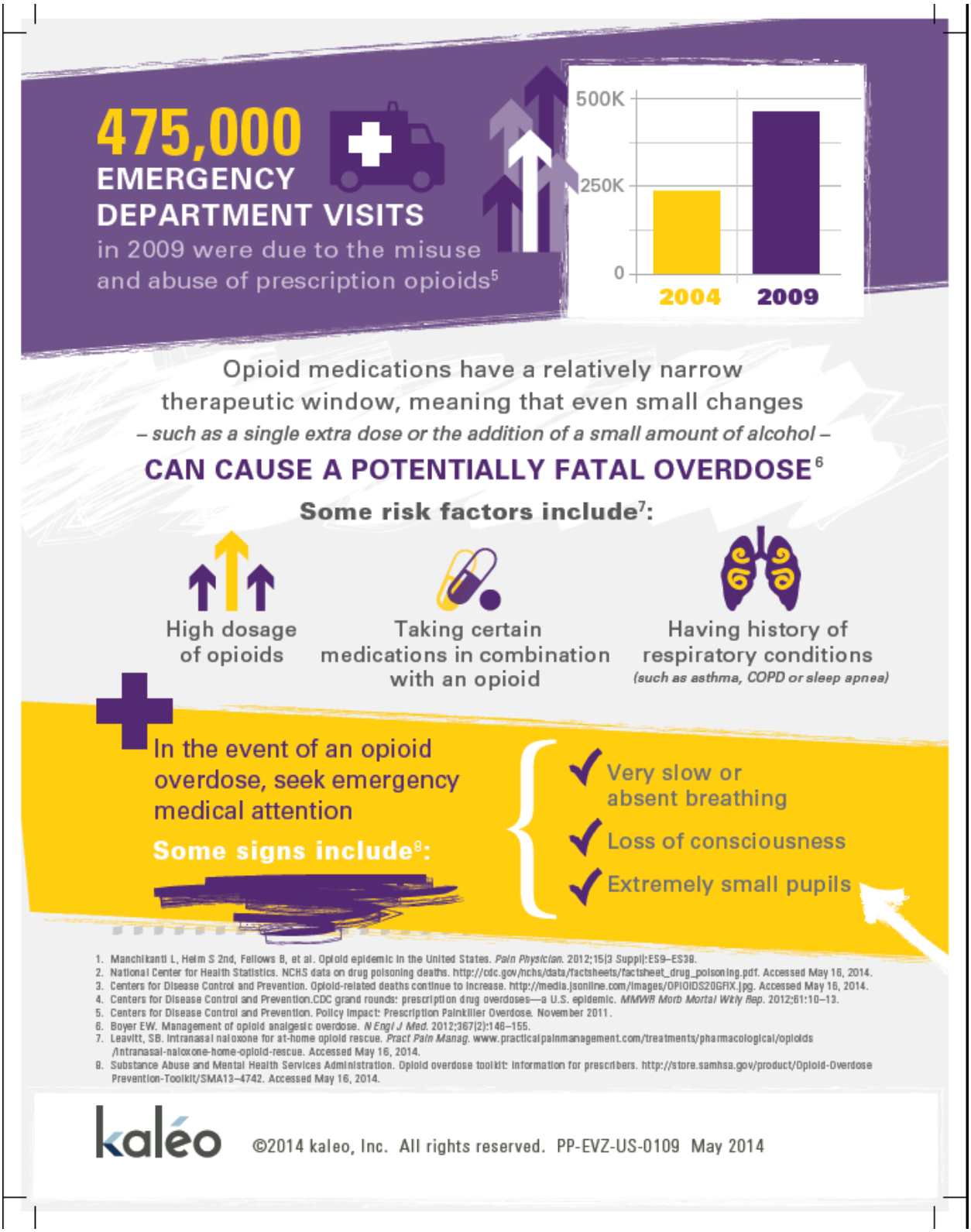
Injectable naloxone

This requires assembly. Follow the instructions below.



APPENDIX E


THINGS YOU MAY NOT KNOW
ABOUT ACCIDENTAL OPIOID OVERDOSE
238M
PRESCRIPTIONS
for opioid medications were filled in 2011, up from 82M in 2001[1]
Rx
opioids
DEATH RATE
Deaths per 100,000 people
20
15
10
5
0
2000
2005
2010
Year
DRUG POISONING has now surpassed AUTOMOBILE COLLISIONS as the leading cause of accidental death in the US, driven largely by prescription opioids[2]
In 2010, there were
16,651
DEATHS CAUSED BY OPIOID OVERDOSE,
more than 13,000 of which were unintentional[3]
THAT'S ONE PERSON
36:00
EVERY 36 MINUTES[1]
UP TO
60%
OF OPIOID OVERDOSE DEATHS
occur in medical users[4]


475,000
EMERGENCY DEPARTMENT VISITS
in 2009 were due to the misuse and abuse of prescription opioids[5]
500K
250K
0
2004
2009
Opioid medications have a relatively narrow therapeutic window, meaning that even small changes
– such as a single extra dose or the addition of a small amount of alcohol –
CAN CAUSE A POTENTIALLY FATAL OVERDOSE[6]
Some risk factors include[7]:
High dosage of opioids
Taking certain medications in combination with an opioid
Having history of respiratory conditions
(such as asthma, COPD or sleep apnea)
In the event of an opioid overdose, seek emergency medical attention
Some signs include[8]:
Very slow or absent breathing
Loss of consciousness
Extremely small pupils
1. Manchikanti L, Helm S 2nd, Fellows B, et al. Opioid epidemic in the United States. Pain Physician. 2012;15(3 Suppl):ES9–ES38.
2. National Center for Health Statistics. NCHS data on drug poisoning deaths. http://cdc.gov/nchs/data/factsheets/factsheet_drug_poisoning.pdf. Accessed May 16, 2014.
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APPENDIX F

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

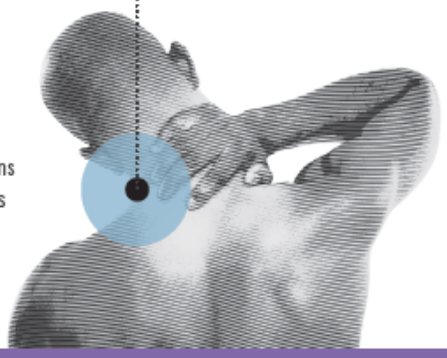
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

CLINICAL REMINDERS

- **Opioids are not first-line or routine therapy for chronic pain**
- **Establish and measure goals for pain and function**
- **Discuss benefits and risks and availability of nonopioid therapies with patient**



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

4 When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5 When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

6 Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7 Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8 Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

9 Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10 When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12 Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

APPENDIX G

Naloxone Product Comparison

	Injectable (and intranasal-IN) generic	Intranasal branded		Injectable generic[1]		Auto-injector branded	
Brand name		Narcan Nasal Spray				Evzio Auto-Injector	
Product comparison							
		 (Product not yet released[2])				(yellow & purple)  (Formulation to be discontinued[3])	(blue & purple) 
FDA approved Labeling includes instructions for layperson use	X (for IV, IM, SC)	X X		X		X X	
Assembly required	X			X			
Fragile	X						
Can titrate dose	X			X			
Strength	1 mg/mL	4 mg/0.1 mL	2mg/0.1mL	0.4 mg/mL	4 mg/10 mL	0.4 mg/0.4mL	2 mg/0.4mL
Storage requirements (All protect from light)	Store at 59-86 °F Fragile: Glass.	Store at 59-77 °F Excursions from 39-104 °F		Store at 68-77 °F Breakable: Glass.		Store at 59-77 °F Excursions from 39-104 °F	
Cost/kit[4]	$$	$$		$		$$$	
Prescription variation							
Refills	Two	Two		Two		Two	
Rx and quantity	#2 2 mL Luer-Jet™ Luer-Lock needleless syringe plus #2 mucosal atomizer devices (MAD-300)	#1 two-pack of two 4 mg/0.1 mL intranasal devices	#1 four-pack of four 2 mg/0.1 mL intranasal devices	#2 single-use 1 mL vials PLUS #2 3 mL syringe w/ 23-25 gauge 1-1.5 inch IM needles	#1 10mL multidose vial PLUS #2 3 mL syringe w/ 23-25 gauge 1-1.5 inch IM needles	#1 two-pack of two 0.4 mg/0.4 mL prefilled auto-injector devices	#1 two-pack of two 2 mg/0.4 mL prefilled auto-injector devices

Naloxone Product Comparison

	Injectable (and intranasal-IN) generic		Intranasal branded		Injectable generic[1]		Auto-injector branded	
Sig. (for suspected opioid overdose)	Spray 1 ml (1/2 of syringe) into each nostril. Repeat after 2-3 minutes if no or minimal response.		Spray 0.1 mL into one nostril. Repeat with second device into other nostril after 2-3 minutes if no or minimal response.		Inject 1 mL in shoulder or thigh. Repeat after 2-3 minutes if no or minimal response.		Inject into outer thigh as directed by English voice-prompt system. Place black side firmly on outer thigh and depress and hold for 5 seconds. Repeat with second device in 2-3 minutes if no or minimal response.	
Ordering information								
How supplied	Box of 10 Luer-Jet™ prefilled glass syringes		Two-pack of single use intranasal devices		Box of 10 or package of 25 single-dose fliptop vials (1 ml)	Case of 25 multi-dose fliptop vials (10 ml)	Two pack of single use auto-injectors + 1 trainer	
Manufacturer	IMS/ Amphastar	Teleflex (off-label IN adapter)	Adapt Pharma		Pfizer, Mylan and West-Ward Pharmaceuticals	Pfizer	kaléo	
Web address	Amphastar.com	Teleflex. com	Narcannasalspray.com		Pfizerinjectables.com Mylan.com West-ward.com	Pfizerinjectables.com	Evzio.com	
Customer service	800-423-4136	866-246-6990	844-462-7226		877-946-7747 (P) 724-514-1800 (M) 800-631-2174 (W)	877-946-7747 (P)	855-773-8946	
NDC	76329-3369-01	DME- no NDC	69547-353-02	69547-212-04	00409-1215-01 (P) 67457-0292-02 (M) 0641-6132-25 (W)	00409-1219-01	60842-030-01	60842-051-01

[1] Pfizer acquired Hospira in 2015. Pfizer has an additional naloxone product, which is ***not recommended*** for layperson and take-home naloxone use because it is complicated to assemble. (Naloxone Hydrochloride Injection, USP, 0.4 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle) NDC# 0409-1782-69)
[2] This product concentration is not yet currently available. As a result, some of the content is left blank.
[3] EVZIO 2 mg is now available. As of February 2017, EVZIO 0.4 mg will no longer be manufactured, but is still currently available and effective.
[4] There is considerable price variance for each product- local pharmacists are able to provide specific local pricing.
Image development supported by 1R01DA038082-01 Friedmann/Rich

APPENDIX H

NARCAN® (naloxone HCl) NASAL SPRAY 4 mg

Fact Sheet

FDA-Approved Nasal Naloxone to Treat Opioid Overdose

ADAPT PHARMA

BACKGROUND: THE OPIOID OVERDOSE EPIDEMIC

- Opioid abuse in the United States has reached epidemic proportions, with deaths due to opioid overdose killing Americans every day.[1]
- Naloxone is an antidote that has been used as a pharmaceutical ingredient for more than 40 years as an emergency treatment to rapidly reverse the life-threatening effects of opioid overdose until medical help arrives.[2]
- There is broad consensus across the medical, advocacy and government communities that increased access to naloxone is a critical component of the emergency treatment of opioid overdose.[3,4,5]
- Historically, naloxone has only been approved by the U.S. Food and Drug Administration (FDA) in injectable formulations. However, the FDA recently encouraged innovations in more user-friendly naloxone delivery systems, especially those that can be given by consumers outside of healthcare settings.[6]

WHAT IS NARCAN® NASAL SPRAY?

- NARCAN® Nasal Spray is an FDA-approved, needle-free naloxone treatment. It provides emergency treatment of known or suspected opioid overdose until emergency medical help arrives. **NARCAN® Nasal Spray is not a substitute for emergency care.**
- NARCAN® Nasal Spray rapidly delivers a 4 mg dose of naloxone in a single concentrated 0.1 ml nasal spray from a compact, ready-to-use device.[7] Each package contains two devices.
- NARCAN® Nasal Spray can be readily administered when an opioid overdose occurs and does not require assembly or specialized training.
- **See below for NARCAN® Nasal Spray indications and important safety information.**

HOW DOES NARCAN® NASAL SPRAY WORK?

- In the case of a known or suspected opioid overdose:
  - **Peel** back the tab to remove NARCAN® Nasal Spray from its package.
  - **Place** the device into one nostril.
  - **Press** the device plunger firmly.
  - **Get emergency help right away.**
- While not a substitute for emergency medical care, timely administration of a sufficient dose of NARCAN® Nasal Spray can help rapidly reverse the life-threatening breathing difficulties that an opioid overdose may cause until emergency medical care can be administered.

WHO SHOULD HAVE NARCAN® NASAL SPRAY?

- NARCAN® Nasal Spray will be available in the coming weeks.
- It may be important for the following groups to have NARCAN® Nasal Spray on hand.
  - Anyone who is taking opioids or at risk of an opioid overdose
  - Friends, family members or acquaintances of someone who may be at risk of an opioid overdose
  - Healthcare professionals
  - First responders, including police, firefighters and EMTs
  - Emergency room personnel
  - Hospital and treatment centers

Full Prescribing Information for NARCAN® Nasal Spray is available at www.NarcanNasalSpray.com and the FDA website.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS
NARCAN® (naloxone hydrochloride) Nasal Spray is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

NARCAN® Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN® Nasal Spray is not a substitute for emergency medical care.

IMPORTANT SAFETY INFORMATION
NARCAN® Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

NARCAN® (naloxone HCl) NASAL SPRAY 4 mg **Fact Sheet**

ADAPT PHARMA

FDA-Approved Nasal Naloxone to Treat Opioid Overdose

Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal and acute withdrawal syndrome. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for development of opioid withdrawal.

Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were observed in a NARCAN® Nasal Spray clinical study: increased blood pressure, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.

See Instructions for Use and full prescribing information in the use of this product.

To report SUSPECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. at 1-844-4NARCAN (1-844-462-7226) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Citations

1 Centers for Disease Control and Prevention. NCHS Data Brief: Drug-poisoning Deaths Involving Heroin: United States, 2000-2013. 2015. Available at: http://www.cdc.gov/nchs/data/databriefs/db190.htm

2 World Health Organization. Naloxone: A Take-home Antidote to Drug Overdose that Saves Lives. 2014. Available at: http://www.who.int/features/2014/naloxone/en/

3 The White House Office of the Press Secretary. FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use. 2015. Available at: https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector

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5 Harm Reduction Coalition. American Medical Association, Harm Reduction Coalition and National Safety Council Urge Increased Focus on Overdose Prevention and Treatment. 2014. Available at: http://www.aafp.org/dam/AAFP/documents/advocacy/prevention/risk/LT-NGA-HarmReduction-021915.pdf

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7 Data on file. Naloxone-Ph1a-002 CSR.

APPENDIX I

NARCAN® (naloxone HCl) NASAL SPRAY

QUICK START GUIDE

Opioid Overdose Response Instructions

Use NARCAN® (naloxone hydrochloride) Nasal Spray for known or suspected opioid overdose in adults and children.
Important: For use in the nose only.
Do not remove or test the NARCAN Nasal Spray until ready to use.

1 Identify Opioid Overdose and Check for Response

Ask person if he or she is okay and shout name.

Shake shoulders and firmly rub the middle of their chest.

Check for signs of an opioid overdose:

- Will not wake up or respond to your voice or touch
- Breathing is very slow, irregular, or has stopped
- Center part of their eye is very small, sometimes called "pinpoint pupils"

Lay the person on their back to receive a dose of NARCAN Nasal Spray.

2 Give NARCAN Nasal Spray

REMOVE NARCAN Nasal Spray from the box.
Peel back the tab with the circle to open the NARCAN Nasal Spray.

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.

Gently insert the tip of the nozzle into either nostril.

- Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril, until your fingers on either side of the nozzle are against the bottom of the person's nose.

Press the plunger firmly to give the dose of NARCAN Nasal Spray.

- Remove the NARCAN Nasal Spray from the nostril after giving the dose.

3 Call for emergency medical help, Evaluate, and Support

Get emergency medical help right away.

Move the person on their side (recovery position) after giving NARCAN Nasal Spray.

Watch the person closely.

If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available.

Repeat Step 2 using a new NARCAN Nasal Spray to give another dose in the other nostril. If additional NARCAN Nasal Sprays are available, repeat step 2 every 2 to 3 minutes until the person responds or emergency medical help is received.

ADAPT PHARMA

For more information about NARCAN Nasal Spray, go to www.narcannasalspray.com, or call 1-844-4NARCAN (1-844-462-7226).
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

APPENDIX J

NIZHOKMA (HELP)

Narcan

Submitted by Family Nurse Practitioner Jolane Conklin

Drug overdose was the leading cause of injury death in Michigan in 2015, over motor vehicle accidents, firearm discharge and suicide. Calhoun County had the highest number of drug related deaths compared to the four nearby counties in 2015. Ottawa County has seen an 85 percent increase in opioid-related deaths between 2015 and 2016. Kent County has seen similar increases as well. In the United States, 91 people die every day from opioid overdoses and at least half of those are from a prescription opioid. Each day, more than 1000 people are treated in emergency departments for not taking opioid medications correctly.

What are opioids?

Opioids are narcotic drugs that may be legally prescribed such as hydrocodone and codeine, or obtained elsewhere, such as heroin or fentanyl. These medications are very powerful by themselves and have the potential to cause unexpected side effects. Mixing these medications with other substances, such as alcohol, anti-anxiety medications, allergy or sleeping pills could increase the risk of an unintentional overdose.

I take pain medicine, am I at risk of an overdose?

Possibly. Although many people take and use opioid medications safely, accidents can occur! Forgetting that a dose has already been taken or taking an extra dose because pain is bad that day could be a problem. Also, changes in doses or taking a friend's or relative's medication could lead to a problem.

How do I know if someone is overdosing?

There are several signs to look for if you suspect that someone has overdosed on opioids. A person may have slow, labored breaths or could even stop breathing. They may also have a weak pulse. People may be slow to respond, disoriented or might not wake up. Additionally, their pupils, which is the dark part of the eye, may be very small.

What can I do if I think someone is overdosing on opioids?

Give Narcan®! Also known by its generic name, naloxone, Narcan® is a medication that acts as an antidote for opioid overdoses. It will not work on someone who has overdosed on crack or cocaine, or has other medical issues, such as a diabetic coma. Although Narcan® can reverse an overdose, it wears off quickly so it is very important to call 911 immediately to get advanced medical care services.

Who should have Narcan®?

The Indian Health Service recommends that anyone taking long-term opioids, taking opioids with other medications that cause drowsiness, have children in the home, are over the age of 65, live with someone who has a substance use disorder, live in remote areas or have difficulty accessing emergency services due to transportation issues, lack of phone or homelessness should have access to Narcan®.

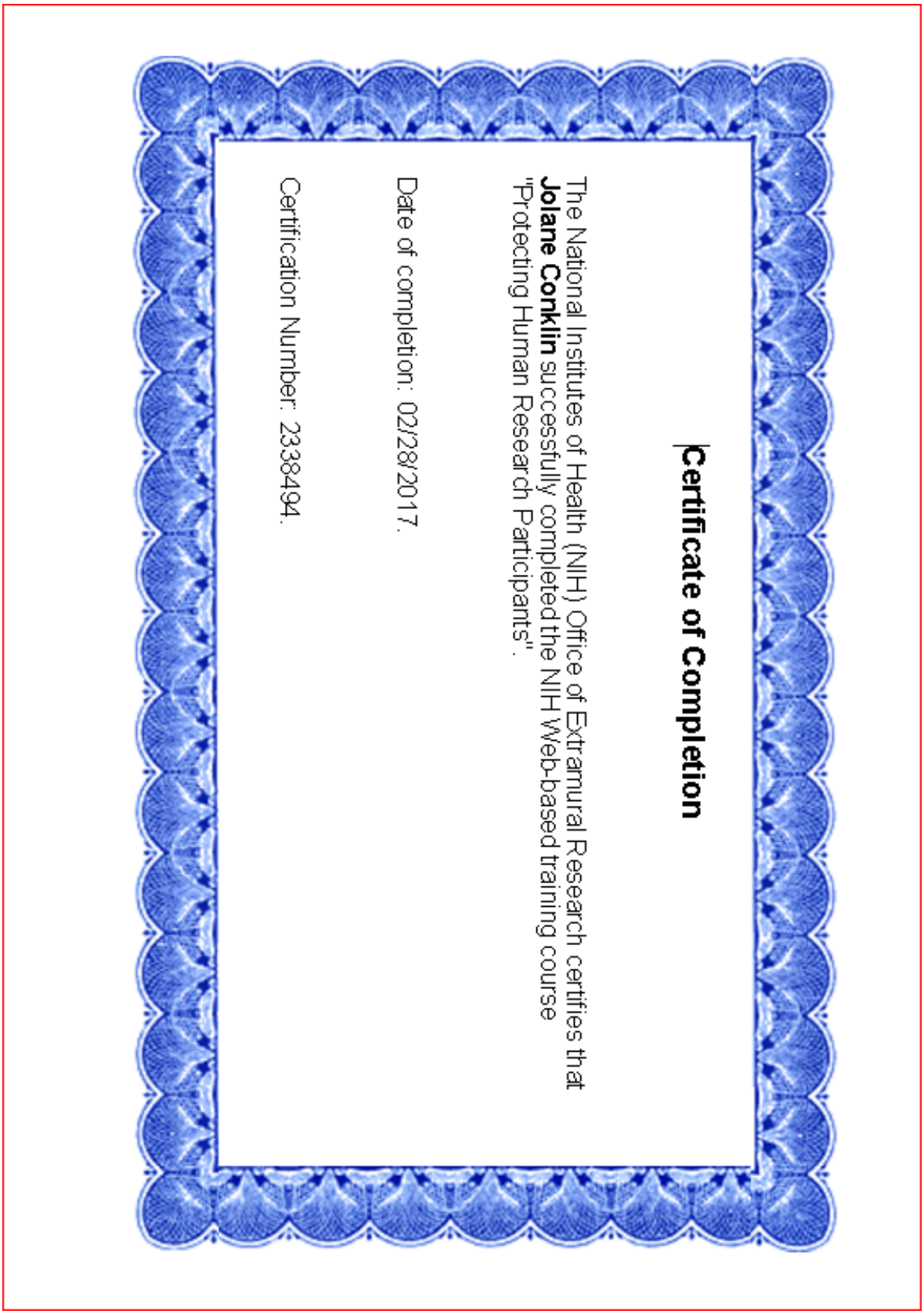
How do I get Narcan®?

The NHBP Health and Human Services Department has naloxone nasal spray available for any client, patient, family member or other related party at risk of overdose. After a brief training and viewing an educational video, a kit will be given to the patient. As always, confidentiality remains a priority.

How do I get more information?

For more information please visit naloxonesaves.org, narcan.com, harmreduction.org or cdc.gov or contact the NHBP Health and Human Services Department at 269.729.4422

APPENDIX K



Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Jolane Conklin** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 02/28/2017.

Certification Number: 2338494.