11-18-2021

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DOI: <https://doi.org/10.46409/sr.SIQK4480>

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Development and Implementation of an Opioid Risk-Reduction Strategy

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This Manuscript Partially Fulfills the Requirements for the

Doctor of Nursing Practice Program and is Approved by:

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Date of Final Approval: November 18, 2021

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Development and Implementation of an Opioid Risk-Reduction Strategy

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Abstract

Practice Problem: Accidental overdose is a continued concern for those who are prescribed opioids, and it is essential that healthcare members intensify prevention and response measures in order to prevent death or misuse from this medication.

PICOT: The PICOT question that guided this project was: “In adult patients at an outpatient chronic pain management clinic (P), how does development and implementation of a safe opioid risk-reduction office policy (I), compared to usual practice (C), improve patient rates of naloxone availability and health literacy (O) over eight weeks (T)?”

Evidence: The CDC’s *Guideline for Prescribing Opioids for Chronic Pain*, the Surgeon General’s *Advisory on Naloxone and Opioid Overdose*, and the U.S Department of Health and Human Services website were used to gather evidence-based components for information and practice changes.

Intervention: This project created a safe opioid risk-reduction strategy in the form of a new office protocol that ensured naloxone was received with instruction on what to do in the event of an overdose or life-threatening respiratory reaction to opioids and other safety information. The providers assessed the change in knowledge by using the teach back method.

Outcome: The results showed improvement in the availability of naloxone as a reversal agent as well as increased understanding of safe opioid storage, disposal, and drug interactions.

Conclusion: The manuscript reports barriers, successes, and challenges discovered during the project. The recommendations can be applied to other outpatient clinic sites to enhance the safety of all patients who manage their chronic pain with the use of prescription opioids.

Development and Implementation of a Safe Opioid Risk-Reduction Strategy

Over the last several years, accidental overdose has become a common cause of preventable deaths. (Martino et al., 2019). This is a major public health issue. Unfortunately, both providers and the public lack understanding of the serious risks associated with opioid use (Agency for Healthcare Research and Quality, 2019).

The Centers for Disease Control and Prevention (CDC) identified patients who had a greater risk of prescription opioid overdose as “those who were prescribed high daily dosages of opioids for chronic pain, who concurrently used benzodiazepines with opioids, and/or had a history of a substance use disorder” (2019, para. 11). Adults with limited health literacy have difficulty managing their chronic conditions, which leads to greater hospitalization rates and higher healthcare expenses (Ylitalo et al., 2018). Naloxone hydrochloride is a competitive opioid antagonist that binds to the mu receptors in the body (CDC, 2019). This medication can rapidly “reverse the effects of opioids including those associated with overdose such as respiratory depression” and increased access to naloxone can reduce overdose death by 35-50% (National Institutes of Health, 2017, U.S Department of Health and Human Services [HHS], 2018a, p.1). Regrettably, this life-saving medication is not always available during situations when it is needed the most (CDC, 2019).

This evidenced-based project (EBP) created a safe opioid risk-reduction strategy in the form of a new office protocol designed to ensure all patients using prescription opioids received a prescription for naloxone and instruction on what to do in the event of an overdose or life-threatening respiratory reaction to opioids (Next Harm Reduction, Inc., 2020). For those who could not afford the medication, a shipment of Narcan was provided to them through a collaboration with Next Harm Reduction, Inc. (2020). The CDC and The American Society of

Regional Anesthesia and Pain Medicine (ASRA) recommended patient handouts were also used to increase understanding of the potential dangers of opioids and reviewed the safe storage, disposal, tapering medications, and potential interactions with other substances (ASRA, n.d.; HHS, 2018b). This project reduced the risk of accidental overdose and ensured the safe use of prescription opioid medication.

Significance of the Practice Problem

During the last 15 years overdoses from synthetic and non-synthetic opioid use have increased fourfold in the United States (Frieden & Houry, 2016). During the years 1999 to 2017, nearly 400,000 people died from drug overdoses involving prescription or illicit opioids (CDC, 2020). Nearly 40 percent of those deaths were a direct result of prescription opioid overuse or misuse. Neville and Foley (2020) reported the total of yearly opioid related deaths outnumbered the annual mortality rates caused by recent wars, motor vehicle accidents, gun violence, and HIV combined. The authors argued these deaths were in part a result of increased efforts to improve pain management, especially since the inception of pain as a fifth vital sign in 1996. Some have termed this “the biggest public health epidemic of a generation” (Florence et al., 2021, p. 218).

The overdose crisis affects society on all levels. A considerable economic burden has been triggered by the rise in opioid related morbidity and mortality rates. One estimation is that the total cost of prescription opioid misuse in the United States is close to 79 billion dollars a year (CDC, 2019). The combined costs of opioid use disorder and fatal opioid overdose was estimated to be as high as one trillion dollars in the year 2017 (Florence et al., 2021). These losses are associated with issues including “premature mortality, criminal justice, childcare and family assistance, lost productivity, and healthcare services” (Neville & Foley, 2020, p. 10).

Most of the economic burden, however, can be attributed to loss of life and reduced quality of living (Florence et al., 2021).

The EBP change clinic is in an urban environment in Southwestern Pennsylvania. On a statewide level, the prevalence of opioid use disorder was 5.54 per 1,000 commercially insured residents which totaled almost 40,000 persons in 2016 (Davenport et al., 2019). These figures accounted for an increased cost of “\$16,277 per patient and totals nearly 650 million dollars in yearly costs” (p. 71). Data from a 2020 analysis indicated this area of Pennsylvania was below the state average for median household income, median house value, and house age (City Data, n.d.). The renting percentage and length of stay after moving were also above state average. The percentage of this population with a bachelor's degree or higher and the number of college students was below state average. The website states that the percentage of those with a high school degree or higher was 86.8%, a bachelor's degree or higher was 12.9%, and those with a graduate or professional degree was 3.1%. The unemployment rate was 7.8%, which was slightly higher than the state average of 6.1%.

To curb the increase in prescription opioid overdose rates, several harm reduction strategies, including use of naloxone for home rescue have been recommended (Dowell et al., 2016; Frieden & Houry, 2016; Wyse et al., 2018). However, at the clinic where this EBP project was implemented, even though providers were encouraged to prescribe naloxone, usually in the form of Narcan, many patients still were not receiving this potentially lifesaving medication. Identified potential barriers to prescribing naloxone include “stigma toward opioid users, fear of negative consequences such as increased drug use, time constraints, billing and reimbursement complications, low self confidence in having discussions with patients, and lack of clinician education” (Martino et al., 2019, p. 69). There was no formal office protocol or tracking method

to make sure patients understood the importance of naloxone, how to administer it, or safe handling of their opioid prescriptions (G. Hites, personal communication, January 11, 2021).

PICOT Question

The PICOT question: “In adult patients at an outpatient chronic pain management clinic (P), how does development and implementation of a safe opioid risk-reduction office policy (I), compared to usual practice (C), improve patient rates of naloxone availability and health literacy (O) over eight weeks (T)?” was created to find the best evidence-based practice literature available that would support formulation of the project (Echevarria & Walker, 2014).

For this project, the population targeted was adult patients attending an outpatient interventional pain management clinic, that were aged between eighteen and ninety-nine years with no defined race or ethnicity. The individual conditions varied, but all participants had a diagnosis of pain lasting greater than three months and were prescribed opioids to help manage their chronic pain.

The intervention guided the development and implementation of a safe opioid office policy. The *CDC’s Guideline for Prescribing Opioids for Chronic Pain*, the Surgeon General’s *Advisory on Naloxone and Opioid Overdose*, and the U.S Department of Health and Human Services website were used to gather evidence-based components for the information and practice changes (ASRA, n.d.; Frieden & Houry, 2016; HHS, 2017, 2018b). The carefully chosen resources were those designed for chronic pain patients regardless of the office settings in which they presented.

The comparison to usual practice was measured at baseline and post implementation through the provider checklist, the prescription drug monitoring program (PDMP), and the teach-back method. The data evaluations took place in two groups, at baseline and at the four week

follow up visit. The teach-back method is an “evidence–based, patient-centered intervention that promotes health literacy, patient engagement and adherence, safety, and quality, using a universal precaution approach” (Denault et al., 2019, para. 4).

Evidence-Based Practice Framework and Change Theory

This section introduces the framework and change theory models that guided the project development. Specifically, the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) model and Lewin's theory of change were utilized.

Framework

To ensure the appropriate research findings and best practices for this EBP change the JHNEBP framework was followed (Dang & Dearholt, 2017). This structure employed a three-step process called “PET: practice question, evidence, and translation” (see Appendix A). The *practice question* stage consisted of the initial team development, definition of the practice problem, and finally, identification and meeting with stakeholders and leadership members. In the *evidence* stage, quality literature was collected and appraised to determine recommendations for the project proposal. During the *translation* stage, synthesized data was funneled into the final action plan which defined the implementation, evaluation, and dissemination phases of the EBP project.

Change Theory

To facilitate alterations in behaviors, it was first important to understand the mechanisms behind the process of change (Lewin, 1951). Lewin's theory of change was used to guide the desired improvements in self-care behaviors of the patient and the providers during the EBP change project. Identifying the opposing forces that encourage or hinder change increased the likelihood of success and sustainability. The terms *unfreeze*, *change*, and *refreeze* are

characteristics of Lewin's three-step model reviewed in Figure 1. During this project, the participant was initially prompted to alter their customary process to overcome their current behavior (unfreeze). This allowed them to view their typical actions from a different perspective and to realize the desired transformation (change). Finally, the changes were consistently implemented, and this behavior became the "new normal" (refreeze). The process concluded with the integration of the project opioid safety policy components into the standard routine of the organization for all practice locations in Pennsylvania.

Evidence Search Strategy

To ensure a comprehensive search for strong evidence, relevant literature was initially identified through an electronic search of databases. The search included the following subject terms: "*chronic pain management*," and "*opioid*." This was further investigated with the expander terms: "*safety practices*," "*naloxone*," and "*self-care behaviors*." Databases searched were: The Cumulative Index to Nursing and Allied Health Literature via smart text searching, Joanna Briggs Institute EBP, Wolters Kluwer OVID, and Science Direct. Additionally, a thorough search was made via Google Scholar and Cochrane PICO search engines. This generated 2,673 articles of possible interest. Duplicate articles were removed and then narrowed by application of inclusion and exclusion criteria to final number of 14.

Evidence Search Results

The following inclusion criteria were applied to the initial 2,673 literature search results: (1) adult (<18 years of age), (2) articles published within the last five years, (3) United States studies, and (4) outpatient setting. This left 362 articles remaining. Articles were then further eliminated based upon the following exclusion criteria (1) non-English language, (2) non-opioid management, (3) cancer or palliative care, and (4) secondary sources. Peer-reviewed sources

chosen were comprised of books, journal articles, published papers and grey literature. Limiters were added that include “*patient safety*,” and “*education*.” These steps yielded 37 articles. Potential literature was further narrowed by a critical review of abstracts and subject matter was examined for relevancy. This thorough review ensured the article chosen discussed safety practices related to chronic pain patients who were prescribed opioids, and that the research information was appropriate to the EBP change process.

A total of fourteen articles were selected for the literature review, as shown in Figure 2. The collection included research, systematic reviews, and best practice guidelines. Of the total, five focused on opioid safety and/or naloxone prescriptions, three related to personal or organizational health literacy. See articles in Appendix A: Primary Research Review. Two systematic reviews of literature, listed in Appendix B, related to improved self-care capability. Four best practice articles supported the use of opioid risk reduction tools, such as those included in the practice policy for this EBP change and are shown in Appendix C: Consensus Statement and Guidelines. The underlying goal of increased safe opioid use was evident in each article.

The readings obtained were evaluated and labeled by level and quality using the JHNEBP model (Dang & Dearholt, 2017, Appendix D). As shown in Table 1, all the articles were rated as I through V evidence levels and determined to have no less than an A/B rating with the majority (71%) categorized as high quality- A ranked sources. Therefore, these resources were determined to be suitable valid research materials that supported the EBP project changes.

Themes with Practice Recommendations

The practice recommendation themes revealed from the final search results are further examined in this section. Project participants, practice settings, naloxone use, education, and barriers were analyzed in depth to determine final practice proposals.

Subjects

All literature study subjects were either adult patients receiving medications classified as opioids for the purpose of reduction in chronic pain, or practitioners (physicians, pharmacists, nurse practitioners, and physician assistants) who prescribed opioids and/or educated recipients on naloxone (Martino et al., 2019; Wyse et al., 2018). Article summaries are provided in Appendices A and B.

Several studies were conducted at the Department of Veterans Affairs (VA) and the population was noted to be predominately Caucasian males (Seal et al., 2019; Tiffany et al., 2015). There were concerns that these results provided an overrepresentation of this demographic group. However, since this group tends to be most affected by opioid overdose, as evidenced by Figure 3 and Table 2, the results were determined to be valid. Veterans are part of the population of patients seen at the EBP change project location which also makes inclusion of these study results appropriate (G. Hites, personal communication, February 25, 2021). The study periods ranged from four to 52 weeks in duration.

Practice Setting

All practice study sites were in outpatient facilities except for one meta-analysis and one research study (Devries et al., 2017; Kadakia et al., 2020). However, all data were applicable to this EBP change project. It is not necessary to specifically link the impact of opioid-related education provided by the healthcare provider to a specific setting (Kadakia et al., 2020). Overall, overdose education and naloxone distribution programs were found to be successful regardless of the practice location (Devries et al., 2017). For this project, therefore, the distribution of educational materials and practice guidelines did not require adjustments based on the project practice specialty or setting.

Naloxone

Several high-quality studies or practice recommendations focused specifically upon the reversal agent naloxone as a stand-alone intervention or in conjunction with an overall safety plan (Devries et al., 2017; HHS, 2018a; Jones et al., 2019; Martino et al., 2019; Seal et al., 2019; Tiffany et al., 2015). All outcomes showed strong support for increased provider prescribing habits, improved access to supply, and greater patient knowledge of this medication. Intranasal use, as opposed to intramuscular injection, was identified as the preferred delivery method. This was based on patient preference, willingness to administer, safety measures (such as reduced likelihood for needle stick injuries) and ease of use. The brand name medication, Narcan, was the most prescribed and used form of naloxone.

Education

Every piece of literature mentioned the impact that education had on reducing opioid risk, including overdose. Prescription counseling and instruction had a “positive impact on medication adherence and health outcomes” (Kadakia et al., 2020, p. e32). Several studies utilized targeted educational methods to increase patient knowledge (Devries et al., 2017; Highland et al., 2020; Kadakia et al., 2020; Seal et al., 2019). Individual learning styles have become increasingly dependent on digital technologies so microlearning was noted to be an effective method that improved health literacy (Wang et al., 2020). Enhanced clinician knowledge of risk reduction strategies also decreased the potential harm of opioid use for the chronic pain patient (Ducoffe et al., 2016; HHS, 2018b; Jones et al., 2019; Marszalek et al., 2020; Martino et al., 2019; Wyse et al., 2018). Comprehension abilities were indicated by the results of patient health literacy evaluations (Tiffany et al., 2015; Wang et al., 2020; Ziadni et al., 2018). The most effective delivery methods were video and written education at a third-grade level distributed in a

collaborative manner (Devries et al., 2017; Frieden & Houry, 2016; Kadakia et al., 2020; Seal et al., 2019).

From the provider perspective, tools found to reduce the risk of opioid harm included urine drug tests, state prescription monitoring programs, depression and abuse potential screening, discussions about medication interactions, safe storage and disposal, and patient access to an opioid reversal agent in the event of an overdose.

Barriers

Several obstacles to harm reduction health literacy were highlighted in the available literature. For example, women were noted to have greater difficulty with self-care than men and patients from low-income populations were less likely to be fully educated on the dangers of opioids (Ylitalo et al., 2018; Ziadni et al., 2018). Some patients were reluctant to accept a prescription for naloxone since the risk of overdose was viewed as only for those who “abused” opioid medications, had an opioid use disorder, or obtained them illegally (Tiffany et al., 2015). Self-pay or under insured clients had limited access to opioid reversal agents (Devries et al., 2017; Dowell et al., 2016). Identified barriers for providers included time constraints, preconceived ideals surrounding opioid use, and lack of knowledge (Martino et al., 2019; Seal et al., 2019; Wyse et al., 2018).

Recommendation

All articles emphasized the staggering statistics of accidental overdoses associated with the use of prescription opioids. Death rates are reduced by adopting a combination of assessments, measures, or actions that emphasize changes within healthcare systems. The information provided from the literature review acknowledged common problems with chronic pain patients and offered clinical strategies successful in managing these identified issues.

Integrating evidenced based changes reduced the risks of death and other harms. In summary, the EBP project change recommendation to develop and implement a safe opioid risk-reduction office policy as a strategy to reduce opioid overdose was fully supported by the evidence.

Setting, Stakeholders, and Systems Change

The setting for this project was an outpatient interventional pain management clinic specializing in managing patients with chronic pain issues through various evaluations and treatments. This organizational leadership believed in a balanced and multi-disciplinary approach. Medication management was one of the methods used to improve quality of life and activities of daily living for patients suffering from chronic pain. They also promoted injection therapy, chiropractic care, massage, physical therapy, and use of spinal cord stimulators. Depression is a common co-diagnosis for those with long term health problems, and more than half of US adults with mental health diagnoses received a prescribed opioid (Rogers et al., 2020). Recognizing this, the facility evaluated and referred as needed for mood and opioid misuse disorders.

This site facility was one of eight in Pennsylvania. Physicians, physician assistants, or nurse practitioner providers rotated to provide patient care at the different locations. A SWOT analysis was initially created in order to better understand the adjustments needed to successfully implement the EBP project steps. It was important to evaluate the strategic positioning of the organization before developing internal strategies. The individual strength, weaknesses, opportunities, and threats determined are listed in Appendix D.

This micro level practice change project was implemented to directly improve safety through scripted conversation, process measures, and handouts (Nevis et al., 2008). The opportunity to increase the safe use of opioids was first identified through conversation with a

DNP provider who practiced at the location. There was no formal policy in place with set guidelines or consistency in patient handouts indicating best practice. This project was designed to ensure continuity of care among providers so that all patients received naloxone with instruction, and that understanding of this education was demonstrated. The teach-back method was chosen as an easy method that ensured both parties shared the same information and increased effective communication of health advice or knowledge (Institute for Healthcare Improvement Open School [IHI], 2016).

The stakeholders were internal and external members of the organization. Internal patrons identified were board members, providers, and other employees, such as clerical and clinical support staff. External participants with a vested interest in the clinic were patients and their families, insurance companies, pharmaceutical firms, and government. Organizational support was obtained after meeting with the CEO and the CNO to review key elements of the EBP change project.

Further collaboration was necessary from the outside agency Next Harm Reduction, an “online and mail-based harm reduction platform designed to reduce opioid overdose deaths” (Next Harm Reduction, Inc., 2020, para. 1). This non-for-profit organization was the backup source of supply for identified patients who could not obtain naloxone through a local pharmacy. This pilot project was designed to trial at one office with the long-term goal to implement the policy changes at other sites to create sustainable clinical improvements.

Implementation with Timeline and Budget

The Lewin change theory (1951) guided the development of this project. Driving forces, that facilitate movement to the desired direction, as well as potential inhibiting forces that pushed in the opposite direction, were identified as the pilot project was developed.

Step one, unfreeze (Lewin, 1951), focused on preparing the patient and provider for changes through staff teaching and online meetings with office staff and providers. The providers were shown the short video from IHI and given the naloxone handout seen in Appendix E to encourage understanding of the teach-back method and adherence. The goals of this stage were to create understanding of why these changes were important and how they would be accomplished. This built motivation and readiness for patient care. Overcoming the identified weakness of the organizational resistance to change relied on the strength of the providers established patient rapport and their willingness to improve the current process. The efforts in Step One were supported by the administration and expert practitioners who recognized the importance of this project, as noted in Appendix D.

Step two, change (Lewin, 1951) involved employee efforts to implement the changes as previously outlined. The project manager (PM) and staff worked together to achieve the desired outcomes of increased naloxone rates and improved patient safety awareness. The front desk staff provided the patient information *Naloxone/Narcan Safety and Use and Prescription Opioids: What You Need to Know*, listed in Appendix F at the first office visit. The practitioners instructed the patients who verbally indicated needed assistance to obtain naloxone to the Next Distro website. A designated laptop was used to allow them to watch the video and register for home delivery of the reversal agent, as well as an instruction card given so this process could be completed at home. The conversation guide in Appendix G was used to ensure consistency of information and facilitated open communication. The PM was to update in office posters with Narcan or naloxone information as in Appendix H.

Step three, refreezing, accomplished integration of the newly desired behaviors (Lewin, 1951). At the patients four week follow up visit, the provider used the checklist in Appendix I to

assess understanding of information and confirm naloxone was available to the patient. This information supported the integration of new practices into the organization, as well as identified any needed adjustments to the process. Step three implemented effective behaviors and desired outcomes into the new standard of care and ensured these advances were permanent.

The overall timeframe for the project was eight weeks. The EBP change process and evaluation occurred after obtaining all required course approvals. The USAHS approval process was completed by the Evidence-Based Practice Review Council, and email notification was given prior to implementation. The main project SMART objectives, seen in Appendix J, were as follows:

1. The PM will develop and implement an evidence-based safe opioid risk-reduction office policy for adult patients receiving care in an outpatient chronic pain management clinic by June 1, 2021 (or within 8 weeks of project approval).
2. At the end of the 8-week implementation period, the rate of prescribing provider adherence to concurrent prescription for naloxone therapy with any opioid prescription will increase to a rate of 95% or greater.
3. At the end of the 8-week implementation period, the rate of initiation to fill naloxone therapy via the patient's pharmacy or Next Distro will increase to a rate of 95% or greater as determined by provider feedback after they review the PDMP.
4. At the end of the 8-week implementation period, the patient's safe-opioid self-care behaviors knowledge will increase by 50% or more, post-patient knowledge intervention, as evidenced by the teach back method.

Appendix J lists team leaders and members involved in the process. A strong understanding of the underlying objectives was critical to convey the purpose behind these changes to the group.

Open communication between all members included emails to the staff, and board members. The PM direct email and phone number was made available to staff for any questions or concerns. Cost was minimal and met the previously projected amount of less than \$100.00. The majority was spent on educational handout supplies, the actual cost of printing office posters was higher than anticipated. There were no outside funding sources or additional agency involvement.

Results

The data was collected at the practice site by one provider due to an unexpected change in staffing. There were no identified HIPAA violations since no records were kept that could identify specific patients. All information was kept confidential and did not recognize patient demographic or include any identifying information. All aggregate data was accessible only to the provider and the PM. The use or disclosure of health information involved no more than a minimal risk to the privacy of individuals. A binder held all the project forms and was locked in the providers office. The analysis was done by the PM with the use of the Intellectus Statistics (2021).

The internally created collection tool in Appendix I was a checklist with face validity and used to accumulate project information. It is a follow up recommendation that this process measure tool be revised to simplify further use as there was some confusion on the pre and post questions. Having the same format for the group one baseline and four-week follow-up group two will strengthen the integrity of the questionnaire and increase the reliability and validity of this assessment for future projects.

All established clinic patients were included in the pilot project. No one declined to participate, all but two were taking opioid prescription medication, and all were English speaking. There were initially 107 participating patients. Two members no longer qualified at the

four-week follow up and were removed prior to analysis. The project participants self-identified gender and method of payment are listed by percentage in Table 3. Thirty-nine persons identified as male and 68 as female. The most often used payment sources were Medicare and Medicaid.

All categories of measures, benchmarks and statistical tests used to determine the impact of this EBP change project on increased opioid safety are described in Appendix K. Frequencies and percentages were calculated for the 107 patients who received the safety packet, NEXT Distro Narcan information, and were offered a prescription for naloxone at the initial visit at 100%. A majority of the 105 second group participants were able to show knowledge of safe-opioid self-care behaviors as assessed by the teach-back method ($n = 102$, 97%). The above descriptive data can be seen summarized in Table 4.

A chi-square test of independence was conducted to determine if patients who had unexpired naloxone were independent variables and presented a change between groups 1 and group 2 (IS, 2021). The rate of prescribing provider adherence measured before and after project implementation was determined by the provider checklist. The results of the chi-square test were not significant based on an alpha value of 0.05, $\chi^2(1) = 2.67$, $p = .102$ as shown in Table 5. This suggested that the two could be independent of one another and implied that the observed frequencies were not significantly different than the expected frequencies. It is clinically significant to note that 102 patients out of 107 (95%) already had an unexpired form of naloxone, as verified by the PMP, at the beginning of the project evaluation. This showed the providers were already doing an excellent job of making sure this important reversal agent was available to their patients who were prescribed opioids.

To examine whether a patient was able to verbalize by the teach back method, how and when to correctly use naloxone, a chi-square test of independence was conducted on the group 1

pre and group 2 post implementation data (IS, 2021). These results of the chi-square test were significant based on an alpha value of 0.05, $\chi^2(1) = 60.89$, $p < .001$. This suggested the education provided by the practitioner made an impact on an important component of opioid safety. Table 6 presents the results of the chi-square test.

Also of clinical significance is that 34 Narcan devices were attained via the collaboration between the clinical site and the non-for-profit NEXT Distro organization as shown in Table 4. This provided supplies for patients who financially were not able to obtain this elsewhere through their insurance or local pharmacy. Similar resources for additional clinical sites discovered during this project research were shared with the stakeholders in other states to further support sustainability.

Any improvement in knowledge that increased the safe use of opioid or naloxone availability was determined to be clinically significant. The reduced likelihood of death by overdose was a meaningful clinical change even if not labeled as statistically significant. This EBP project identified need for a consistent source of education, continued provider involvement, and sustained future project implementations at other sites. The interventions effectively impacted the practice concern of opioid safety and risk-reduction that initiated this project.

Impact

This project was implemented to ensure that a consistent message of safety was presented to the population of patients who required opioids to help manage their chronic pain. Even though opioids have an inherent potential to cause harm, they have been shown to provide effective relief in a certain patient population (Seal et al., 2019; Wyse et al., 2018). Part of the successful use of these medications includes risk mitigation. The providers involved were willing

to take on the task of delivering the evidenced based steps of the plan designed with the goal of increased safe opioid use behaviors. Based on the data collected during the project, the practitioners were already diligent in ensuring that the reversal agent naloxone was encouraged and prescribed for their patients. This project increased the availability the reversal medication to those patients unable to afford it or were hesitant to recognize the importance of proper opioid storage, disposal, or use. During the previous practice protocol, education was provided, but usually verbally and there were no designated handouts or method to assess comprehension. The EBP changes initiated aligned with the practice guidelines from numerous sources such as the CDC, the U.S. Surgeons General, and the U.S. Department of Health & Human Service Inter-Agency Task Force as referenced in Appendix C.

Providing practitioner training, as well as patient education, helped alleviate some of the recognized barriers for naloxone use such as time constraints, preconceived ideals surrounding opioid use, lack of knowledge, and stigma to having or needing a reversal agent (Martino et al., 2019; Seal et al., 2019; Wyse et al., 2018). Providers were introduced to the effectiveness and ease of the teach back method as an educational and evaluation option. This tool can be applied to other aspects of patient care.

Initially, limitations restricted the accessibility of Narcan at no charge to participants who resided in Pennsylvania. During the collaboration with the non-for-profit organizations additional sources were identified that applied to practice sites in other states. This maintains sustainability of the pilot project and supports continuation at additional locations in Virginia, New Jersey, and Maryland. The educational components were well received by both the patients, and stakeholders. They were concluded to be “easy to understand, comprehensive, and welcomed” (G. Hites, personal communication, September 9, 2021). The posters in Appendix H

were not implemented due to funding issues during this project but will be utilized at subsequent practice sites.

Ongoing evaluation for other office sites will be managed by the provider trainers and individual clinic managers. All resources including patient handouts, provider education, and project data was given to the organization and distributed based on the initial success of this project. Only minimal costs are expected for expansion and are mostly for printing costs. The affordability and simplicity of the project design supports the adaptation of future project changes.

Dissemination

Within the USAHS facility, a poster board presentation of the EBP change project results was submitted for review on December 12, 2021. The Third-Party Copyright and SOAR@USA Electronic Submission Statements were completed, and the final approved manuscript project was submitted for publishing in the Scholarship and Open Access Repository at USAHS. The authors updated curriculum vitae includes a link to this work.

The conclusion of this EBP change project was presented to the organizational providers and staff after receiving final approval for the project report. This was done via an online Power Point presentation and a copy of the manuscript was emailed to the board members. During the project, the CEO and CNO, were kept up to date on the progress and findings via email and informal in person conversations.

To allow for a wider dissemination audience, an abstract was submitted to the American Society for Pain Management Nursing for consideration of an evidenced-based practice poster and oral presentation. Journal submissions discussing the practice issue and project findings were

offered to The Journal of the American Academy of Nurse Practitioners and Pain Management Nursing.

Conclusion

The EBP change project successfully increased the safe use of prescription opioid medication and in doing so, reduced the risk of overdose or other harms. This was done through implementing an office policy that expanded the availability of naloxone, and improved patient, and provider knowledge. Clinically, this was significant in that the steps taken achieved a reduction of the likelihood of an accidental overdose or death. This project design can easily be applied by healthcare practitioners at other outpatient clinic sites to prevent a significant public health concern. Improvements in health literacy reduce mortality rates as well as the associated costs and effects of an unintended opioid overdose. Enhanced prevention planning and access to reversal treatment options protect patients who use prescriptions opioids.

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Table 1*Quality Guide Summary*

evidence level	a: high quality	a/b: high/good quality	b: good quality	c: low quality
I (4/14)	3		1	
II (3/14)	2		1	
III (3/14)	1	2		
IV (3/14)	3			
V (1/14)	1			

Table 2

Drug Overdose Deaths Involving Natural and Semisynthetic Opioids Male/Female Combined

Year	1999	2000	2005	2010	2012	2013	2014	2015	2016
White	2.2	2.3	4.4	8.3	8.2	8.2	8.7	9.0	10.2
Black or African American	1.3	1.2	1.9	3.0	3.0	3.5	3.9	4.1	5.3
American Indian or Alaska Native	*	*	4.1	6.4	10.5	7.3	8.2	7.6	7.1
Asian or Pacific Islander	*	*	0.3	0.9	0.9	0.8	0.9	0.8	1.1
Hispanic or Latino	2.6	1.8	2.1	2.4	2.8	3.0	2.8	2.9	3.2
White, not Hispanic or Latino	2.0	2.4	4.9	9.5	9.3	9.4	10	10.6	11.9
Black, not Hispanic or Latino	1.3	1.2	2.0	2.8	3.1	3.3	4	4.3	5.6

Note. * Missing data; Numbers are per 100,000 resident population. Race, gender, year groups and cause of death involving natural and semisynthetic opioids were used to compile data from the 1999-2019 CDC Wonder Online Database retrieved January 23, 2021

<https://wonder.cdc.gov/controller/datarequest/D76.jsessionid=3222538284C09A233E33AB342F>

[B4](#). In the public domain.

Table 3*Frequency Table for Nominal Variables*

Variable	Group		
	1	2	Missing
Sex			
F	68 (64%)	65 (62%)	0 (0%)
M	39 (36%)	40 (38%)	0 (0%)
Missing	0 (0%)	0 (0%)	0 (0%)
Total	107 (100%)	105* (100%)	0 (100%)
MOP			
MD	45 (42%)	40 (38%)	0 (0%)
C	29 (27%)	22 (21%)	0 (0%)
MC	32 (30%)	43 (41%)	0 (0%)
SP	1 (1%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	0 (0%)
Total	107 (100%)	105* (100%)	0 (100%)

Note. MOP= method of payment; MD= Medicaid, C= Commercial insurance, MC= Medicare, SP= Self-pay * Two participants no longer qualified at the four-week follow up.

Table 4*Frequency Table for Nominal Variables*

Variable	Group		
	1	2	Missing
Pt received safety pkt.			
Y	107 (100%)	0 (0%)	0 (0%)
Missing	0 (0%)		0 (0%)
Total	107 (100%)		0 (100%)
Pt. Received NEXT Narcan Info			
Y	107 (100%)		0 (0%)
Missing	0 (0%)		0 (0%)
Total	107 (100%)		0 (100%)
Pt offered RX			
Y	107 (100%)		0 (0%)
Missing	0 (0%)		0 (0%)
Total	107 (100%)		0 (100%)
NARCAN received from NEXT Distro			
N		71 (68%)	0 (0%)
Y		34 (32%)	0 (0%)
Missing		0 (0%)	0 (0%)
Total		105 (100%)	0 (100%)
Able to TB safe opioid use			
Y		102 (97%)	0 (0%)
N		3 (3%)	0 (0%)
Missing		0 (0%)	0 (0%)
Total		105 (100%)	0 (100%)

Note. Due to rounding error, percentages may not sum to 100%.

Table 5*Observed and Expected Frequencies*

Pt. has unexpired naloxone	Group		χ^2	<i>df</i>	<i>p</i>
	1	2			
Y	102[103.97]	104[102.03]	2.67	1	.102
N	5[3.03]	1[2.97]			

Note. Pt., patient; Values formatted as Observed [Expected].

Table 6*Observed and Expected Frequencies*

	Group		χ^2	<i>df</i>	<i>p</i>
	1	2			
Pt. verbalizes education correctly					
Y	59[82.77]	105[81.23]	60.89	1	< .001
N	48[24.23]	0[23.77]			

Note. Pt., patient; Values formatted as Observed [Expected].

Figure 1

Lewin Change Theory

Note. Figure depicting the stages of Lewin change theory “unfreeze” “change” and “refreeze”.

From *Principles of Management*, (p. 304), 2012, Saylor Academy.

(<https://resources.saylor.org/wwwresources/archived/site/textbooks/Principles%20of%20Management.pdf>). CC BY NC-SA 3.0.

Figure 2*PRISMA Diagram*

Note. Flow of information through the different phases of the EBP Change project literature search strategy. Adapted from: “Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement,” by D. Moher, A. Liberati, J. Tetzlaff, and D. G. Altman, *PLoS Med* 6(7): e1000097 (doi:10.1371/journal.pmed1000097). Copyright 2009 by The PRISMA Group.

Figure 3*National Overdose Deaths Involving Prescription Opioids*

Note. Statistics taken from deaths involving many of the more commonly used drugs available through 2019. From the 1999-2009 CDC Wonder Online Database, released 12/2020.

(<https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates>). In the public domain.

Appendix A

Primary Research Review

			PICOT EBP QUESTION: In adult patients at an outpatient chronic pain management clinic (P), how does development and implementation of a safe opioid risk-reduction office policy (I), compared to usual practice (C), improve patient rates of naloxone availability and health literacy (O) over four weeks (T)				
Article Number	Author and Date Published	Evidence Type	Sample Size	Findings Related to PICOT Question	Measures	Limitations	Evidence Level Quality
			Setting				
1.	Devries, J., et al. (2017).	Quantitative Quasi-experimental Study	N=252 Naloxone prescriptions Large academic hospital healthcare system	1. The steady increase in nalox per month correlates with increased provider trainings and EHR alerts. 2. Source of EHR alerts and changes 3. Naloxone Prescribing Guidelines 4. Overdose education and naloxone distribution program checklist 5. Naloxone was prescribed in response to 13.8% (41/252) of the EHR alerts	Nalox by month compared over 9 months pre- and post-policy change. Demographics of provider, department, and patient EHR summary report records	-large, multi-site health system - hospital based study - pharmacist, techs, ER department and large education department staffing	Level II A
2.	Highland, K. B., et al. (2020).	Quantitative Quasi-experimental Study	N=152 Patients	1. Support for and source of patient, family member, clinician educational videos	Anonymous feedback survey (demographics, video rating, educational approach)	-both pain management and primary care settings in military-based clinics -pilot study	Level II A

				2. Support for and tool for improved clinical pain assessment/DVPRS 3. New pain paradigm-self-management, opioid risk mitigation practices and informed consent	5-point Likert scale Three yes/no assessment questions	-patient anonymity prevents follow up	
3.	Marszalek, D., et al. (2020).	Quantitative experimental Study	<p>N=50 subjects predominately male and white/non-Hispanic, with an average age (range) of 62 years.</p> <p>Veterans in primary care setting</p>	<p>1. Education (via PowerPoint) that describe what opioids are and how to recognize and respond to an overdose (e.g., naloxone education)</p> <p>2. Statistics re: unintentional opioid overdose and how veterans are particularly at risk.</p> <p>3. Medication storage safety</p> <p>4. Risks associated with co-ingesting opioids with alcohol, other drugs, and sedating medications (i.e., benzodiazepines)</p>	<p>means between groups (PC-POP enrollees vs the comparison group) and within groups (PC-POP enrollees only, before and after six months of PC-POP enrollment) preliminary independent-samples t tests utilizing the two-tailed significance test and 95% confidence intervals. generalized linear modeling (GLM) and a single paired-sample t test (for the individual continuous variable, MEDD) to examine whether differences were</p>	<p>-small sample size</p> <p>-veterans in primary care at one geographical site- lack of generalizability</p> <p>-sample of convenience</p> <p>-mostly male white patients</p>	Level I B

					statistically significant before engagement in the PC-POP vs post-PC-POP engagement UDS		
4.	Martino, J.G., et al. (2019).	Mixed methods Cross-sectional Study	N= 72 Physicians and pharmacists Large academic hospital healthcare system	1. Identification of barriers to Nalox 2. Support of provider education and training specifically regarding Nalox	Questionnaire Interviews	- small study sample size -limited to physicians and pharmacists	Level I A
5.	Seal, K. H., et al. (2019)	Mixed Method; Explanatory Randomized Controlled Trial (RTC)	N=100 Patients VA primary care office	1. Support use of SMART patient goals 2. Internal validity increased when objective measures are combined with clinical measures. 3. Collaborative Care Model with motivational interviewing effective measurement of patient education 4. Support for and source of patient-centered educational materials	Current Opioid Misuse Measure The Brief Pain Inventory The World Health Organization Alcohol, Smoking, and Substance Involvement Screening Test The Pain Treatment Satisfaction Scale The Patient Health Questionnaire The Addictions Behavior Checklist Urine Drug Screen	-primary care setting -pilot study -mostly descriptive analyses results	Level I A

					Alcohol Breathalyzer		
6.	Tiffany, E., et al. (2015).	Qualitative Descriptive Study	N=90 pts Veterans receiving opioids for >3 months	1. overdose education and naloxone distribution OEND programs in the US helped to rescue more than 10,000 individuals from opioid overdoses from 1996 to 2010 2. Veterans surveyed appeared comfortable with the idea of using naloxone kits to prevent OOD and many were interested in receiving a kit. 3. intranasal spray kit preferred over injection kit	Structured 30 min interview. DAST-10 AUDIT-C	- sampling was not randomized. -pts limited to the VA -some prior pts in one group had had previous opioid education -93% male pts	Level III A/B
7.	Wyse, J. J., et al. (2019).	Qualitative Descriptive Study	N= 24 clinicians Department of Veterans Affairs	1. changes to policy and practice designed to promote safer prescribing and patient care 2. recognition of the harms associated with long-term opioid therapy (LTOT) 3. initiatives providers utilized to meet opioid	qualitative content analysis AtlasTI, version 7 was used to organize and code the data group coding process, interviews were divided and first coded	-small qualitative sample obtained through convenience sampling methods -all providers who participated in the study were currently employed within VA hospitals	Level III A/B

				safety requirements and address common challenges in caring for patients. 4. information to implement new guidelines around opioid management and minimize the potential for patients to experience opioid-related harms	independently and then exchanged for secondary coding	-may be different regulations based on State of practice	
8.	Ziadni, M., et al. (2018)	Quantitative Multiphasic RTC Study	Phase I N=729 clinic pts Phase II N=578 online pts N= 145 in clinic pts Chronic care Pts validation of the CARE scale was performed in a tertiary pain clinic	1. The CARE scale is a brief, integrated measure that may be used to reveal specific interpersonal and personal impediments to self-care, and identify important therapeutic targets to optimize self-management behaviors	The Brief Pain Inventory (BPI)-Short Form19 The Patient-reported Outcomes Measurement Information System (PROMIS) The Pain Catastrophizing Scale (PCS)1	-presence of chronic pain was self-reported and medical diagnoses were not confirmed. -demographics for both studies revealed that both samples were predominantly female and middle aged. -phase I predominantly Caucasian and college educated	Level I A

Note. HER, electronic health records; MEDD, morphine equivalent daily dose; LTOT, long term opioid therapy; Nalox, naloxone education/prescription; PC-POP, Primary Care Pain Education and Opioid Monitoring Program; PDMP, prescription drug monitoring program; PTS, patients; UDS, urine drug screen; VA/DoD, Veterans Affairs/Department of Defense

Appendix B

Systematic Review

			PICOT EBP QUESTION: In adult patients at an outpatient chronic pain management clinic (P), how does development and implementation of a safe opioid risk-reduction strategy toolkit (I), compared to usual practice (C), improve health literacy and self-care behaviors (O) over eight weeks (T)				
Article Number	Author and Date Published	Evidence Type	Sample Size	Findings Related to PICOT Question	Measures	Limitations	Evidence Level Quality
			Setting				
1.	Kadakia, N. N., et al. (2020).	Qualitative Synthesis Systematic Review	10 articles	1. the results do not support one method of pt education as being superior to another. 2. Two studies measured knowledge of medication as a primary outcome. 3. Statistical significance shown for improvements in knowledge	Pain self-efficacy Questionnaire Prescription Opioid Difficulty Scale	- number of included studies - consistent results and recommendation - comprehensive literature review with reference to scientific evidence	Level III A
			Varied ED, pain clinic, primary care, level 1 trauma center, medical center				
2.	Wang, C., et al. (2020).	Quantitative Synthesis Systematic Review	26 articles	1. Micro learning interventions using short videos were most popular. 2. Studies showed statistically significant positive effect of microlearning on	Self-care behavioral changes Health literacy score Wellness score Healthy behavior change.	-one teen study -only 4 studies contained equal distribution between gender groups - learning was focused on varied chronic health conditions -not all US studies -some studies with high to mod bias risks	Level II B
			Varied Clinical, university, community				

			, and department of corrections	improved knowledge and health literacy behaviors	Treatment adherence Health product use and misuse		
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Note. Pt., patient.

Appendix C

Consensus Statement/Guidelines

			PICOT EBP QUESTION: In adult patients at an outpatient chronic pain management clinic (P), how does development and implementation of a safe opioid risk-reduction strategy toolkit (I), compared to usual practice (C), improve health literacy and self-care behaviors (O) over eight weeks (T)				
Article Number	Author and Date Published	Evidence Type	Sample Size	Findings Related to PICOT Question	Measures	Limitations	Evidence Level Quality
			Setting				
1.	Dowell, D., et al. (2016).	Center for Disease Control and Prevention Guidelines	N/A U.S.	1. Supports nalox and education as a critical component to stopping OOD 2. Resources for tool kit including clinician and pt education. 3. Includes safe disposal and usage education	N/A	N/A	Level IV A
2.	Ducoffe, A. R., et al. (2016).	Office of Disease Prevention and Health Promotion The National Action Plan for Adverse Drug Event Prevention	N/A Outpatient	1. Supports nalox and education as a critical component to stopping OOD. 2. Resources for tool kit including clinician and pt education. 3. Includes safe disposal and usage education	N/A	-original report includes recommendations for anticoagulants, and diabetes agents	Level IV A

3.	U.S. Department of Health & Human Services. (2019).	U.S. Department of Health & Human Service inter-agency task force	N/A	1. Supports nalox and education as a critical component to stopping OOD. 2. Resources for tool kit including clinician and pt education. 3. Includes safe disposal and usage education	N/A	N/A	Level IV A
		Best practices	U.S.				
4.	U.S. Department of Health & Human Services. (2018).	US Surgeons General	N/A	1. Supports nalox and education as a critical component to stopping OOD. 2. Resources for tool kit including clinician and pt education.	N/A	Mainly addresses nalox information	Level V A
		Advisory Statement					
			U.S.				

Note: nalox, naloxone prescription; OOD, opioid overdose

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
<ul style="list-style-type: none">•Subspecialists expertise•Willingness to improve process•Good rapport with patients•Supportive administration	<ul style="list-style-type: none">•New staff•Time constraints•Resistance to change	<ul style="list-style-type: none">•Political influence•Culture of safety•Electronic health records	<ul style="list-style-type: none">•Government regulations•Competing clinics•Low health literacy•Attitudes towards opioids

Appendix E

Provider Teach-Back Method Video

https://youtu.be/bzpJJYF_tKY

Note. Obtained from IHI Open School, Available through open access, no changes made.

Provider Naloxone Handout

<p style="text-align: center;">Naloxone: The Opioid Reversal Drug that Saves Lives <i>How Healthcare Providers and Patients Can Better Utilize this Life-Saving Drug</i></p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Encouraging signs in the U.S. response to the opioid crisis</p> <ul style="list-style-type: none"> • Significant decrease in opioid prescribing • Reduction in prescription opioid misuse • Fewer individuals with prescription opioid use disorder • More than 50% reduction in first time heroin users </div> <p>The Centers for Disease Control and Prevention (CDC) reports that 70,237 Americans died from drug overdoses in 2017, of which 47,600 were opioid related. Also in 2017, 11.1 million people reported misuse of prescription opioid pain medications, nearly 900,000 people used heroin, and 2.1 million people suffered from an opioid use disorder.</p> <p>CDC's Guideline for Prescribing Opioids for Chronic Pain, as well as other medical and professional society guidelines, have played a vital role to improve the appropriate prescribing of opioids and reduce the likelihood of misuse, addiction, and other opioid-related harms. <i>Positive results</i> from our efforts can be found across the country, but the fact remains that opioid prescriptions remain common – with more than 13 million dispensed per month in America. While these powerful medications can provide important pain relief to many in need, they pose a very real risk for addiction, overdose, and death, as well as diversion for misuse among family members and friends.</p> <p>Taking action with Naloxone Because of this ongoing crisis and the continued deaths from opioids (prescription opioids, heroin, and illicit synthetic opioids like fentanyl), we must continue an "all hands on deck" approach to prevent opioid misuse and treat those with opioid use disorder, to decrease the deadly effects of addiction until sustained recovery is achieved. One such intervention that can reduce overdose deaths is naloxone, a drug antagonist that reverses the effects of opioids and can be life-saving when an opioid overdose occurs.</p> <p>In April 2018, the U.S. Surgeon General called for heightened awareness and availability of naloxone to reverse the effects of opioid overdose. In the weeks and months since, we've seen a rise in the dispensing of the opioid antagonist – but there are additional ways to improve this response and ultimately, save lives.</p> <p>Data clearly indicate a significant, persistent gap in our response – the infrequent co-prescribing of naloxone to patients who are prescribed opioids and/or those who are at high risk of experiencing (or responding to) an opioid overdose. National data on patients to whom clinicians should consider co-prescribing naloxone show that less than 1% of these patients actually receive a naloxone prescription.</p> <p>Recommendations for when to prescribe and/or co-prescribe naloxone Naloxone is highly effective and has saved lives from opioid overdoses, but can only do so if it is in the right hands, at the right time. Healthcare providers have a critical role in assuring this occurs across all populations at risk.</p>	<p>In order to reduce the risk of overdose deaths, clinicians should strongly consider prescribing or co-prescribing naloxone, and providing education about its use for the following patients who are at risk of opioid overdose:</p> <ul style="list-style-type: none"> • Patients prescribed opioids who: <ul style="list-style-type: none"> ○ Are receiving opioids at a dosage of 50 morphine milligram equivalents (MME) per day or greater (the CDC's MME calculator can be accessed here). ○ Have respiratory conditions such as chronic obstructive pulmonary disease (COPD) or obstructive sleep apnea (regardless of opioid dose); ○ Have been prescribed benzodiazepines (regardless of opioid dose). ○ Have a non-opioid substance use disorder, report excessive alcohol use, or have a mental health disorder (regardless of opioid dose). • Patients at high risk for experiencing or responding to an opioid overdose, including individuals: <ul style="list-style-type: none"> ○ Using heroin, illicit synthetic opioids or misusing prescription opioids. ○ Using other illicit drugs such as stimulants, including methamphetamine and cocaine, which could potentially be contaminated with illicit synthetic opioids like fentanyl. ○ Receiving treatment for opioid use disorder, including medication-assisted treatment with methadone, buprenorphine, or naltrexone. ○ With a history of opioid misuse that were recently released from incarceration or other controlled settings where tolerance to opioids has been lost. <p>Key facts about Naloxone Naloxone can reverse the life-threatening respiratory depression associated with opioid overdose.</p> <p>A variety of naloxone products (nasal spray, injection, auto-injection) are available to respond to an overdose. Most health insurance plans, including Medicaid and Medicare plans, will cover at least one form of naloxone. There are also several programs at the state or local level that may supply free or low-cost naloxone to those at risk and without insurance coverage.</p> <p>What to know if you are a patient, or caring for a patient: While prescription opioids can be appropriate for the treatment of certain types of pain, they can also lead to physical dependence, addiction, overdose, and death. It is important to understand your risk factors, the type and duration of your opioid prescriptions, and how you can minimize your risk – and your family's risk – by having naloxone and knowing how to use it. Talking with your healthcare providers is the first step. If you or a loved one is at risk for an opioid overdose (see list above), it is important that you have naloxone on hand.</p> <p>According to the CDC, patients taking opioid dosages at or above 50 MME/day are twice as likely to overdose as those taking dosages of 20 MME/day, and the risk further increases as the MME/day increases. Prescribing naloxone for at-risk patients and co-prescribing naloxone for patients taking opioids for pain that meet or exceed this threshold has the potential to save lives.</p> <p>For more information, please visit: https://www.hhs.gov/opioids/treatment/overdose-response/index.html.</p>
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Note. From HHS.Gov (<https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf>). In the public domain.

Appendix F

Handouts

PRESCRIPTION OPIOIDS: WHAT YOU NEED TO KNOW

Prescription opioids can be used to help relieve moderate-to-severe pain and are often prescribed following a surgery or injury, or for certain health conditions. These medications can be an important part of treatment but also come with serious risks. It is important to work with your health care provider to make sure you are getting the safest, most effective care.

WHAT ARE THE RISKS AND SIDE EFFECTS OF OPIOID USE?

Prescription opioids carry serious risks of addiction and overdose, especially with prolonged use. An opioid overdose, often marked by slowed breathing, can cause sudden death. The use of prescription opioids can have a number of side effects as well, even when taken as directed:

- Tolerance—meaning you might need to take more of a medication for the same pain relief
- Physical dependence—meaning you have symptoms of withdrawal when a medication is stopped
- Increased sensitivity to pain
- Constipation
- Nausea, vomiting, and dry mouth
- Sleepiness and dizziness
- Confusion
- Depression
- Low levels of testosterone that can result in lower sex drive, energy, and strength
- Itching and sweating

As many as 1 in 4 PEOPLE* receiving prescription opioids long term in a primary care setting struggles with addiction.

* Findings from one study

RISKS ARE GREATER WITH:

- History of drug misuse, substance use disorder, or overdose
- Mental health conditions (such as depression or anxiety)
- Sleep apnea
- Older age (65 years or older)
- Pregnancy

Avoid alcohol while taking prescription opioids. Also, unless specifically advised by your health care provider, medications to avoid include:

- Benzodiazepines (such as Xanax or Valium)
- Muscle relaxants (such as Soma or Flexeril)
- Hypnotics (such as Ambien or Lunesta)
- Other prescription opioids

KNOW YOUR OPTIONS

Talk to your health care provider about ways to manage your pain that don't involve prescription opioids. Some of these options **may actually work better** and have fewer risks and side effects. Options may include:

- ❑ Pain relievers such as acetaminophen, ibuprofen, and naproxen
- ❑ Some medications that are also used for depression or seizures
- ❑ Physical therapy and exercise
- ❑ Cognitive behavioral therapy, a psychological, goal-directed approach, in which patients learn how to modify physical, behavioral, and emotional triggers of pain and stress.

IF YOU ARE PRESCRIBED OPIOIDS FOR PAIN:

- ❑ Never take opioids in greater amounts or more often than prescribed.
- ❑ Follow up with your primary health care provider within ____ days.
 - Work together to create a plan on how to manage your pain.
 - Talk about ways to help manage your pain that don't involve prescription opioids.
 - Talk about any and all concerns and side effects.
- ❑ Help prevent misuse and abuse.
 - Never sell or share prescription opioids.
 - Never use another person's prescription opioids.
- ❑ Store prescription opioids in a secure place and out of reach of others (this may include visitors, children, friends, and family).
- ❑ Safely dispose of unused prescription opioids. Find your community drug take-back program or your pharmacy mail-back program, or flush them down the toilet, following guidance from the Food and Drug Administration (www.fda.gov/Drugs/ResourcesForYou).
- ❑ Visit www.cdc.gov/drugoverdose to learn about the risks of opioid abuse and overdose.
- ❑ If you believe you may be struggling with addiction, tell your health care provider and ask for guidance or call SAMHSA's National Helpline at 1-800-662-HELP.

Be Informed! Make sure you know the name of your medication, how much and how often to take it, and its potential risks & side effects.

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

Note. From the CDC Prescription Opioids: What You Need to Know, no changes made.

(<https://www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf>). In the public domain.

How to use a naloxone kit in the event of an overdose

an informational booklet for opioid pain treatment

If someone has overdosed, a naloxone kit can be used to save them.

You can get a kit from a specially trained pharmacist without a prescription, but it may not be covered by your medical insurance unless your doctor writes an order.

Naloxone is also known by the brand name Narcan.

created as a collaboration between
US Health Center for Damage in the Public Interest
and US Health Medication Center

What does an overdose look like?

Learn the signs of a opioid overdose and educate those around you.

Three strong signs of overdose are:

- tiny, pinpoint pupils
- slow and shallow breathing
- unconsciousness and/or unresponsiveness

Can naloxone be harmful?

Serious side effects of naloxone are very rare.

The most common side effect is opioid withdrawal, since naloxone reverses the effect of opioids. Common opioid withdrawal symptoms include aches, irritability, sweating, runny nose, diarrhea, nausea, and vomiting.

It's most important to give someone naloxone if you think they are experiencing an overdose because it can save them from brain damage or even death.

How do I know when to use naloxone?

If you think someone is experiencing an opioid overdose, it does not hurt to give naloxone.

Naloxone reverses the effects of opioids such as heroin, methadone, morphine, opium, codeine, or hydrocodone. It does not reverse the effects of other types of drugs like alcohol or stimulants like cocaine. If the person has mixed drugs and an opioid is involved, the person will likely start breathing but continue to be sedated from the other drugs.

How can I tell if it's working?

If someone is experiencing an opioid overdose and is given naloxone, they should wake up in 2–3 minutes.

If the person does not wake up in 3 minutes or loses consciousness again after 30–90 minutes, give them a second dose of naloxone.

Stay with the person until help arrives.

What do I need to do?

- 1 Try to wake the person up
- 2 Give the first dose of naloxone
- 3 **Call 911**
- 4 Check for breathing
- 5 Be prepared to give a second dose of naloxone if needed

1
Try to wake the person up

Shake them and shout.

If there is no response, **grind your knuckles into their breastbone** for 5 to 10 seconds.

4
Check for breathing

Give CPR if you have been trained

Or, do rescue breathing:

- 1 Tilt the head back, open the mouth, and pinch the nose
- 2 **start with 2 breaths** into the mouth
- 3 then, **give 1 breath every 5 seconds**
- 4 **continue** until help arrives

2
Give naloxone the label may say "Narcan"

nasal spray

Naloxone nasal spray works even if the person is not breathing.

Peel the package open and hold the device. **Do not press** until ready to give naloxone.

Place the tip in the nostril.

Press button firmly.

or

nasal atomizer spray

Naloxone atomizer spray works even if the person is not breathing.

Pull off safety caps.

Screw pieces together. **Do not press** until ready to give naloxone.

Spray **one half** of the medicine into **each nostril**.

or

injection

Flip off the cap to reveal the latex seal on the top of the bottle.

Turn bottle upside down and pull the plunger on the syringe.

Inject into muscle such as the **shoulders, thighs, or buttocks.** Push the plunger all the way down.

3

call 911

5
Be prepared to give a second dose of naloxone

3 min

If the person does not wake up in 3 minutes, give a second dose of naloxone.

Turn the person on their side to prevent choking.

Naloxone wears off in **30 to 90 minutes.**

Note. From “How to Use a Naloxone Kit in the Event of an Overdose,” by UC Davis Center for Design and UC Davis Medical Center, 2020.

(<https://naloxonesaves.org/wp-content/uploads/sites/19608/2020/02/How-to-Use-Naloxone-Brochure-ALL-formulations2.pdf>). CC BY NC-

ND 4.0.

Appendix G

Provider Information

First OV

“Please read these two handouts before your next visit so we can talk about the information on safer opioid use and go over any questions you have. We want to be sure every patient understands the risks to opioid use. We want you and your family to be as safe as possible.” (checkbox)

“I am going to prescribe Narcan for you today. It is very important that anyone who has opioids in the home have this in case of an emergency. It is like a fire-extinguisher- no one plans on using it but are glad they have one if needed. Will your insurance pay for this, or do you want to have it shipped to you?

If they already have RX- “please check the expiration date and let us know when it needs to be refilled or if you felt you would benefit from having an extra one to carry with you I can prescribe that too.”

“Do you feel very comfortable giving someone Narcan and when to use it?” (checkbox)

“There is information on when and how to give Narcan and we can talk about any questions when you come back.”

Second OV

“I know I gave you 2 papers to read last month. To make sure that I am giving you all the information that you need what can we talk about so that you are comfortable with how to take and store your medication? Do you know where you would dispose of your medications if you do not need them anymore?” (checkbox)

“Do you have Narcan available to you?” Check PDMP and EMR for Narcan filled since the last OV (checkbox)

If no RX- “I really want to make sure that you have this reversal medication so that you are safe. What can I do so that we can get it to you?”

“Can you explain to me your understanding of how and when you would give someone Narcan?” (checkbox)

Note. Posters from “Prevent and Protect”- site by: web360 (<https://prevent-protect.org/>). Copyright © 2021- Customizable posters with a blank permission to use and adapt any material on the site, in the public domain.

Appendix I
Provider Checklist

OFFICE VISIT #1		DATE:		
Provider initials-				
	YES	NO	N/A	Comments:
The patient was given the two project handouts.				
The patient was offered a Narcan RX.				
The patient has previously received Narcan from a pharmacy within the last year. Verified from PDMP/EMR.				

The patient is going to receive Narcan from NEXT distro and watch the video.				
The patient can correctly verbalize how and when to use Narcan.				
OFFICE VISIT # 2			DATE:	
Provider initials-				
	YES	NO	N/A	Comments:
The patient verbalizes the safe opioid use in teach-back format				
The patient has received Narcan from a pharmacy. Verified from PDMP/EMR				

Or they have brought it in to this visit				
The patient received Narcan from NEXT distro Or is pending shipment				
The patient does not have Narcan and was re-educated on use and verbalizes understanding via teach-back method				
The patient can correctly verbalize how and when to use Narcan.				

Appendix J

Timeline Chart

Project Title: Development and Implementation of a Safe Opioid Risk-Reduction Office Policy

Project Description: An EBP Change Project to Improve Health Literacy and the Safe Use of Opioids at an Outpatient Pain Clinic

Project Lead: Heather Darmetko MSN, FNP Team Members: Dr. Rao CMO, Christina Marshall CNO, Greg Hites DNP, TBD MA, TBD Office Manager, TBD NP, MP IT

Project start
date:

Mon, 1/11/2021

Project End Date: 12/14/2021

TASK	ASSIGNED TO	START	END
Literature Review	Project Manager H.D.	1/11/21	1/24/21
SWOT Org. Analysis	Project Manager H.D.	1/14/21	1/21/21
Stakeholder Determination	Project Manager H.D.	1/16/21	1/18/21
PICOT Statement	Project Manager H.D.	1/18/21	1/24/21
Identify Project Champions	Project Manager H.D, DNP G.H.	2/14/21	2/18/21
Protocol Development	Project Manager H.D.	2/28/21	3/21/21
Preceptor Approval	Project Manager H.D.	3/11/21	4/11/21
Submit Project Proposal	Project Manager H.D.	1/10/21	4/4/21

EPRC Submission	USA Faculty	5/16/21	5/23/21
IRB Approval	Project Manager H.D.	5/23/21	5/25/21
Approved Project Org. Submission	CMO Dr. R	5/24/21	5/27/21
Budget Approval	CNO C.M.	5/24/21	5/27/21
Final Process Flowchart	Office Manager, Lead MA	5/30/21	5/31/21
Finalize EHR for Project	Lead IT	5/30/21	6/3/21
Collect Baseline Data	Project Manager H.D.	5/30/21	6/7/21
Office Protocol Review	CNO C.M.	5/30/21	5/31/21
Provider Presentation	Project Manager H.D.	6/2/21	6/2/21
Lunch and Learn Office Presentation	Project Manager H.D.	6/4/21	6/4/21
Staff Email	Project Manager H.D.	6/7/21	6/7/21
Patient Enrollment	Office Manager	6/7/21	6/18/21
Collect Project Patient Data	Project Manager H.D.	6/12/21	6/13/21
Collect Project Patient Data	Project Manager H.D.	6/19/21	6/20/21
Staff Process Review	Provider GH	6/8/21	6/8/21

Handout Process Review and Revision PRN	Lead MA Office Mgr. DNP	6/8/21	6/9/2021
Staff Email	Project Manager H.D.	6/20/21	6/20/21
Board members Email	Project Manager H.D.	6/27/21	6/27/21
Post Patient Survey #2	Project Manager H.D.	7/4/21	7/17/21
Collect EHR Measures 8 weeks	Project Manager H.D.	7/18/21	8/1/21
Provider Debriefing	Providers	7/14/21	7/14/21
Staff/Board members Email	Project Manager H.D.	7/18/21	7/18/21
60-day Review Meeting	CMO Dr. R CNO C.M. Project Manager H.D.	9/13/21	9/13/2021
Finalize data collection	Project Manager H.D.	9/13/21	9/17/21
Evaluate Outcome Measures to Create Project Findings	Project Manager H.D.	9/17/21	9/27/21
Submit final project manuscript to primary faculty	USA, Project Manager H.D.	11/22/21	11/28/21
Publish Findings-submit final approved project manuscript to SOAR	Project Manager H.D.	11/22/21	11/28/21
Disseminate Findings	Dr. Rao, CM, GH, Project Manager H.D.	11/29/21	11/29/21
Completion/Thank you Email	Project Manager H.D.	12/3/21	12/3/21

Appendix K

Evaluation Plan for: Development and Implementation of a Safe Opioid Risk-Reduction Strategy Toolkit**Project Design: pre and post design** **Heather Darmetko MSN, APRN, FNP**

This is an evidenced based practice project to improve patient outcomes at an interventional outpatient pain clinic. The purpose is to increase patient and provider knowledge on safe use of prescription opioids by development and implementation of an office policy.

MEASURES	CATEGORIES					TIME for DATA COLLECTION				Data Description	STATISTICAL TEST				BASELINE	GOAL	
	OUTCOME	PROCESS	BALANCING	FINANCIAL	SUSTAINABILITY	Baseline	1 week	2 weeks	4 weeks		paired t-test	unpaired t-test	χ^2	Other	Values	4 weeks	8 weeks
Average 1. The rate of prescribing provider adherence will be measured with a percentage change of before and after project implementation-data is collected by the PDMP. Average is obtained by adding the total score amount from each patient and dividing by the number of patients.	X					X			x	Nominal		X					≥ 95 %

<p>Average 2. The number of filled naloxone prescriptions will be evaluated by a percentage change of pre and post project implementation. Yes/No- data is collected from PDMP by the PM.</p>	X					X						Nominal		X				≥ 95 %
<p>Percentage of patients who received Narcan from Next Distro. As determined from provider checklist. This data with the denominator as the total of patients who received supply. The numerator is the number of patients who participated.</p>			X	X		X	X	X	X			Ratio		X				
<p>Average 3. The determination of patient's knowledge of safe-opioid self-care behaviors will be assessed by a comparison of pre- and post-patient knowledge verified by provider checklist. The scores are averaged by adding test scores and dividing by the total number of tests.</p>	X					X			X			Ordinal		X				≥95 %

Percent of Project Participants. Done by a PM review of EMR. Denominator is the number of project patients. Numerator is the number of patient in the 2 week collection period.														
	X				X		X	X			Ratio		X	
Percent of patient packets handed out. Done by a review of distributed material after 1 week. Total is the number of project patients.														
	X				X	X	X	X			Nominal			

Percentage of correct process checks for EMR. Done by PM review of project patients to make sure provider checklist is complete and is updated. Denominator is number of patients. Numerator number of correctly assessed patients.														
	X					X	X	X	X		Ratio		X	