Doctor of Nursing Practice Project

Orthopedic-Trauma Opioid Prescribing Guideline Adherence Initiative

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Abstract

The Centers for Disease Control and Prevention (CDC) recommends using opioid prescribing guidelines, including screening for opioid misuse, when monitoring adults ages 18 to 64 on opioid therapy. However, adherence to these opioid prescribing guidelines is currently sporadic and inconsistent, leading to poor patient outcomes. *Purpose:* The purpose of this evidence-based project is to determine if the implementation of provider education improves the use of standardized opioid prescribing guidelines when managing adults, 18 to 64, on opioid therapy. *Goals*: The primary goals were to improve provider knowledge regarding opioid management, increase the use of standardized opioid prescribing guidelines, and to increase the use of risk mitigation strategies. Provider knowledge, comfort, and confidence outcomes were directly measured using a pre- and post-education survey, the *Providers' Experiences with Prescribing Opioids. Methods:* Data collection included a retrospective chart review to evaluate provider documentation and adherence to guidelines and risk mitigation strategies. A total of nine providers were available during the project, and three participated in the education modules. Low participation rates were suspected of being influenced by the Coronavirus' global pandemic outbreak (COVID-19). After reviewing 343 charts, a total of 34 patients met inclusion criteria, completed a *Prescription Opioid Misuse Index* (POMI) screen for unhealthy medication use, and a review for overdose risks. Although the implementation of provider education did not improve the use of the opioid prescribing guidelines, further outcomes indicated that the use of opioid prescribing guidelines improved risk mitigation and identification of unhealthy medication use.

Keywords: opioid, misuse, risk mitigation, prescribing guidelines, monitoring

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Dedication

Special recognition is extended to my husband, Anthony M. Stechschulte for your unwavering support. My children Allysa, Jordan, Kelvin, and Stevan, for their never-ending encouragement, understanding, and prayers during this very long journey. I also dedicate this work to those who suffer from opioid addiction and who have lost a loved one to this deadly disease.

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Section 1: Problem Statement and Background

Problem Statement

Current opioid prescribing guidelines recommend continuous monitoring of opioid therapy and screening for opioid misuse among adults ages 18 to 64 (Centers for Disease Control and Prevention (CDC), 2019). However, adherence to these guidelines is sporadic and inconsistent, which can cause significant health and social consequences (Samuels, McDonald, & McCormick, 2019). The use of opioid prescribing guidelines and early recognition of those with opioid misuse have been shown to improve patient outcomes (Samuels et al.). Lack of standardized opioid prescribing guidelines can cause significant patient harm, including misuse and overdose.

Description

Opioid misuse involves a patient not taking a prescription as prescribed, resulting in unhealthy medication use (American Society of Addiction Medicine (ASAM), 2013). Opioid abuse is defined as use for non-medical purposes, the diversion of prescribed opioids, or the illicit use of heroin. Opioid use disorder (OUD) is considered a disease and an addiction to an opioid that involves misuse. (ASAM). Although each level of unhealthy medication misuse, abuse, or addiction needs to be addressed, each level requires a different intervention. For the remainder of this paper, the term opioid misuse will be used as a general term to address the current opioid crisis.

Opioid misuse is the leading cause of mortality and morbidity for people under 50 years of age in the United States (National Institute on Drug Abuse (NIDA), 2019). Since 2010, there has been a 286% increase in opioid-related overdose deaths per 100,000 people (NIDA). A person is more likely to die from an opioid overdose than from a motor vehicle accident (NIDA).

In the United States, 115 people die every day from opioid misuse (NIDA). According to the NIDA, 70,237 persons died in 2017 from an opioid overdose in the United States. Ohio ranked second with 4,854 in overdose death rates in 2017, of which 523 deaths were related to prescription opioids (NIDA).

A small decline in overdose deaths has occurred since 2018 in Ohio due to naloxone distribution efforts (Toles, K., 2018). However, Lucas County has demonstrated a rising trend in overdose rates, with 227 deaths in 2018 compared to 157 deaths in 2017 (Toles). Lucas County has the highest opioid overdose-related deaths in Northwest Ohio (Ohio Department of Health, 2018; Toles, K., 2018). Furthermore, for each overdose, an additional 890 more people suffer on some level with misuse, abuse, or addiction and are at a high risk of overdose (NIDA, 2019). The advent of naloxone distribution, opioid awareness, and the implementation of prescribing guidelines have had a positive effect on saving lives. It is now time to focus efforts on helping the additional 890 people suffering from opioid misuse, through education, screening, and preventative monitoring.

According to the CDC (2016), chronic pain is pain lasting longer than three to six months, whereas acute pain is less than three months. Among those who have chronic, noncancer pain lasting more than three months, over 50% suffer from opioid misuse (NIDA). Recent pain guidelines for chronic and acute pain were issued in 2016 from the Centers for Disease Control and Prevention (CDC). The CDC recommends using these opioid prescribing guidelines, including administrating an opioid misuse screening tool among all adults, monitoring those on opioid therapy. Adherence to current CDC guidelines, however, remains low (CDC, 2019). The United States Preventative Services Task Force (USPSTF) issued a Grade B recommendation to screen all adults, 18 to 64, for unhealthy drug use (2019). The integration of opioid prescribing

guidelines and screening for misuse into an electronic health record (EHR) can improve thousands of Americans' quality of life on opioid therapy.

Prevalence

Five million Americans have used prescription opioids for non-medical use within the past year (NIDA, 2019). One-third of those patients who have misused an opioid prescription met the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-V) criteria (Appendix A) for opioid use disorder (American Psychiatric Association, 2013). The highest incidence of opioid misuse is among unemployed males 18 to 25 years of age and those with comorbid illness, including mental health disorders, and those who suffer from chronic pain (NIDA, 2019). Mental health disorders, such as anxiety and depression, affect 50% of those who misuse opioids. Interestingly, those with mental health illness also receive over half of the opioid prescriptions (Davis, Lin, & Liu, 2017; NIDA, 2019).

Post-surgical prescribing patterns associated with opioid overdose include more than 90 morphine equivalent dosing (MED) per day, and duration of opioid use longer than three months (Cochran, Bacci, & Ylioja, 2016). A MED of more than 50 per day doubles the risk of overdose, with those at 90 MED per day correlated with an increase in death-related overdose (CDC, 2019). A retrospective study of orthopedic surgical patients found that these patients are often prescribed more than 114 MED per day, with Percocet being the most widely prescribed at discharge from the hospital (Ruder, Wally, & Oliverio, 2017). Continued use of an opioid beyond three months after orthopedic surgery occurs in 6 % after inpatient discharge (Brummett et al., 2017). Among the 6% who use beyond three months, 50% subsequently developed an opioid use disorder and remained on the opioid for an additional five or more years (Cochran et al., 2016; Brummett et al., 2017).

Background

In the early 1990s, armed with the knowledge that adequate pain control improved function and quality of life, pharmaceutical companies marketed long-acting opioid pain relievers as not addictive (Phillips, Ford, & Bonnie, 2017). Along with the belief that long-acting opioids were a safe option for treating pain, The Joint Commission on Accreditation of Healthcare Organizations (JC) in 2001 began to require that providers treat pain aggressively, as a 'fifth vital sign,' with opioid therapy as the standard of care (Joint Commission, 2017). By 2012 the surge in prescribing opioid medications led to 259 million prescriptions for opioids being dispensed, which is enough to give a 30-day supply of medication to every adult in America (CDC, 2016).

A systematic review performed by the John Hopkins University School of Medicine found that between 67% and 92% of patients reported having leftover opioids after a scheduled surgical procedure (Bicket, Long, & Pronovost, 2017). The overprescribing of opioids for surgical procedures has led to unused medication being diverted for other purposes leading to serious misuse (Bicket et al.). The correlation between current opioid statistics and opioid past prescribing trends is prima facie or accepted as fact until proven otherwise (Bicket et al.).

Significance

Opioid misuse has a significant economic burden on communities and has devastated families and individuals (Office of Disease Prevention and Health Promotion (ODPHP), 2019). The current opioid crisis has estimated to be a national cost of $78.5 billion annually, with nearly one-third of the cost going to treatment (NIDA, 2019). People who have opioid misuse, on average, have 8.7% higher direct health care costs (CDC, 2019). Further costs include lost productivity due to missed work, healthcare-related illness, and legal costs associated with illicit

use and distribution of opioids (NIDA). However, the burden goes far beyond economic costs, as it affects public health with increased crime rates, the spread of illnesses such as hepatitis and HIV, children being born with neonatal abstinence syndrome, and addicted parents perpetrating neglect (NIDA). The number of child abuse and neglect cases has gone up 25% since 2017 (Lucas County Children's Services, 2019). It is anticipated that by the end of 2020, over 20,000 Ohio children have been placed into foster care (Lucas County Children's Services). The cases of neonatal abstinence syndrome have risen from 2 cases per 1,000 in 2006 up to 14 cases per 1,000 births in 2017 (Ohio Department of Health, 2019).

Supporting Evidence

External Evidence

An evaluation of the external environment supports that the opioid crisis in the United States has now become an epidemic (NIDA, 2019). In 2017, the Health and Human Service Department issued a public health emergency to address the opioid crisis (NIDA). Healthy People 2020 has an objective, "Substance Use', set on "reducing substance abuse to protect the health, safety, and quality of life for all" (ODPHP, 2019). The overarching goal has been on harm reduction by decreasing risks associated with opioid misuse through a team approach (CDC, 2019). This approach encompasses supporting providers and empowering consumers to make safe opioid choices (CDC). In early 2019, the CDC and the USPSTF issued opioid prescribing guidelines to mitigate the risks associated with high daily MED use. Furthermore, the Comprehensive Addiction and Recovery Act of 2016 addresses prevention through education, mitigating risks with safe opioid prescribing, emergency naloxone distribution, and expanding treatment centers for opioid use disorder (American Society of Addiction Medicine (ASAM), 2015).

Providers need to use caution when prescribing opioids and mitigate risks through adherence to opioid prescribing guidelines to promote safe prescribing and monitoring practices with a *Stepwise Approach to Opioid Prescribing Guidelines* (Appendix E) (CDC, 2019). Recent CDC guidelines (2016) for opioid monitoring include screening for unhealthy behavior and monitoring overdose risk with opioid therapy. These guidelines encourage the limiting of opioid prescriptions for three days or less for acute pain, evaluating harms and benefits every three months for chronic pain therapy, assessing for risks and harms associated with an opioid, improving communication between providers and patients, and discussing risks and benefits of any opioid therapy (CDC, 2016). Furthermore, according to the prescribing guidelines, all patients currently on an opioid are to be screened for misuse, receive opioid education, and should have signed an initial short-term risk agreement (Appendix F) to document understanding of risks associated with opioid therapy. Patients on opioid therapy longer than three months should have signed a long-term medication agreement (Appendix G) to document understanding the risks associated with long-term opioid use.

The CDC guidelines further encourage the use of alternatives to opioids in place of or in conjunction with current opioid therapy. Encourages providers to establish pain and function goals with the patient to decrease the duration of opioid use. Providers should review the state's prescription drug monitoring program (PDMP), documenting the MED per day and overdose risk score (ORS) every three months to identify overdose risks. Providers should encourage naloxone access for more than 50 MED a day with a co-sedative prescription, age greater than 64, or a chronic comorbid condition has proven to help mitigate overdose risks. Finally, connecting those with suspected opioid misuse to behavioral counseling resources, referrals, or offering medication-assisted treatment (MAT) mitigates risks associated with unhealthy opioid

medication use. The use of opioid prescribing guidelines can improve patient outcomes when used from the initiation and throughout the monitoring of opioid therapy (CDC, 2016).

External Evidence Orthopedic Specialty

The literature indicates that orthopedic surgeons are third in prescribing opioids for pain, behind family-practice and internal medicine. Higher pill counts of opioids have been noted among surgeons to ensure patients have enough to maintain pain control after a surgical procedure (Brummett et al., 2017). The orthopedic trauma specialty manages a disproportionate number of adults who misuse opioids. Thus, the orthopedic trauma population at an increased risk for opioid misuse (Ruder et al., 2017). Up to twenty-five percent of orthopedic-trauma patients meet opioid misuse criteria (Ruder et al.). The American Association of Orthopedic-Trauma Surgeons (AAOS) announced that a comprehensive opioid program is necessary to decrease the misuse and abuse of those patients receiving opioid therapy (AAOS, 2015). Providers who care for this population have been placed in a precarious position when prescribing opioids to help control pain. Despite this paradigm, current prescribing patterns cannot continue and have significantly contributed to the current opioid crisis (NIDA, 2019).

Internal Evidence

A sizable not-for-profit hospital system has expressed a desire to improve current prescribing practices within an orthopedic-trauma clinic. The target facility recognized the need for standardized opioid monitoring when attempting to refer patients to MAT. However, the clinic struggled with discerning patients exhibiting opioid misuse behaviors from those having risks for overdose. Upon further inquiry, providers report that ten to thirty percent of their patient population suffers from opioid misuse (personal communication, October 2019). A site assessment revealed that the clinic did not have a standardized approach to monitoring patients'

opioid therapy. The state PDMP was not consistently accessed, as providers reported access approximately 50% of the time (personal communication, October 2019).

Patient education about opioid risk was sporadic, and rarely were opioid risks discussed with patients during their visit. Providers believed that the risks with opioids are implicitly known to a patient when given an opioid prescription. The clinic did not use short-term risk agreements or long-term medication agreements. According to the 2016 CDC prescribing guidelines, the patient and the provider should sign a short-term risk agreement upon opioid therapy initiation. A risk agreement would ensure that risks and benefits were understood when the opioid is first prescribed. A risk agreement and medication agreement ensure a verbal discussion occurs, and the patient agrees with the opioid therapy. The target facility had policies in place to use these medication agreements for those patients on opioids. However, the facility's target clinic does not utilize any such agreements. This inquiry revealed a need for a standardized policy for monitoring opioid therapy within the targeted ambulatory orthopedic trauma clinic.

Section II: Purpose and Project Goals

Purpose Statement and Project Type

The purpose of the evidence-based quality improvement project was to integrate current evidence-based opioid prescribing guidelines to standardize documentation and monitoring practices when managing adult patients on opioid therapy.

PICO-T

In a population of adults ages 18 to 64 currently on opioid therapy, in an ambulatory trauma orthopedic clinic of a targeted Level I Trauma Center, does provider education on current standardized opioid monitoring guidelines result in the following 1) improve provider knowledge, comfort, and confidence with opioid monitoring after four weeks education, 2)

improve the use of standardized monitoring practices, and 3) improve the use of risk mitigation strategies for this population eight weeks after the initial four weeks of education intervention?

Goals and Outcomes

The primary goal since project initiation (Appendix B) was to improve provider knowledge, comfort, and confidence with opioid monitoring. The improvement of provider knowledge has been shown to increase long-term adherence and continued use of guidelines (Pearson, Moman, Moeschler, & Eldrige, 2017). The aim was to implement a series of four weekly educational modules regarding opioid management. The objectives were measured via a pre- and post-educational survey (Appendix C). The three objectives measured were to:

- improve provider knowledge of contributing factors to adverse events
- improve provider comfort with monitoring opioid therapy
- improved provider confidence with opioid management strategies

The second goal (Appendix B2) was to improve standardized opioid monitoring practices, as evidenced by screening for unhealthy medication use, providing patient education, and reviewing the PDMP. The objectives were to have at least 75% compliance with:

- screening with the POMI screening tool (Appendix D) regarding opioid use
- documentation of patient education regarding current opioid therapy
- documentation of state PDMP access on the day of the visit

The third goal (Appendix B3) was to improve the use of risk mitigation strategies. As evidenced by three objectives, including improving naloxone access, the use of medication agreements, and the use of interprofessional communication.

The first objective was to improve access to naloxone, as evidenced by at least 75%:

- naloxone access on those patients with 50 MED per day or more

- naloxone access for an overdose risk score (ORS) of 450 or more

The second objective was to improve the use of opioid risk agreements, as evidenced by at least 75%:

- documentation of short-term initiation risk agreement (Appendix F)
- documentation of long-term opioid agreement (Appendix G)

The third objective was to improve interprofessional communication, as evidenced by at least 75%:

- documentation of primary care provider (PCP) interprofessional communication
- documentation of referral information given if needed

Section III: Guiding Frameworks

Evidence-Based Practice Model

The John Hopkins Nursing Evidence-Based Practice Model (JHNEBP) guided this evidence-based practice project. The JHNEBP model design involved three phases: practice, evidence, and translation (PET) (Dearholt, & Dang, 2018). The first phase was developing a practice question and performing a literature search. The second phase involved conducting a synthesis of the evidence and forming an action plan. Finally, the third phase translated the evidence into practice by determining feasibility, implementing the action plan, and then disseminating the findings (Dearholt & Dang).

The Transtheoretical Model

The Transtheoretical Model (TTM) is a theory from psychology, postulated by Prochaska & Velicer in the 1970s. The TTM was used to guide the providers in assessing a patient's willingness to make a lasting change in behaviors. Likewise, the TTM also guided the providers

through their own change stages to begin changes regarding their current opioid monitoring practices. The six change stages include pre-contemplation, contemplation, determination, action, maintenance, and recurrence (Prochaska, & Velicer, 1997). TTM was chosen to help providers understand where a patient might be in their journey on opioid therapy, along with their journey of practice change. The first four stages were most relevant to this project and guided behavior change to enhance shared decision making and the education processes. However, providers were educated that a patient might not be ready to move onto the next change stage. Regardless of where a patient might be in their readiness for change, standards of care needed to be completed to ensure safe patient outcomes.

Shared decision making (SDM) and discussions helped decrease limitations associated with the TTM. One limitation of the TTM theory was the assumption that a person would successfully acquire resources to be successful in behavioral change. However, the theory does not take other factors, such as past experiences, into account. Such factors as patient resources and previous attempts with behavioral changes needed to be assessed, discussed, and documented (Prochaska & Velicer, 1997). A plan of care based on SDM was formed that placed the patient at the center of care.

Screening, Brief Intervention, Referral to Treatment

The CDC and Substance Abuse and Mental Health Services (SAMHSA) recommend utilizing the S-BiRt (screening, brief intervention, referral to treatment) framework to help identify misuse and prevent problematic use of opioid medication (SAMHSA, 2017). SAMHSA's *Technical Assistance Publication (TAP) 33*: *Systems-level Implementation of Screening, Brief Intervention, and Referral Treatment* was a resource to help facilitate the S-BiRt tool (SAMHSA, 2017). Although S-BiRt has been highly recommended, a universal screening

tool for unhealthy medication use has not been identified. However, several tools have shown promise, including the POMI behavioral screen for opioid misuse (Appendix D), which was utilized for this project.

Project Concept Map

When conceptualizing the process and the anticipated goals for this evidence-based practice change project, each concept interaction was demonstrated in the conceptual project map, *Opioid Prescribing Guideline Adherence Initiative* (Appendix H). The concept map was a visual representation of how the project concepts are interrelated to the project goals. The goals were represented inside the clouds at the top of the concept map. Then, as demonstrated with the path of feet, when a patient arrived at the clinic, they may have arrived already taking an opioid. Most patients arrived in the pre-contemplation stage, unaware that they might have unhealthy medication use or are at risk for opioid overdose. Meeting the patient in their stage of change offered a platform to educate and encourage future change.

Upon being screened with the POMI, the patient may become aware of their unhealthy medication use or problematic use for the first time. This new information allowed the patient the opportunity to move from the pre-contemplation stage into the contemplation stage. However, some patients chose to remain in a state of denial, thus in the stage of pre-contemplation. The clinician's role was to come alongside the patient to form a care plan, as depicted by the feet, encourage SDM, communicating empathy to meet the patient where they were in the change process. Conversations determined whether the patient understood the meaning of screening results. A plan of care was developed based on SDM that fostered a sense of self-efficacy, with the patient laying the foundation for future change.

However, the patient's current change stage did not affect the provider's obligation to complete S-BiRt. Primary education regarding risks and benefits was the standard of care for every patient on opioid therapy, regardless of the patient's change stage. Every patient verbalized understanding their care plan and how opioid therapy had been just one part of that treatment plan. The provider guided the patient to the next change stage but understood it was not the provider's duty to make that person change but rather an opportunity for future conversation.

Providers were educated that empathy is the ability to neutralize one's emotions to objectively help a patient through a time when emotions can disrupt judgment (Austin, 2019). Empathy did not mean the provider agreed with the patient's actions. Providers were to use empathy to find the motivation to help the patient through any distress, without allowing one's feelings to disrupt standards in care. Empathy helped providers navigate through the barriers often associated with a patient not wanting to change. Empathetic communication was used to let the patient know that even if they were not ready for change, providers met the patient where they were at that moment while completing the standards of care.

Section IV: Review of the Literature

Search Strategies

The second phase of the JHNEBP model involved evaluating the current evidence, including literature, guidelines, expert opinion, and systematic reviews. A literature search had been performed utilizing a PICO-T search strategy worksheet in 2019. A total of five databases were accessed: CINHAL, Medline, EBSCOhost, ERIC, and Proquest databases using key terms: (orthopedic OR orthopaedic) AND (trauma) AND (opioid) AND (screen or risk) AND (guideline). The search was limited to those articles from 2009-2019, peer-reviewed, English language, and full text. The literature search strategy results (Appendix I) revealed a total of

8,842 potential articles from all databases. After removing duplicate articles, 2,703 abstracts remained for further consideration. The number of articles was quickly reduced after applying inclusion and exclusion criteria, to 46 articles for further consideration. Inclusion criteria included adults 18 years of age or older, pain, opioid, systematic review, opioid screen, and studies using a widely accepted assessment tool. Exclusion criteria included those articles that had dealt with inpatient, pediatrics, chronic cancer pain, commentaries, editorials, and were removed. Of the 46 articles, 12 of these articles added substantial evidence and adequate rigor. Furthermore, clinical guidelines and care standards were also searched via the Internet using key terms: guidelines, opioid misuse, screening risk, pain, and opioid risk. Five clinical guidelines were reviewed and found to be of rigor, adding five more pieces of evidence to the summary table for a total of 17 items.

Synthesis and Analysis of the Evidence

Each article was appraised using the JHNEBP tools to determine the quality and level of evidence. The complete synthesis and analysis of the current evidence indicated consistent evidence to continue the implementation of the opioid prescribing guidelines, especially within the orthopedic trauma population. The synthesis (Appendix J) did not find any Level I evidence. Two Level II studies of quality were found to support screening for unhealthy opioid use as beneficial. Four Level III studies of quality were found to support that among those patients who have orthopedic surgery. These studies indicated that those patients discharged from the hospital with 90 MED per day or had been on an opioid longer than three months had the highest risk of developing opioid use disorder (Morris & Mir, 2016). Seven Level IV pieces of evidence, including the clinical guidelines published by the American Association of Orthopedic Surgeons, the Centers for Disease and Prevention, and the American Pain Society, were found

recommending that adherence to opioid prescribing guidelines and early education strategies improve care and have been shown to reduce risks associated with opioid therapy (AAOS, 2019). Finally, four Level V articles of high quality recommend that screening and brief intervention start primary prevention of unhealthy opioid use.

Project Justification

Finding a successful implementation of a similar project served as validation that this evidence-based practice change was feasible. A similar project had been implemented successfully in Rhode Island in 2018, in which opioid prescribing guidelines were integrated into an electronic health system (Samuels et al., 2019). Prevention through guideline adherence is more cost-effective than treatment for those with a substance use disorder (SAMHSA, 2019). The impact of determining a reliable and efficient way to monitor those patients on opioid therapy has proven to change individual lives, families, and communities.

However, current opioid prescribing guidelines are voluntary for provider adherence. The use of clinical guidelines should be used to form a relationship of understanding between the patient and the provider, which is the beginning of shared decision making (SDM). Unfortunately, recent opioid prescribing guidelines have been used to make the sweeping and broad cessation of all opioid prescribing, to avoid legalities associated with non-compliance (Dineen, 2019). The sudden cessation of opioid therapy has had detrimental effects on patients, including severe withdrawal symptoms, psychological stress, uncontrolled pain, and even suicide (CDC, 2019). Adherence to opioid prescribing guideline use was meant to guide clinical decision-making and not to be viewed as a reason to stop all therapy. Patient circumstances need to be taken into every clinical decision regardless of whether that decision is to stop, taper, or continue opioid therapy (Dineen).

Finally, the authors of a third article substantiated the use of protocols to serve as a model to engage patients with suspected opioid misuse (McNeely, Kumar, & Rieckmann, 2019). Based on qualitative data obtained from several focus groups, the implementation of opioid guidelines can reduce adverse health consequences associated with opioid misuse. Early recognition and opioid misuse interventions are highly effective, yet underutilized (McNeely et al.). The authors describe implementation barriers often experienced when attempting to set up referrals for treatment. Such barriers included patient barriers described were concerns about consequences with disclosing unhealthy medication use and confidentiality. Provider barriers included lack of clinical knowledge, time pressures, lack of resources, and difficulty accessing behavioral health treatments for patients (McNeely et al.).

Feasibility

The third and final phase of the JHNEBP model involved determining project feasibility, implementing the action plan, and disseminating the project findings (Dearholt & Dang, 2018). Substantial evidence (Appendix J) has been found to support a practice change to initiate opioid prescribing guidelines, including a screen for unhealthy medication use, within the ambulatory orthopedic trauma setting. The implications of these findings indicated a need for a change to current processes, along with securing subsequent policies and procedures to guide future practice (Dearholt & Dang, 2018). The clinical practice guidelines for pain management, the U.S. Preventative Services Task Force (2019), and the Association of Orthopedic Surgeons (2015) recommend monitoring all adults 18-64 for opioid misuse while on opioid therapy. Implementation is also supported by the targeted organization, as noted by initial staff inquiry, provider interest, and administrative approval.

Section V: Project Development

Project Timeline

The project scope and charter were formed with a stakeholder analysis and project team formation. Organizational leaders, administrators, site managers, and staff were identified. Several meetings were held over a few months, which helped gain insight into the organizational mission and goals. After the stakeholders were identified and support was obtained, a stakeholder analysis tool helped delineated roles and responsibilities. Key facilitators and DNP committee members developed a project timeline (Appendix K) with subsequent milestones that further set the project into motion. The first phase of the project planning included completing an action planning tool, which began in August 2019. The action planning tool ensured the successful translation of the research into practice. Some goals were to secure a project leader, identify change champions, identify barriers, strengths, current resources, and confirm support from other departments such as technology, research, quality, and risk. A complete literature review was conducted, a charter write-up was completed, identification of barriers was completed, and the establishment of relationships with facilitators was completed by December 2019.

Project site and Population

The EBP project implementation site was a non-profit health system located in Northwest, Ohio. The target facility was a Level I Trauma Center, which performed 12,276 orthopedic procedures in 2017. The targeted ambulatory orthopedic trauma clinic within the facility includes three orthopedic trauma surgeons, six physician assistants, and ancillary staff. Care included managing patients with acute and chronic opioid therapy; however, standard monitoring and screening for unhealthy medication use did not exist.

Site Assessment

During the first phase, an evaluation of the internal environment included a site assessment of the targeted orthopedic-trauma clinic. An informational technology (IT) checklist was performed with the organizational informatics facilitator's help. It was found that a current information system already existed and could support the practice change. The organization implemented a similar screening for social determinants of health (SDOH) in 2017. According to the organizational IT facilitator, systems already existed for needed guideline documentation within the organization's electronic health record and planned to be integrated into the project.

A site assessment found that the organization currently uses electronic health systems to meet quality standards of care. The Health Effectiveness Data and Information Set (HEDIS) are quality measures currently being monitored within the organization and are designed to measure health plan performance (U.S. Centers for Medicare & Medicaid Services (CMS), 2019). HEDIS recommends three measures specific to drug monitoring (CMS). The first is monitoring adequate care, which includes screening for unhealthy medication use or dependence. A second measure is the utilization of drug-related services for those who screen positive for unhealthy use misuse requiring a referral for further care. Finally, the third measure was to implement the tracking of those patients with unhealthy use of drugs or alcohol via electronic health systems (CMS). Electronic health systems were found to be in use within the clinic and were modified to improve performance gaps among those receiving opioid therapy.

Project Members Roles and Responsibilities

Identifying stakeholders within the targeted organization began with assessing current organizational readiness and culture (Dearholt & Dang, 2018). The identified stakeholders included the medical director of orthopedics, a lead researcher within the hospital, and other physicians, physician assistants, office managers, nurses, and medical assistants. The

stakeholders were contacted, and when support was achieved, the project began to move forward. The Doctoral Nursing Practice (DNP) student's committee comprised a content who had expertise on opioid addiction and treatment, the Chair who had experience with the Regional Opioid Task Force, and a committee member who had expertise in adolescent mental health and opioid misuse.

Organizational support included a project leader, change champions, and members of the orthopedic trauma team. The DNP student investigator's role involved establishing a trusting relationship with the orthopedic surgeons and staff, allowing access to the site. Furthermore, the research team offered valuable resources, such as Survey Monkey and the use of statistical analysis software. Finding team members within the project site was determined by project fit, feasibility, and appropriateness of the recommendation (Dearholt & Dang, 2018). Project goals and objectives were aligned with organizational goals and expectations to ensure future sustainability (Hebda et al., 2019).

Barriers and Facilitators

Barriers were identified and placed into three categories: organizational, site-specific, and community. Organizational barriers included approval from administration, the information technology department, and obtaining approval from the institutional review board (IRB). Further site-specific barriers included staff approval and evaluation of current workflow patterns. Most staff members expressed apprehension in anticipated patient reluctance and lack of time as reasons for implementation failure. Finally, community barriers included identifying resources within the community that could be reliable and easily accessed by patients when needed. Solutions to barriers were found after consulting with key stakeholders and facilitators to arrange

access to needed resources, including referrals for chronic pain management, counseling, and medication-assisted treatment for opioid use disorder.

Providers expressed concerns regarding liability by providing a prescription for naloxone for those found at high risk for overdose. Although laypersons support access to naloxone, some health professionals remain reluctant to prescribe naloxone. The reluctant prescribing of naloxone is due to perceived legal risks associated with prescribing naloxone to pain patients (Davis, C., Burris, S., & Belesky, L., et al., 2017). The State of Ohio Board of Pharmacy recognizes the need to reassure providers of the safety and efficacy of naloxone. The recommendation is to follow the Ohio law ORC.473.941, which permits a provider to supply a prescription for naloxone to any person at risk for overdose as the benefits outweigh any risk (State of Ohio Pharmacy Board, 2019). It has been clarified by the medical and legal communities that the prescribing of naloxone "is consistent with state and federal laws, and carries the same risks with generally providing health care" (Burris et al., 2001). However, this recommendation was met with resistance and was not able to be fully implemented in the targeted clinic. Therefore, to overcome this barrier for this project, community resources were utilized for patients to gain free access to naloxone.

Cost-Benefit Analysis

Project costs (Appendix L) were relatively low. The implementation of opioid prescribing guidelines was done through current EHR software, EPIC. The highest expense planned had been the reimbursement of staff wages for their time spent in project education. The economic return had been estimated to increase a provider's relative value unit (RVU) per visit by 40 percent (SAMHSA, 2017). However, due to a global pandemic of the Coronavirus-19, the project budget had to be modified after the project proposal. Organizational resources were

utilized as much as feasible to limit expenses. It was anticipated that initial returns would be higher as the guidelines and screen were first implemented. It had been anticipated that screening rates and reimbursement would decline once this population screening had been saturated. However, a full return on investment was not seen due to the limitations of COVID-19 that decreased provider documentation, thus reimbursement rates.

Section VI: Implementation Process

Institutional Review Board

When research involves human subjects, it is essential to ensure that the research is conducted according to the guidelines set forth by the Office of Human Research Protections. The University IRB and the targeted organizational IRB approval was secured before initiating the proposed project. Ethical principles were respected and integrated into the planning of the project. The project director obtained consent from the organization's internal review board (IRB) to access patient health records. Precautions were taken to maintain patient health information (PHI) by removing patient identifiers from data collected and stored safely onto a password-protected drive. No PHI was ever downloaded. Patient PHI was accessed only on-site and was limited to data on the day of the visit. Finally, the project director considered and planned for the obligation to intervene if a person was at high risk of overdose. The project director ensured that resources were available for any participant at high risk for overdose. Such resources included naloxone access, education, and treatment resources. Supplying naloxone is a moral and ethical obligation to all participants at risk for overdose, even if a referral for treatment is unnecessary.

Preference and Values

When monitoring opioid therapy, patient preferences and values were considered through shared decision making. Shared decision making occurred when the practitioner and patient worked collaboratively to consider all options to form a treatment plan that worked well for both parties (National Council for Behavioral Health (NCBH), 2019). After discussing screening results and informing the patient, a patient was allowed time to ask further questions to understand the results meaning. Patients were carefully guided through the pre-contemplation stage of change (Prochaska & Velicer, 1997). Patient-specific barriers to change were identified to find the driving and restraining forces to help initiate change (Prochaska & Velicer). Providing education materials on opioid risks, opioid overdose, and naloxone helped facilitate patient understanding so that each patient could weigh all of their options. Supporting patients with shared decision-making has been shown to improve patient outcomes (NCBH). A person is more apt to be open to change if the decision is shared (NCBH).

Section VII: Methods

The intervention included educating providers on current prescribing guidelines from the CDC series, *Opioid overdose training for providers* (2019). The interactive series was a valuable resource that provided the foundation to educate providers regarding opioid management. Provider consent (Appendix M) had been obtained via Survey Monkey before education per IRB request. Carefully selected CDC modules focusing on the project outcomes were chosen for implementing the weekly education modules for the four weeks of provider education. The CDC education modules were delivered to the provider via organizational email with links to the modules embedded in the email. Provider compliance with the education modules was demonstrated through provider acknowledgment of viewing the module via Survey Monkey. Other education materials, including educational posters with interactive QR codes educating on

opioid misuse, provider roles, and helpful interactive tools to support opioid management, were provided via weekly email. After the four weeks of provider education, the next eight-weeks were designated for staff guideline implementation and data collection on the adherence to prescribing guidelines.

Due to COVID-19, the completion of the necessary informatic changes and requests could not be fulfilled. The inability to make the needed IT setups and requests required paper screening and manual extraction of data. Education modules were given via email and survey monkey as in-person luncheons, and education was not feasible due to social distancing and quarantining. However, the project continued despite the changes the project had to undertake.

Sample Size & Tests

A total of nine clinical providers were available to participate in the project, including three physicians (MD) and six physician assistants (PA). The project's primary sample involved a convenience sampling among adults ages 18 to 64, currently on opioid therapy. A power analysis was performed to ensure that an adequate sample size of patient charts had been reviewed. To ensure 75% of patients selected received the screening, with a 5% margin (70%-80%), and a 95% confidence interval, 288 charts needed to be reviewed.

An exploratory data analysis was performed to detect trends and patterns of data utilizing descriptive and inferential statistics. The one-proportion and two-proportion asymptotic Z-tests were used to describe the sample characteristics and provider guideline adherence patterns. The one-proportion and two-proportion Z-tests were more powerful and efficient for this data analysis than Spearman's correlation and Wilcoxon sign tests, based on the data obtained (J. Chen, personal communication, September 8, 2020).

Inclusion & Exclusion Criteria

The providers who wanted to participate in the project consented via Survey Monkey. Education was sent to all nine providers as consent was anonymous. Adult patients ages 18 to 64 years of age with an orthopedic diagnosis and current opioid use were included. Persons younger than18 years of age, older than 64 years of age, or those who required an interpretive service were excluded.

Measurement Instruments

A pre- and post-education survey was used to measure provider knowledge, confidence, and comfort. *The Providers' Experiences with Prescribing Opioids Survey* (Appendix C) is a modified version of *The Physicians' Experiences with Prescribing Opioids for Chronic Pain* (Wenghofer, Wilson, & Kahan, 2011). Modifications to the survey were performed after permission was obtained from the original author, Wenghofer, via email. The original survey changes included having the word *physicians* changed to *providers*, removing reference to chronic, and removing the third page. The term chronic was removed to decrease confusion among providers as the clinic manages acute pain, although the questions are pertinent to the project. The decision to remove the third page of questions was made due to time constraints and irrelevancy to the project goals and outcomes. The questions were placed into Survey Monkey to be completed by providers pre- and post-education.

The Providers' Experiences with Prescribing Opioids Survey measured providers' knowledge, confidence, and comfort, regarding opioid prescribing, 6a, 6b, and 10 (Wenghofer et al., 2011). Available survey responses for these specific questions a provider could choose ranged from not at all concerned, a little concerned, not sure, somewhat concerned, to very concerned. The survey had been used to describe knowledge, confidence, and comfort when prescribing opioids among Canadian providers (Wenghofer et al.). Furthermore, the survey had

been used in at least two similar studies. The most extensive study was among 1000 physicians with 658 respondents, with most practicing in larger urban areas (Wenghofer et al.). Specific reliability and validity for the provider survey have not been published. However, the use of this survey has demonstrated a way to measure a change in a provider's knowledge, comfort, and confidence regarding prescribing and monitoring opioid therapy (Wenghofer et al.).

The second instrument was *The Prescription Opioid Misuse Index* (POMI) (Appendix D), which measured participant behaviors associated with opioid use among the sample group. The POMI screening tool was chosen due to ease of use for the patient, ease of use for the staff, and contained questions aligning with DSM-5 criteria (Appendix A) for behaviors associated with opioid misuse. The *Prescription Opioid Misuse Index* (POMI) has a high specificity of 0.923 and high sensitivity of 0.82, along with a Cronbach *a* 0.85 with identifying those with opioid misuse (Knisely, Wunsch, Cropsey, et al., 2008; Cochran et al., 2016). The POMI asked six questions regarding current behaviors associated with their current opioid prescription; each question had a 'yes' or 'no' answer. Those patients who score two to three 'yes' answers have been found to have behaviors with unhealthy use. Those patients who score more than four have behaviors associated with an opioid use disorder defined by the DSM-V, with a specificity and sensitivity of 0.100 (Knisely et al.). Most opioid risk screening tools include questions regarding demographics and social determinants of health. However, most opioid risk screenings describe little about behaviors associated with diagnostic criteria for opioid misuse or abuse. Since the POMI screen asked about behaviors, which can change over time, this screening tool was chosen for project implementation, as behaviors should be screened every three to six months per CDC guidelines.

Data Collection Procedure

Data were collected on the provider group and the patient group. The effects of provider education on current opioid prescribing guidelines were measured both directly and indirectly. Direct measures included a pre-and post-education survey. Indirect measures included provider required documentation following current prescribing guidelines, as noted in the patient EHR. The direct provider data were secured through Survey Monkey to maintain anonymity and limit social bias. Eight communications occurred, including consent for participation, a pre-education survey, four weekly education acknowledgments, a post-education survey after the eight weeks of guideline implementation, and a PowerPoint to refamiliarize providers with the project.

The project director used the patient data to assess current risks associated with opioid therapy, demographic data, and pertinent medical history. Due to the pandemic COVID-19, collection procedures were modified, and patient data were collected via manual extraction daily during the patient visit. Initial data were placed into an Excel spreadsheet daily during the screening and education process. The date of the participant visit, along with a participant-specific identifier, was used to trace back to an electronic health record if needed for future reference. Each participant had been given an identifier, which included their initials, age, and gender. For instance, NM40M had the initials N.M. and was a forty-year-old male. No two participants ended up with the same identifier. Project data were inputted on an Excel spreadsheet and Statistical Package for Social Sciences (SPSS) for descriptive analysis. The descriptive analysis included frequencies, standard deviations, and mean, along with subsequent parametric testing.

Data collection began with patient schedules having been reviewed the day before their appointment to find participants who met inclusion criteria. The staff was notified of potential participants and were flagged for screening within the EHR. The events leading to performing a

patient POMI screen began once a participant arrived for a regularly scheduled office visit. The medical assistant then informed the project director when the patient had been placed in a private patient room to await the provider. During the waiting time, the patient was approached for project consent. The project director and participant read and acknowledged the patient consent form. Then the patient was given the cover letter for future reference. After the patient's consent was obtained, the project director discussed the education folder containing information on opioid risks and opioid overdose prevention. The patient was left to complete the six question POMI screening tool to evaluate current medication use, while the project director accessed the EHR to determine overdose risk. After completing the POMI screen, the project director returned to the room to discuss all screening results, current MED, ORS score, and overdose risk.

During the patient encounter, the providers should have documented screening results and interpretation, education, PDMP access with MED, and ORS scores. Upon completion of the visit, communication was sent to the primary care provider (PCP) regarding current opioid therapy via electronic health records. If a patient did not have a primary care provider, a referral was given for a PCP. The next day, a review of the EHR noted provider documentation adherence to screening, education, PDMP access, and PCP communication.

Section VIII: Statistical Analysis

A total of 9 providers were available during the project time frame, and three gave consent for participation. All three participants were physician assistants. During the four weeks of education, three providers engaged in the weeks one and two learning modules. The learning modules had no further interaction during weeks three through four from any provider. The project was reintroduced via a PowerPoint with voice-over after an inadequate response was noted in week three. The onset of the global pandemic involving the coronavirus COVID-19 was

the reason for the unexpected low participation with provider education. The COVID-19 pandemic's timing was unfortunate and had a negative impact on this project, as indicated by clinicians, who expressed a sense of being overwhelmed. Also, patient acuity levels had increased, which further contributed to low participation due to time consumption. At the project's onset, unforeseen events challenged the project director to focus on modifications to continue and complete the project.

Knowing that there would be limitations with provider data collection, the project was still completed. A total of 343 charts were randomly selected over eleven days based on patients with a scheduled office visit (Table 1). Sixty patients were marked as potential participants who had met the inclusion criteria. Subsequently, 34 fully completed the screening and education process. Reasons for not screening all potential candidates included four patients who declined participation, seven were missed in staff error, 11 patients canceled their appointments, and four met the exclusion criteria. A total of 34 patients were screened with both the behavioral screen and for overdose risks along with education.

The project had three goals, with nine subsequent outcomes measured, *Completed Project Goals and Outcomes* (Appendix O). However, upon completing the project, three of the nine outcomes had been met, while six outcomes remained unmet. Although no goal had been completely met, goal one and goal two had the most outcomes met, whereas goal three had no outcomes met.

Table 1

Orthopedic-Trauma Opioid Prescribing Guideline Adherence Initiative DATA June - August 2020										
WEEKDAY	TOTAL PATIENTS	POTENTIAL SCREENED	NUMBER SCREENED	PT DECLINED	STAFF MISSED	CANCELLED/ NO SHOW	EXCLUDED OTHER	CANCEL/NS ON OPIOID	POSSIBLE >64 TO SCREEN	AT RISK >64
THUR	58	7	3	3	0	1	0	1	7	0
FRI	15	2	0	0	1	2	0	1	2	0
TUES	36	11	4	1	1	3	0	3	5	1
FRI	16	2	1	0	1	0	0	0	0	0
TUES	31	4	4	0	0	0	0	0	4	1
WED	32	6	3	0	0	2	1	2	2	1
MON	21	5	3	0	1	1	1	1	2	1
THUR	45	13	9	0	3	1	0	1	3	1
MON	32	2	2	0	0	0	0	0	7	0
TUES	40	6	4	0	0	0	2	0	4	0
FRI	17	2	1	0	0	1	0	1	2	1
	343	60	34	4	7	11	4	10	38	6

Note: Daily data collection among all adults during the project.PT-patient, NS-no show. 2020**.**

Goal 1 & Outcomes

The first goal was to identify if provider knowledge, comfort, and confidence with opioid monitoring improved after implementing CDC opioid prescribing education modules through direct measures with a pre- and post-education survey (Table 2). Three providers responded to the pre-education survey, and one provider completed the post-education survey. The project director saw a change that occurred with an improvement in knowledge, an improvement in comfort, but a decrease in confidence. However, there were limitations to the analysis due to low response rates.

Table 2

Goal 1 and Outcomes								
Goal 1: *Improve provider knowledge, comfort, and confidence with monitoring opioid therapy.*		**Intervention**	**Measure**	**Responses pre-education**	**Responses post-education**	**Pre-education**	**Post-education**	**Discussion**
Outcome 1	Improve provider **knowledge** of contributing factors to adverse events	CDC education modules	question 10	3	1	somewhat concerned and very concerned	very concerned and not sure	A change occurred and improved**
Outcome 2	Improve provider **comfort** with monitoring opioid therapy		question 6A	3	1	strongly to somewhat disagree	somewhat agree	A change occurred, slightly improved
Outcome 3	Improve provider **confidence** with management strategies		question 6B	3	1	somewhat agree	not sure	A change occurred, not improved

Note. Goal 1 with outcomes for Opioid Prescribing Adherence Initiative Orthopedic-Trauma. 2020. ******The outcome was met.

Outcome 1 was to improve provider knowledge associated with factors that contribute to adverse events as measured by question 10 on the pre- and post-education survey (Table 2). Available survey responses ranged from “not concerned,” a “little concerned,” “not sure,” “somewhat concerned,” to “very concerned” regarding contributing factors. Before education, three providers responded as “somewhat concerned” about (‘getting into trouble with the College of Physicians and Surgeons’), whereas one provider opinion changed to “very concerned” after the education. Three providers’ responses were “very concerned” before education regarding (‘risk for overdose’). The providers’ responses after education were “not sure.” The project director found the descriptive analysis trended a change occurred, with a small improvement.

Outcome 2 was to improve provider comfort with monitoring opioid therapy as measured by question 6A on the pre- and post-education survey (Table 2). Available survey responses ranged from “strongly agree,” “somewhat agree,” “not sure,” “somewhat disagree,” to “strongly agree.” Descriptively, the response data regarding (‘I am comfortable prescribing opioids for pain’) before education was “strongly disagree” and “somewhat agree,” whereas, after education,

the response changed to “somewhat agree.” The project director reviewed the data and found the change in responses demonstrated that the education materials affected the provider’s comfort with opioid prescribing. The small change was determined to be a small improvement.

Outcome 3 was to improve provider confidence with opioids monitoring as measured by question 6B on the pre- and post-education survey (Table 2). Available survey responses ranged from “strongly agree,” “somewhat agree,” “not sure,” “somewhat disagree,” to “strongly agree.” Descriptively, the response data regarding (‘I am confident in my clinical skills in prescribing opioids’) before education was “somewhat agree,” whereas, after education, the responses changed to “not sure.” The project director found an improvement in confidence among providers, although it was challenging to demonstrate statistically due to inadequate responses.

Goal 2 & Outcomes

The second goal was to identify if standardized monitoring practices improved by at least 75% after provider education on standardized prescribing practices, as measured by provider completion of POMI screening, documentation of patient education, and PDMP access (Table 3). The project director found that although screening for unhealthy medication use improved, this was due to the project director having completed the screening. However, standardized monitoring practices did not improve as the providers did not substantiate the patient intervention with adequate documentation. Without documentation, reimbursement for these services could not be rendered. Provider behavior had not statistically changed regarding the documentation of services performed.

Table 3

Goal 2 and Outcomes							
Goal 2: *Improve the use of standardized monitoring practices*		**Intervention**	**Measure**	**Sample**	**Sample Rate**	**p-value**	**Inference**
Outcome 1	At least 75% **POMI screen**	Education on standardized prescribing guidelines	POMI score 0-6	34	34/46 = 73.91%	0.8648	Met
Outcome 2	At least 75% **patient education** given		documentation education given	0	0/34		Not met
Outcome 3	At least 75% **PDMP access**		documentation PDMP access	7	7/34 = 20.59%		Not met

Note. Goal 2 Improve the use of standardized monitoring practices with outcomes. Opioid Prescribing Adherence Initiative Orthopedic-Trauma. POMI-prescription opioid misuse index, PDMP-prescription drug monitoring program. 2020.

Outcome 1 was to have at least 75% of patients screened utilizing the POMI screen for opioid misuse behaviors as measured by a documented POMI score (Table 3). The project director performed the POMI screening on 34 patients, then shared the results with staff. Out of 46 potential patients, 34 were screened, and 12 patients had not been screened. The POMI screen sample was 34/46=73.91%, indicating that nearly 75% of patients had been screened. The significance level, 0.05, and p-value 0.8648 lacked statistical significance to claim that less than 75% were given the POMI screen. Thus, statistically, the outcome had been met.

Outcome 2 was to have at least 75% documentation that patient opioid education had been given as measured by documentation in the patient visit note (Table 3). The project director gave all 34 patients education regarding opioid therapy, including an educational folder and verbal education. However, none of the 34 patients had documentation of the patient education on opioids within the visit note. The patients had received opioid education but because the subsequent lack of documentation meant the outcome had not been met, as provider behaviors had not changed.

Outcome 3 was to have at least 75% access to the state PDMP the day of the visit, as measured by provider documentation (Table 3). Seven of the 34 patients had documentation of the state PDMP having been accessed on the day of the visit. The sample rate was 7/34 = 20.59%; this did not meet the 75% screening goal. The implications regarding a lack of PDMP access implied a lack of compliance with guidelines; thus, the outcome was not met. The outcomes were thought to have been limited by low education engagement.

Goal 3 & Outcomes

The third goal was to identify if risk mitigation strategies improved after implementing CDC opioid prescribing education modules; as measured through provider documentation of patient access to naloxone, the use of opioid agreements, and the use of interprofessional collaboration. The access to naloxone, the use of opioid agreements, and interprofessional communication did improve due to project director involvement. However, the project goals were not met due to lack of documentation to support the intervention.

Table 4

Goal 3: *Improve the use of risk mitigation strategies.*		**Intervention**	**Data Point**	**Sample**	**Sample Rate**	**p-value**	**Inference**
Outcome 1	At least 75% co-prescription for **naloxone if > 50 MED** per day	Educate on overdose prevention strategies	MED	5	5/11 = 45.5%	0.0236	Not met
Outcome2	At least 75% co-prescription for **naloxone if > 460 ORS** score		ORS	8	8/12 =66.7%	0.505	Met

Note. Goal 3 Improve risk mitigation strategies, including outcomes one and two, regarding naloxone access. Opioid Prescribing Adherence Initiative Orthopedic-Trauma. MED-morphine equivalent per day, ORS-overdose risk score. 2020.

Outcome 1 was to have at least 75% access to naloxone for those patients with more than 50 MED score per day (Table 4). The project director's analysis of the data indicated that out of 11 patients with more than 50 MED per day, five had access to naloxone. The p-value, 0.0236,

favors the claim that less than 75% received a naloxone prescription when the MED score was more than 50 per day. Thus, the outcome was not met.

Outcome 2 was to have at least 75% access to naloxone for those patients with more than 450 ORS risk score (Table 4). Out of 12 patients with an ORS of more than 450, 8 patients had access to naloxone. The sample rate is 8/12=66.7% and is close to 75%. The p-value, 0.505, this could not disprove that less that 75% had access to naloxone; thus, the outcome was met. However, this interpretation is limited due to the low sample size.

Outcome 3 was to have at least 75% use of an opioid short-term risk agreement (Table 5). Out of 46 patients ages, six patients had a signed opioid short-term risk agreement. The sample rate is 6/46=13%, p-value <0.0001, which was statistically significant. The project director analyzed the data and found that less than 75% use of an opioid short-term risk agreement occurred. The sample value is much less than the proposed 75%. Thus, the outcome was not met. Most patients had been started on opioid therapy before the appointment, typically while inpatient. The highest prescribers for these short-term opioids were orthopedics (n=13) and hospital providers (n=10). Anecdotally, providers reported that because the short-term opioid was being discontinued, there was no need to sign an agreement at the time of the visit.

Table 5

Goal 3 Use of Opioid Agreements: Outcomes 3 & 4							
Goal 3: *Improve risk mitigation: opioid agreements*		**Intervention**	**Measure**	**Sample**	**Sample Rate**	**p-value**	**Inference**
Outcome 3	At least 75% use of opioid **short-term risk agreement**	CDC modules: Educate on opioid agreements	Documentated short-term agreement	6	6/46 = 13%	0.0001	Not met
Outcome 4	At least 75% use of opioid **long-term risk agreement**		Documentated long-term agreement	6	6/18 = 33.3%	0.0001	Not met

Note. Goal 3 Improve risk mitigation strategies, including outcomes three and four, the use of opioid agreements. Opioid Prescribing Adherence Initiative Orthopedic-Trauma. 2020.

Outcome 4 was to have at least 75% use of an opioid long-term risk agreement for patients on an opioid for more than six months, as demonstrated by documentation of the agreement (Table 5). Eighteen patients were on an opioid longer than six months. Six of those 18 patients had documentation of a chronic opioid medication agreement. The sample rate was 6/18=33.3%, p-value <0.0001, indicating statistical significance. The project director analyzed the data and determined that less than 75% use of an opioid long-term risk agreement occurred; thus, the outcome was not met. Again, anecdotally, among those on long term opioids, the providers believed the ordering provider should complete the management agreement. Chronic pain management (n=9) and primary care (n=4) managed the most chronic opioid therapy.

Outcome 5 was to have at least 75% documentation of interprofessional communication with the PCP, as demonstrated by documentation of the agreement (Table 6). Out of the 46 patients, 31 had an interprofessional communication sent to the PCP. The sample rate was 31/46=67.4%, a p-value of 0.2334 determined that at least 75% could have been screened. Thus, statistically, the outcome had been met but was limited due to small sample size.

Table 6

Goal 3 Interprofessional Communication: Outcomes 5 & 6							
Goal 3: *Improve risk mitigation: interprofessional communication*		**Intervention**	**Meaure**	**Sample**	**Sample Rate**	**p-value**	**Inference**
Outcome 5	At least 75% PCP **interprofessional communication**	CDC Modules: Educate on interprofessional collaboration processes	Documented letter sent	31	31/46 = 67.4%	0.23334	Met
Outcome 6	At least 75% **referral** information given		Documented referral given	0	0/4 =0%	0.0001	Not Met

Note. Goal 3 Improve risk mitigation strategies, including outcomes five and six, the use of interprofessional communication. Opioid Prescribing Adherence Initiative Orthopedic-Trauma. PCP-primary care provider. 2020.

Outcome 6 was to have at least 75% referral to a PCP for those patients without a PCP; as demonstrated by documentation of a letter in the EHR (Table 6). Four patients did not have a

PCP. However, no follow-up referral was given. Furthermore, all four patients had scored two or more on the POMI screen, indicating a high necessity for a referral. No subsequent documentation of behavioral health resources had been given either within their visit note. Anecdotally, the project director provided behavioral health resource pamphlets to all four subjects. Upon analysis of the data, the project director determined that the outcome was not met.

Additional Findings 18-64 years of age

The low participation rate among providers skewed the data analyses. The lack of provider participation began a series of steps to identify these data limitations. Identifying data limitations would guide future monitoring programs, especially during high stress, such as amidst a global pandemic. Thus, other descriptive statistics were performed. The analyses beyond project goals and outcomes were performed to understand participants and strategically target future implementation processes. During the pandemic, the increased sense of isolation and breakdown in social systems led to an 18% increase in opioid-related overdose rates across America (Weiner, S., 2020). The increase in overdose rates indicated that one should be more vigilant of those at high risk for aberrant behaviors, placing them at risk for overdose during times of social isolation. Thus, indicating the need for organizational guidelines that are easy to implement, document, and incorporate into the electronic health record.

Finally, among those patients 18 to 64 years of age on an opioid, oxycodone was prescribed 58.7% of the time. Hydrocodone was the second most prescribed, 30.5% (Table 7). The characteristics of adults at risk for overdose were Caucasian, female, and around 45 years of age (Figure 3). This description did not follow the national description of those at risk for overdose, as mentioned earlier in this paper. Finally, those 18 patients on an opioid for more than

six months, 33.3% were at a higher risk for overdose, compared to the 14% higher overdose risk among patients on an opioid less than three months.

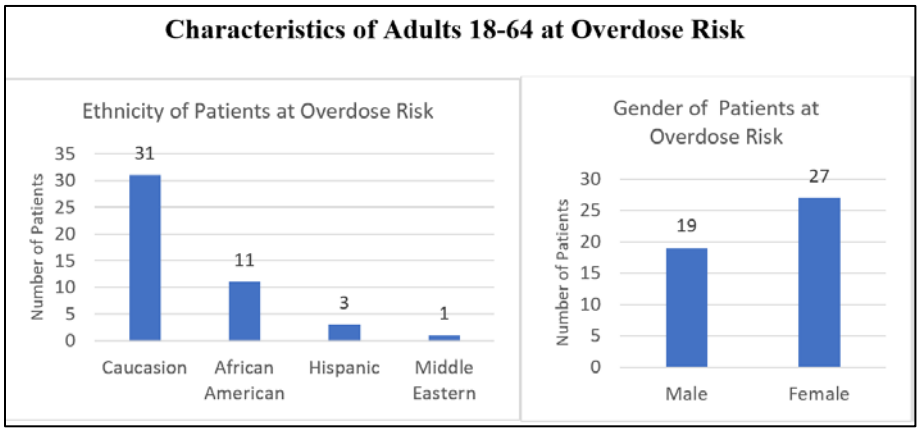
Table 7

Most Commonly Prescribed Opioids

Opioid	Oxycodone	Hydrocodone	Morphine	Tramadol	Other
Patients	27	14	0	2	3
Percentage	58.7%	30.5%	0	4.3%	6.5%

Note. Most commonly prescribed opioids within orthopedic-trauma. 2020.

Figure 3



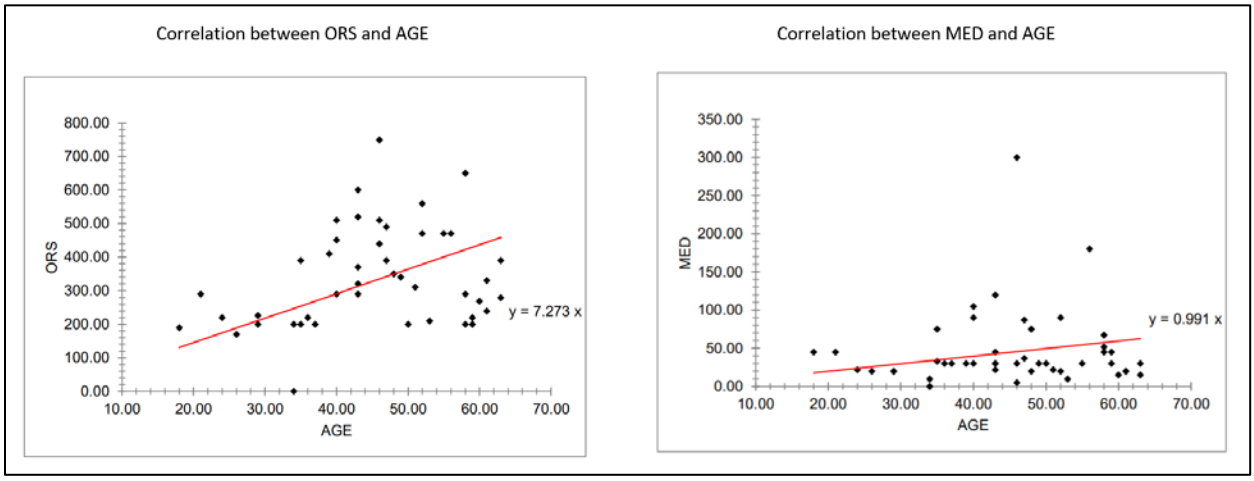
Note. Characteristics of adults ages 18 to 64 at overdose risk within orthopedic-trauma. 2020.

Adults older than 64 years of age

It was noticed that patients older than 64 years were on an opioid frequently however, these participants were excluded from this project due to age (Table 1). Although these patients could not participate in the behavior screening for misuse, USPSTF recommends only those 18

to 64 be screened for unhealthy medication use (USPSTF, 2019). The clinic staff wanted to know if this population was at risk of overdose and should be monitored. Furthermore, among the 35 patients older than 64, six patients were at risk for overdose compared to 10 in those younger than 64; the p-value, less than 0.0001 for both analyses, which was statistically significant. The project director interpreted the regression analysis and found a strong correlation between ORS and AGE and MED; as age increases, so does MED and the ORS scores, suggesting an increase in overdose risks (Figure 4).

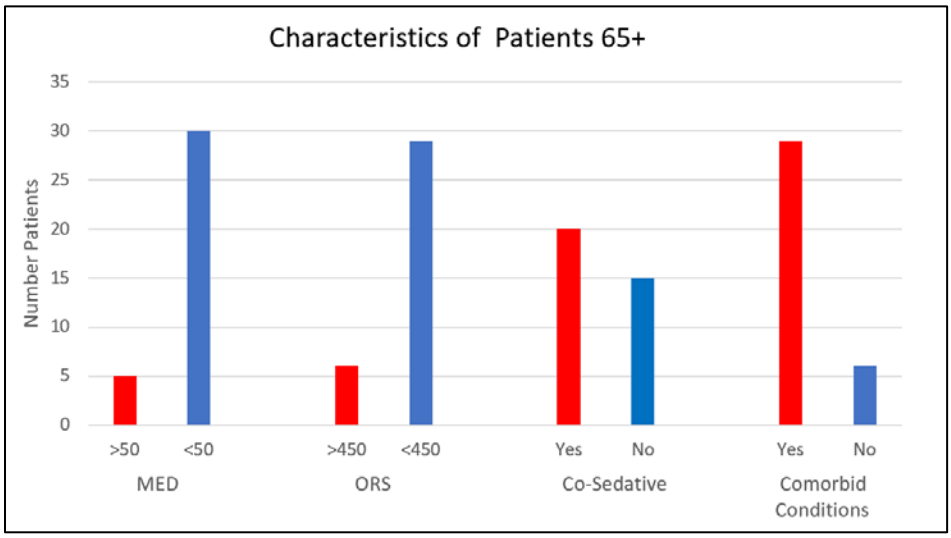
Figure 4



Note. Correlation of ORS score and MED on all patients during the project. ORS-overdose risk score, MED-morphine equivalent per day. 2020.

Although the older than the 64-year-old population are less likely to have misused opioids, the risk for overdose is still significant. It is compounded with the increased use of sedatives and comorbidities (Figure 5). Although it would not be necessary to screen those older than 64 for misuse, it would be prudent to screen for overdose risks and educate on the risks associated with sedatives and comorbid conditions.

Figure 5



Note. Characteristics of patients older than 64 years of age during the project. MED-morphine equivalent per day, ORS-overdose risk score. 2020.

Section IX: Summary

Limitations

With the subsequent low response rates to education, the sample smaller size significantly limited this doctoral evidence-based project. Initial interest in the project was made during a site assessment nine months earlier. Due to the pandemic of COVID-19, the ability to further develop relationships and education proved complicated. Initially, the first couple of months of the pandemic had been slower with patient appointments due to quarantining and was thought to have been an excellent time to initiate education. However, upon initiation of education, the COVID-19 restrictions were being lifted. Thus, an influx of patients occurred,

including a higher acuity of trauma patients resulting in limited provider time. Subsequently, providers were asked about the unforeseen barriers to inadequate response and documentation rates. Several providers mentioned that low participation was due to limited time and the physical and mental exhaustion that came with the additional COVID-19 workload.

Social bias needed to be considered when administering the provider survey with the project (Suter, N.W., 2012). Social bias could have occurred if participants answered with socially acceptable responses on the self-reported survey. However, the use of the pre- and post-survey had previously demonstrated much variability in answers among previously published results without bias (Wenghofer et al., 2011). Based on the answers provided, anonymity with Survey Monkey did provide a way to decrease this bias. Social bias could have also limited the POMI screen and needed to be considered. Patients might have been reluctant to share personal behaviors regarding their opioid use patterns to protect themselves.

We need to consider the difference between monitoring unhealthy behaviors associated with opioid use and risks associated with overdose. When implementing the POMI screen in future projects, the POMI screen should monitor behavior changes associated with opioid misuse. The ORS score and MED per day should be used as a reference in monitoring overdose risks. As the CDC guidelines recommend, continual efforts need to be made to monitor for misuse and mitigate overdose risks. The risks for overdose are not necessarily associated with patient behaviors, but rather a provider's prescribing actions.

Sustainability

Ensuring sustainability once the project had been completed was the true essence of this doctoral practice change project. The human element can be challenging and is needed for successful change to occur. The human element is to remember that change occurs in small

steps, and any change in behaviors is considered a success (Lawson, Weekes, & Hill, 2018). It was encouraging that amid the turmoil, the staff began the process of change. The staff and providers moved from the pre-contemplation stage and into the contemplation stage. Staff and providers began to consider the changes and raised awareness toward monitoring opioid therapy. To successfully move the staff and providers onto the determination stage, one would need a further commitment to the change process.

Finally, sustainability can be tied to a financial incentive with the reimbursement for screening and education. However, the reimbursement for guideline implementation during this project had not proven successful due to the required documentation time. In the future, ensuring information systems allow quick access to information and optimize documentation in the electronic health record would be of financial benefit (Lawson et al., 2018).

Policy Development

Current organizational policies were reviewed during the site assessment process. The current policies and guidelines regarding opioid management were found to be vague and were not being followed. The early inclusion of all staff at the targeted orthopedic-trauma clinic encouraged buy-in and ownership of the project, which helped the project completion and policy revisions. An opioid prescribing manual was left at the clinic for future reference, to foster this relationship. The manual included site-specific policies, workflow charts, visit checklists, risk assessment algorithms, CDC education, opioid disposal sites, and county resources. As a team, each member can each play a role in identifying at risk for overdose, providing education, documenting, and placing referrals for those patients on opioid therapy.

Dissemination

The final and fifth phase of project development is dissemination. Key milestones included the final project write-up, clinic specific policies, and disseminating the findings to key stakeholders and facilitators. This final phase was completed in October 2020 with a PowerPoint elaborating project findings. Due to the lack of revenue for reimbursement, it might be more difficult to secure future organizational support. A culture that supports safe opioid prescribing across the continuum would be necessary to ensure patient safety and high-quality care delivery. The implications would be to improve further education among those providers when monitoring opioid therapy to ensure safe outcomes. Disseminating the findings will be essential to sustain organizational change processes. The project director plans on preparing a manuscript for publication in a peer-reviewed journal, to help support guideline initiatives in the future.

DNP Essentials

Healthcare today is rapidly changing and advancing. The need for doctorly prepared advanced practice nurses is needed more than ever to improve organizational best practices changes. A nurse who has earned a Doctor of Nursing Practice (DNP) is prepared to initiate innovative ways to improve patient outcomes such as with implementing clinical guidelines. The *Essentials of Doctoral Education for Advanced Nursing Practice* supports this quality improvement project's fundamental goal to implement evidence-based organizational changes to improve patient outcomes. The current state of healthcare has shown that change has become inevitable; however, people can be resistant to change due to fear, anxiety, and lack of motivation (Allaoui, A. & Benmousa, R., 2020). The *Essentials of Doctoral Education for Advanced Nursing Practice* develops and evaluates new practice changes that integrate science, current evidence-based knowledge supported by relevant theories (AACN, 2006).

This DNP student has demonstrated all eight essentials throughout this project implementation. The scientific underpinnings for practice were demonstrated with a wide array of knowledge on opioid use disorder and opioid management with the subsequent ability to translate that knowledge into a practice change. Organizational and systems leadership had been demonstrated through improved patient and health care outcomes on the systems level. This project has the opportunity to change the way opioids are managed across the entire continuum of care within the organization. This student has demonstrated the knowledge and skills related to information technology and patient care to manage individuals and populations on opioids. The changes in current policies with opioid management have further demonstrated advocacy for health care policy and reform to improve patients' health care outcomes on opioid therapy. The implementation of interprofessional communication helped improve behavioral monitoring and the clinical prevention of overdose risks associated with opioid therapy. Developing an evidence-based approach to opioid management embraces the essence of becoming a DNP. This evidence-based practice change has served as an effective way to develop the essentials needed to improve health care outcomes.

Discussion & Considerations

Further discussion needs to occur regarding the differences between monitoring overdose risks and opioid misuse. These two concepts are distinct from each other; however, neither should be separated when monitoring a patient on opioid therapy. Each concept adds valuable information to assess a patient's risks for overdose and misuse. One way to clarify these different concepts is to discuss objective versus subjective measures that a provider can utilize to monitor patients' opioid therapy.

Clarifying the use of objective and subjective measures is needed to help mitigate risks associated with opioid therapy. Objective data are observable measures obtained from observation, physical assessment, or diagnostic testing and are quantifiable (Daniels, R, 2020). Subject data are based on a patient's perception, feelings, or concerns, and typically are not quantifiable, as they can vary between patients (Daniels). Objective measures such as the MED per day, the ORS score, PDMP access, the co-prescription of sedatives, comorbid conditions, and age are ways to measure an individual's overdose risk. These objective ways of measuring are provider controlled and are one way a provider can help mitigate risks with opioid therapy based on factual data that can be trended.

For instance, among the 34 patients screened with the POMI, 30 patients scored zero, three patients scored one to two, and one patient scored a three. Among the four patients who scored one or more on the POMI screen, only one participant was at risk for opioid misuse. That is, one person out of 34 had the potential for opioid misuse or 3%. Whereas, among those 30 patients who scored zero, 20% were at risk for overdose. Among the three patients scoring one to two, 67% were at risk for overdose. Thus, the POMI score is not an indicator of overdose risk and should only be used to monitor behaviors associated with unhealthy opioid use.

The use of such objective data proved to be helpful when addressing overdose risks with patients. When approached with objective data, patients were open to hearing more about overdose risk mitigation. Anecdotally, patients were concerned about their overdose risks based on facts and were pleased to know providers were monitoring their risks. Using objective data rather than relying on subjective data, such as patient screening tools, could decrease triggered defensive behavior mechanisms among patients. Although subjective screening tools are necessary for monitoring, these tools do not account for all the risks associated with opioids.

Such subjective tools focus on aberrant patient behaviors; however, it does not assess overdose risks. The use of combined objective and subjective measures could improve patient-provider communication and improve patient outcomes. The use of these tools should serve as a platform to initiate shared decision-making regarding patient care while on opioid therapy.

It is often difficult to discern between aberrant behavior, misuse, and abuse. The CDC currently recommends screening for misuse; however, no specific tool has been deemed suitable for screening. When determining a screening tool, the ambiguity that occurs can lead to unintended consequences or a lack of improved outcomes. The use of demographic screening tools, such as the ORT, has proven beneficial when assessing risks upon initiating opioid therapy. However, these tools would not serve those being monitored on opioid therapy as the questions are based on information that does not change. Behavior-based screening tools can stratify opioid risks and standardize language regarding behavior changes such as aberrant behavior, misuse, and abuse.

Conclusion

In summary, the use of opioid prescribing guidelines has proven to improve outcomes by identifying those at risk for overdose, early identification of any misuse or abuse, and increased referral to treatment (SAMHSA, 2019). However, the implementation of provider education implementation did not improve knowledge, comfort, and confidence with opioid prescribing. Nor did the education change provider behaviors regarding the documentation needed for monitoring opioid therapy. The literature indicates that orthopedic trauma providers see a disproportionate number of people at high risk for opioid use disorder (Morris & Mir, 2016). Orthopedic providers are among the top three prescribers of opioids (Brummett et al., 2017).

Implementing systems-based monitoring guidelines for opioid therapy among adults can improve patient safety and improve patient outcomes (CDC, 2019).

References

Allaoui, Ali, & Benmousa, R. (2020). Employee's attitudes toward change. Journal of Organizational Change Management, 33(2); 253-288. Retrieved from https://www.emerald.com/insight/content/doi/10.1108/JOCM-08-2018-0232/full/html.

American Academy of Orthopaedic Surgeons (AAOS). (2015). *Opioid Use, Misuse, and Abuse in Orthopaedic Practice: Information Statement.* https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1045%20Opioid%20Use,%20Misuse,%20and%20Abuse%20in%20Practice.pdf

American Association of Colleges of Nursing (AACN). (2006). The essentials of doctoral education for advanced nursing practice. https://www.pncb.org/sites/default/files/2017-02/Essentials_of_DNP_Education.pdf

American Psychiatric Association (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.). Washington, DC. https://doi.org/10.1176/appi.books.9780890425596

American Society of Addiction Medicine. (2013). Terminology related to the spectrum of unhealthy substance use. https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2014/08/01/terminology-related-to-the-spectrum-of-unhealthy-substance-use

American Society of Addiction Medicine. (2015). National practice guidelines: For the use of medications in the treatment of addiction involving opioid use. https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf

Austin, M. W. (2019). Empathy in health care: why empathy in the doctor-patient relationship is better for everyone. *Psychology Today [online]*. https://www.psychologytoday.com/us/blog/ethics-everyone/201903/empathy-in-healthcare

Bicket, M., Long, J., & Pronovost, P. (2017). Prescription opioids commonly unused after surgery: a systematic review. *Journal of the American Medical Association of Surgery, 152*(11): 1066-1071. https://www.ncbi.nlm.nih.gov/pubmed/28768328

Brummett, C., Waljee, J., & Goesling, J. (2017). New persistent opioid use after minor and major surgical procedures in US adults. *Journal of the American Medical Association Surgery*. https://www.ncbi.nlm.nih.gov/pubmed/28403427

Burris, S., Norland, J., & Edlin, B. (2001). Legal aspects of providing naloxone to heroin users in the United States. *Temple Law School Working Papers, International Drug Policy 137.* Retrieved from http://prescribetoprevent.org/wp2015/wp-content/uploads/2012/11/burris_legalaspectsofprescribing.pdf

Centers for Disease Control and Prevention. (2019). *Opioid overdose: training for providers, interactive series [online]*. https://www.cdc.gov/drugoverdose/training/index.html

Centers for Disease Control and Prevention. (2016). CDC guidelines for prescribing opioids for chronic pain. US Department of Health and Human Services. https://www.cdc.gov/drugoverdose/prescribing/guideline.html

Centers for Medicare & Medicaid Services (CMS). (2019). Screening, brief intervention, and referral to treatment (SBIRT) services. Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/SBIRT-Factsheet-ICN904084TextOnly.pdf

Cochran, G., Bacci, J., & Ylioja, T. (2016). Prescription opioid use: patient characteristics and misuse in community pharmacy. *Journal of the American Pharmacy Association, 56*(3): 248-256. https://www.japha.org/article/S1544-3191(16)00123-0/fulltext

Davis, M., Lin, L., & Liu, H. (2017). Prescription opioid use among adults with mental health disorders in the United States. *Journal of the American Board of Family Medicine [online]*. https://www.ncbi.nlm.nih.gov/pubmed/28720623

Daniels, R. (2020). Nursing fundamentals: caring & clinical decision making. Delamar Cengage Learning.

Davis, C., Burris, S., Beletsky, L., et al. (2017). Co-prescribing naloxone does not increase liability risk. Substance Abuse, 37(4): 498-500. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567808/

Dearholt, S., & Dang, D. (2018). *John Hopkins nursing evidence-based practice model and guidelines* (3rd ed.). Indianapolis, IN, Sigma Theta Tau International.

Dineen, K. (2019). Definitions matter: a taxonomy of inappropriate prescribing to shape effective opioid policy and reduce patient harm. *Journal of Kansas Law Review, 67*(5), 961-1011. https://kuscholarworks.ku.edu/bitstream/handle/1808/29337/Dineen_2019_Definitions%20Matter.pdf?sequence=1&isAllowed=y

Hebda, T., Hunter, K., & Czar, P. (2019). *Handbook of informatics for nurses and healthcare professionals* (6th ed.). New York, NY, Pearson Publishing

J. Chen. (September,8 2020). Personal communication discussing statistical analysis.

Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). (2017). The joint commissions pain standards: origins and evolution. *Healthcare Quality Evaluation*

Division. Retrieved from https://www.jointcommission.org/-/media/tjc/documents/resources/pain-management/pain_std_history_web_version_05122017pdf.pdf?db=web&hash=E7D12A5C3BE9DF031F3D8FE0D8509580

Knisely, J., Wunsch, M., Cropsey, K., & Campbell, E. (2008). Prescription opioid misuse index: a brief questionnaire to assess misuse. *Journal of Substance Abuse Treatment, 35*: 380-386. https://www.journalofsubstanceabusetreatment.com/article/S0740-5472(08)00035-4/fulltext

Lucas County Children Services. (2019). Opiate epidemic continues to create a crisis for Lucas County Children Services. *Lucas County Trauma Coalition*. Retrieved from http://lctraumacoalition.org/opiate-epidemic-continues-to-create-crisis-for-lucas-co-children-services/

Lawson, T., Weekes, L., & Hill, M. (2018). Ensuring the success and sustainability of a quality improvement project. *British Journal of Anesthesia, 18*(5): 147-152. https://bjaed.org/article/S2058-5349(18)30029-5/fulltext

McNeely, J., Kumar, P., & Rieckmann, T. (2018). Barriers and facilitators affecting the implementation of substance use screening in primary care clinics: a qualitative study of patients, providers, and staff. *Addiction Science & Clinical Practice, 13*(8), 1-15. https://ascpjournal.biomedcentral.com/track/pdf/10.1186/s13722-018-0110-8

Morris, B., & Mir, H. (2016). The opioid epidemic and orthopedic outcomes: implications and strategies. *Techniques in Orthopaedic, 31*(4): 215-217. https://insights.ovid.com/article/00013611-201612000-00003

National Council for Behavioral Health (NCBH). (2019). *The SHARE approach: a model for shared decision making*. https://www.thenationalcouncil.org/blog/resource/share-approach-model-shared-decision-making/

National Institute on Drug Abuse (NIDA). (2019). Ohio opioid summary: Opioid-related deaths. *National Institute of Health*. https://www.drugabuse.gov/opioid-summaries-by-state/ohio-opioid-summary

National Institute on Drug Abuse (NIDA). (2019). Overdose death rates. *National Institute of Health*. https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

Office of Disease Prevention and Health Promotion (ODPHP). (2019*). Healthy People 2020: Topics & Objectives*. https://www.healthypeople.gov/2020/topics-objectives

Ohio Department of Health (ODH). (2018). Ohio drug overdose data: general findings. Bureau of vital statistics. https://odh.ohio.gov/wps/wcm/connect/gov/d9ee6d3b-bf62-4b4f-8978-d7cfcd11348f/2018_OhioDrugOverdoseReport.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE.Z18_M1HGGIK0N0JO00QO9DDDDM3000-d9ee6d3b-bf62-4b4f-8978-d7cfcd11348f-mXhFqNO

Ohio Department of Health (ODH). (2019). Neonatal abstinence syndrome: hospital reporting in Ohio. https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/violence-injury-prevention-program/resources/nas_hospital_reporting_in_ohio

Pearson, A., Moman, R., Moeschler, S., & Eldrige, J. (2017). Provider confidence in opioid prescribing and chronic pain management: results of the opioid therapy provider survey. *Journal of Pain Research, 10*: 1395-1400. https://www.ncbi.nlm.nih.gov/pubmed/28652805

Phillips, J., Ford, M., & Bonnie, R. (2017). *Pain management and the opioid epidemic*. Washington, DC: National Academies Press.

Prochaska, J., & Velicer, W. (1997). The transtheoretical model of behavior change. *American Journal of Health Promotion, 12*(1): 38-48. https://doi.org/10.4278/0890-1171-12.1.38

Ruder, J., Wally, M., & Oliverio, M. (2017). Patterns of opioid prescribing for an orthopaedic trauma population. *Journal of Orthopaedic Trauma, 31*(6): 179-185. https://insights.ovid.com/crossref?an=00005131-201706000-00013

Samuels, E., McDonald, J., & McCormick, M. (2019). Emergency Department and Hospital Care for Opioid Use Disorder: Implementation of Statewide standards in Rhode Island, 2017-2018. *American Journal of Public Health Practice, 109*(2): 263-266. https://www.ncbi.nlm.nih.gov/pubmed/30571304

State of Ohio Board of Pharmacy. (2019). *Providing of naloxone upon discharge.* Pharmacy.ohio.gov (online). Retrieved from https://www.pharmacy.ohio.gov/Documents/Pubs/Naloxone/Hospital/Guidance%20Document%20-%20Hospitals%20Providing%20Naloxone%20Upon%20Discharge.pdf

Substance Abuse and Mental Health Services Administration (SAMHSA). (1999). TIP 35: Brief interventions and brief therapies for substance abuse. *Center for Substance Abuse Treatment.* Retrieved from https://www.mycasat.org/wp-content/uploads/2017/06/MITIP35_Part1.pdf

Substance Abuse and Mental Health Services Administration (SAMHSA). (2017). Coding for screening and brief intervention reimbursement. Retrieved from

Substance Abuse and Mental Health Services Administration (SAMHSA). (2019). Medication assisted treatment. U.S. Department of Health and Human Services. Retrieved from

Suter, N. W. (2012). *Introduction to educational research: A critical thinking approach. (2nd ed.).* Thousand Oaks, CA.: Sage Publishing Inc. https://dx.doi.org/10.4135/9781483384443.n7

Toles, K. (2018). *Lucas County opiate coalition prevention toolkit.* Toledo Lucas County Health Department. Retrieved from https://www.lucascountyhealth.com/wp-content/uploads/2019/11/Opiate-coalition-toolkit-2019.pdf

United States Preventative Services Task Force. (2019). *USPSTF: Screen adults for illicit drug use.* https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/drug-use-in-adolescents-and-adults-including-pregnant-women-screening

Weiner, S. (July, 2020). COVID-19 and the opioid crisis. American Academy of Medical Colleges (AAMA) (online). Retrieved from https://www.aamc.org/news-insights/covid-19-and-opioid-crisis-when-pandemic-and-epidemic-collide

Wenghofer, E., Wilson, L., & Kahan, M. (2011). Survey of Ontario primary care physicians' experiences with opioid prescribing. *Canadian Family Physician, 57*: 324-332. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3056687/pdf/0570324.pdf

Appendix A

Diagnostic and Statistical Manual of Mental Disorders (DSM)-V Criteria

DSM-5 Criteria for Diagnosis of Opioid Use Disorder

Diagnostic Criteria*
These criteria not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Check all that apply

	Opioids are often taken in larger amounts or over a longer period of time than intended.
	There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
	A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
	Craving, or a strong desire to use opioids.
	Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
	Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
	Important social, occupational or recreational activities are given up or reduced because of opioid use.
	Recurrent opioid use in situations in which it is physically hazardous
	Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.
	*Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid
	*Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms

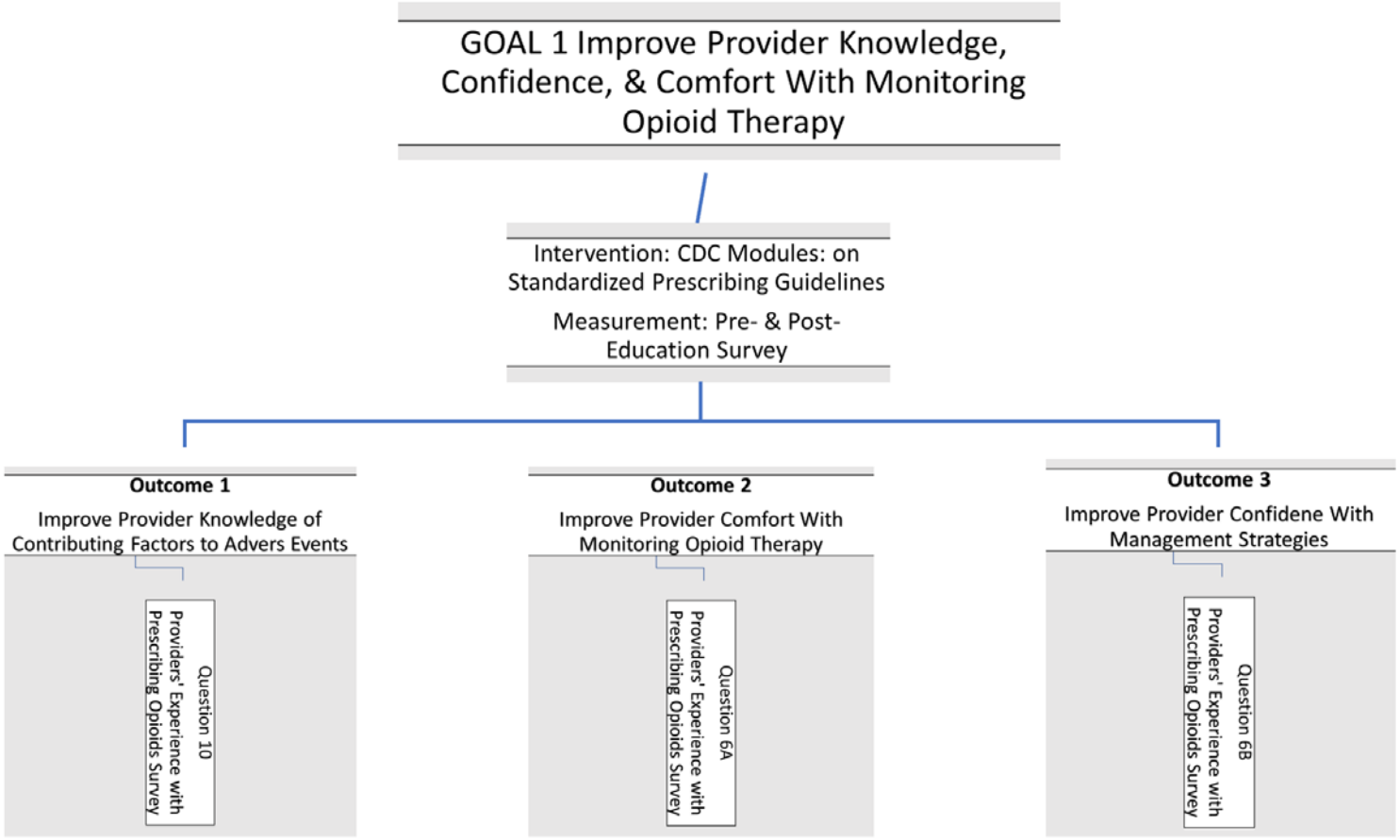
Total Number Boxes Checked: _____

Severity: **Mild**: 2-3 symptoms. **Moderate**: 4-5 symptoms. **Severe**: 6 or more symptoms

Note. The DSM-V Criteria, diagnostic behaviors to diagnosis opioid use disorder. Adapted from American Psychiatric Association. 2013. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, p. 541. Copyright 2013 American Psychiatric Association.

Appendix B

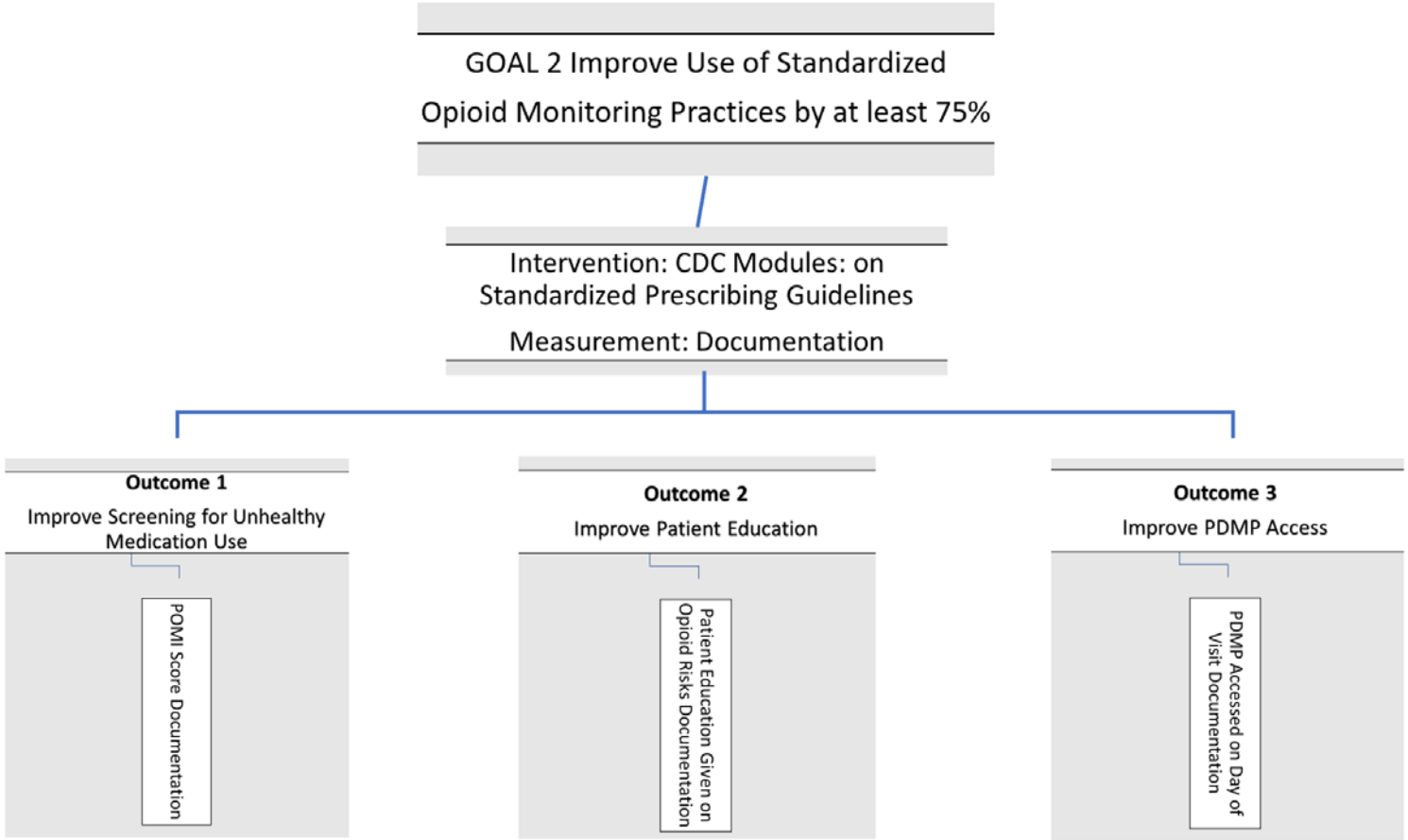
Project Goals, Aims, and Outcomes



Note. Project Goal 1 and Outcomes 2020. Copyright 2020 Stechschulte, A.

Appendix B2

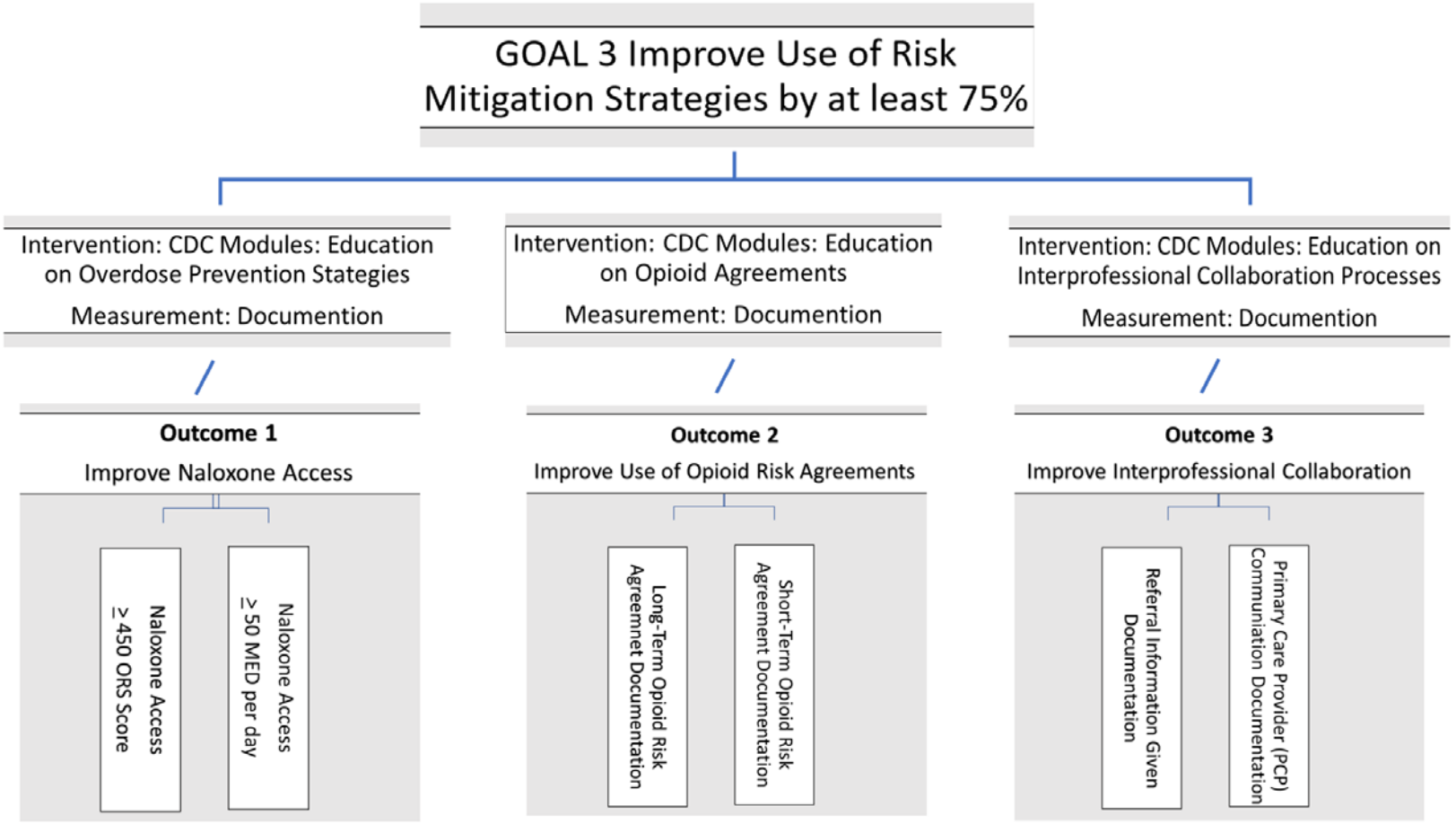
Project Goals & Outcomes



Note. Project Goal 2 and Outcomes 2020. POMI-prescription opioid misuse index, PDMP-prescription drug monitoring program. Copyright 2020 Stechschulte, A.

Appendix B3

Project Goals & Outcomes



Note. Project Goal 3 and Outcomes 2020. MED-morphine equivalent dose, ORS-overdose risk score. Copyright 2020 Stechschulte, A.

Appendix C

Providers' Experiences with Prescribing Opioids Survey Page 1

1. Years in practice: _____

2. Degree: _____ MD _____ DO ____ APRN ___ PA ____ other_____

3. What is the population of your city, town, or practice area?

   ___<5,000 ___ 5,000—10,000 ___10,000-30,000 ___30,000-60,000
   ___>60,000

4. In the last ***three months***, to how many patients have you prescribed opioids for pain?
   ___ 1-5 ___ 6-10 ___ 11-20 ___ > 21 ___ none __ Do Not Know

5. If you answered ***NONE***, why do not prescribe opioids?
   ___ Choose not to provide this service
   ___ No patients
   ___ License restrictions
   ___ Uncertain of efficacy
   ___ Concern about opioid misuse and addiction

6. Please indicate the extent of your agreement with each of the statements below:

	Strongly Agree	Somewhat Agree	Not Sure	Somewhat Disagree	Strongly Disagree
I am comfortable precribing opioids					
I am confident in my clinical skills in prescribing opioids					
Many pain patients experience substantial relief with opioids					
Many pain patients function better with opioids					
Many pain patients become addicted to opioids					
I find it satisfying to prescribe opioids to pain patients					

7. 7a. In the ***past year,*** how many of your patients have had an adverse event due to opioids?
   ___ 1 ___ 2 ___ 3 ___ 4+
   ___ None (proceed to question 8)
   ___Do Not Know (Proceed to question 8)

   7b. Looking at the most recent adverse event: Which opioid was involved_____

Note. Modified *Physicians' experience with prescribing opioids survey*. Wenghofer, E., et al. (2011). Survey of Ontario primary care physicians' experiences with opioid prescribing. *Canadian Family Physician*, 57: 324-332. Copyright 2011.

Appendix C2

Providers' Experiences with Prescribing Opioids Survey Page 2

7c. Please select all that factors that might have contributed to the adverse event:
___ Prescribed dose was too high
___ Patient did not contact the provider/pharmacist about symptoms
___ Patient took more than prescribed
___ Patient took alcohol or sedating drug along with opioid
___ Patient injected, crushed, or snorted the opioid
___Patient refused emergency treatment
___ MD/NP/PA/Pharmacist did not recognize symptoms
___ Lack of interprofessional collaboration
___ Dispensing error
___ MD/NP/PA/pharmacist did not assess risk for overdose (e.g. elderly)
___ Patient/caregiver misunderstanding about dosing
___ Loss of tolerance following a period of non-compliance
___Other _____

8. How many of your patients cause you concern, specifically with respect to their opioid prescription use?
___ 1-3 ___ 4-6 ___ 7-9 ___ >10 ___ NONE (proceed to question 10)

9. Of the patients you have concerns about, which opioid(s) are they taking? Check all that apply:

☐ LA codeine (e.g. Codeine Contin®)
☐ Codeine (e.g. Tylenol #1-4; 222's, Robaxacet 8®)
☐ Oxycodone (e.g. Percocet®)
☐ LA oxycodone (OxyContin®)
☐ Hydromorphone (Dilaudid®)
☐ LA hydromorphone (HydromorphContin®)
☐ Morphine (Statex®)
☐ LA Morphine (e.g. MS Contin®)
☐ Fentanyl patch (e.g. Duragesic®)
☐ Methadone

10. Please rate the extent of your concerns about opioid prescribing:

	Strongly Agree	Somewhat Agree	Not Sure	Somewhat Disagree	Strongly Disagree
Getting patients addicted					
Getting into trouble with College of Physicians & Surgeons					
Non-Compliance (e.g. missed appointments)					
Running out early, demanding fit in appointments, lost scripts					
Overdose					
Lack of addiction treatment resources					
Lack of specialized pain clinics					
Disagreements with patients about opioids					
Patients getting high doses					

Note. Modified *Physicians' experience with prescribing opioids survey*. Wenghofer, E., et al. (2011). Survey of Ontario primary care physicians' experiences with opioid prescribing. *Canadian Family Physician*, 57: 324-332. Copyright 2011.

Appendix C3

Providers' Experiences with Prescribing Opioids Survey Page 3

11. In the past year, have you participated in educational event on opioids for chronic pain?
    ___ YES ___ NO (proceed to question 13)

12. If YES: Describe the event(s)(may select all that apply)
    ___ Presentation at hospital of conference
    ___ Article in Journal
    ___ Pharmaceutical sponsored dinner/workshop
    ___ Other _____

13. Please rate each of the following strategies on how helpful they will be in your management of chronic pain patients on opioids:

	Strongly Agree	Somewhat Agree	Not Sure	Somewhat Disagree	Strongly Disagree
"1-800" Help Line (telephone advice from a clinician)					
Quick reference "Pocket Guide" on opioid prescribing					
One day course on opioid prescribing					
Access to provincial database of patients' prescriptions					
On-line course on opioid prescribing					
College of Physicians and Surgeons guidelines on opioid prescribing					
Guidelines for management of high-risk patients					
Office materials such as treatment agreement, patient information					
Web site with clinical information					
Physician mentor that you can contact by phone/email					

Note. Modified *Physicians' experience with prescribing opioids survey*. Wenghofer, E., et al. (2011). Survey of Ontario primary care physicians' experiences with opioid prescribing. *Canadian Family Physician*, 57: 324-332. Copyright 2011.

Appendix D

Prescription Opioid Misuse Index Screening Tool

	YES	NO
1. Do you ever use MORE of your medication, that is, take a higher dose, than is prescribed to you?		
2. Do you ever use your medication MORE OFTEN, that is, shorten the time between dosages, than is prescribed for you?		
3. Do you ever need early refills for your pain medication?		
4. Do you ever feel high or get a buzz after using your pain medication?		
5. Do you ever take your pain medication because you are upset, using the medication to relieve or cope with problems other than pain?		
6. Have you ever gone to multiple physicians including ER, seeking more of your pain medication?		

Note. The prescription opioid misuse index (POMI) screening tool Adapted from Knisely, J., et al. 2011. *Journal of Substance Abuse Treatment, 34*, p. 5. Copyright 2011 Knisely, J.

Appendix E

Stepwise Approach to Opioid Prescribing Guidelines

Appendix F

Short-Term Risk Agreement

PATIENT ACKNOWLEDGMENT OF RISK OF CONTROLLED SUBSTANCE AND OPIOID USE

Patient Name: _____ Date: _____

Your provider has prescribed a controlled substance or opioid medication to treat your pain. Even when taken as prescribed, these medications are highly addictive and there is a risk of developing a physical and/or psychological dependence.

What is Physical Dependence?

When your body cannot function properly without a drug, you have become physically dependent or addicted. If you suddenly stop taking the drug, painful withdrawal symptoms occur. Some typical withdrawal symptoms can include tremors or "shakes," nausea, diarrhea, chills and body aches.

What is Psychological Dependence?

Also called emotional addiction, it is defined as a compulsion or perceived need to use a drug or substance. In severe cases of psychological addiction, these thoughts become all- consuming. Without help, a psychological dependency can transform a drug into your central focus of life.

RISK OF DEATH

Taking more controlled substances or opiates than prescribed, or mixing sedatives (sleeping pills, muscle relaxants) benzodiazepines (anxiety medications), or alcohol with controlled substances or opiates, can lead to respiratory depression and can be fatal (cause death). *Risks are greater with history of drug misuse, substance use disorder or overdose, mental health conditions (such as depression and anxiety), sleep apnea, age greater than 65, and pregnancy.*

TREATMENT OF PAIN

Prescription controlled substances and opioids can be used to help relieve moderate to severe pain and are often prescribed following a surgery or injury, or for other painful health conditions.

POTENTIAL ALTERNATIVES TO THERAPY

Your provider will discuss with you alternative or complementary treatments for your pain, as appropriate, which may include: physical or occupational therapy; counseling; good nutrition; biofeedback; massage; meditation; gentle exercise; and nonopioid medications.

MEDICATION SAFETY

• Keep all medicines in a safe, preferably locked container, out of sight and out of the reach of children. • Never share these medicines with others. Never take other people's pain medications.

• Always dispose of your medications properly.

• Be aware that controlled substances and opioids may affect your judgment and driving skills.

MEDICATION REFILLS

Prescription controlled substances and opioids will only be prescribed for a 30-day period. You can request a refill from your pharmacy for additional medications. **Patients on controlled substances or opioids will need to be seen by a provider every 90 days** in the office to evaluate pain and pain control. PRESCRIPTION FOR GREATER THAN SEVEN-DAY SUPPLY (complete, if applicable)

- ✓ I certify that the above-named patient requires more than a seven-day supply of medications for the medical condition listed below and a non-opioid alternative is not appropriate to address this condition. List Medical Condition necessitating more than a seven-day supply: _____

ACKNOWLEDGMENTS

I, the undersigned, hereby acknowledge that my provider has discussed with me the above information. I also certify that I have read and understand the above information.

I, the undersigned, hereby acknowledge that I have been given the opportunity to have my questions or concerns addressed to my satisfaction.

Signature of Patient or Patient Representative:	Date/Time:
Provider Signature:	Date/Time:

Appendix G

Long-Term Risk Agreement Page 1

Contract for prescription of Controlled Medication

I_____ being a patient of _____

Provider agrees to the following conditions for my treatment with the following medications and dosages:

***Medication/Dosing addressed by this contract**:*

_____

_____

Diagnosis (es)

I will obtain my medications covered by this contract solely from _____Pharmacy

Address: _____Phone:_____

1. I have read and understand the attached document regarding the controlled medications addressed in this contract.
2. If I am transferring my care from another provider or practice, it is my responsibility to provide prior medical records. If these records cannot be obtained in a reasonable amount of time, the medication (s) will not be continued.
3. My prior records must verify the history I have provided, and my current Provider must agree with the prior treating provider's rationale for the medication in order for it to be continued.
4. My prescription (s) for this medication (s) may not be refillable pursuant to regulations. Furthermore, these prescriptions can be prescribed or refilled only with written prescriptions pursuant to regulation. The paper copies must be picked up in person in accordance with ProMedica Physician Group policy.
5. I will only obtain prescription (s) for this controlled medication (s) from the above Provider. I understand that other members of the Providers group are under no obligation to provide refills for these medications.
6. I will notify all my Providers of this contract and of any medication (s); I am currently taking as well as over the counter medication and notify Provider immediately if I begin taking any additional medication(s).
7. If I need emergency care or hospitalization and receive controlled substances from an outside provider, I will inform them of the existence of this contract and will report any medicine (s) I received to my Provider.
8. I will not accept prescriptions for controlled substance medicine (s) from any other provider while I am on medicine (s) from my current Provider.
9. I will have follow-up appointments with the above Provider or designee every 90 days (month) pursuant to regulations to check my symptoms and medication use.

Appendix G2

Long-Term Risk Agreement Page 2

10. I will request refills for prescription (s) 4 days before the medication (s) runs out in order to allow time for refill. No controlled substance medication will be refilled on weekends, during evening hours, or during any unscheduled visit to the office.
11. I will use only the pharmacy listed above for medication (s) covered by this contract. If there is any need to change the pharmacy, I will notify my Provider and understand that medication refills may be delayed due to this change.
12. I will notify the police if any of the above medication (s) are stolen from me. I understand that this notification or the existence of a police report is not a guarantee that missing medication will be replaced or filled early.
13. I understand that the existence of this contract may be shared with my pharmacy. I also understand that the above Provider may inform my other providers regarding the terms of this contact and the conditions and medication (s) it covers.
14. I also understand that my Provider above may be required to check available state databases to verify my prescription history. Discrepancies or evidence of untruthfulness may result in discontinuation of the prescription and /or my treatment relationship with this Provider and Group.
15. I agree to random drug testing as requested by my Provider. I agree that failure to provide a sample or discrepancies in the test results can result in termination of my care with this Provider and Group.
16. I agree to be truthful and respectful to my Provider and their office staff at all times.
17. I agree to avoid improper use of controlled substances. This includes use of street drugs or deliberate overdosing, selling or trading medication. I understand these actions are dangerous and illegal and will lead to discontinuation of the prescription and my treatment relationship with the Provider and Group. I further understand diversion of this medication (s) is a significant public health problem.
18. I agree to avoid weaning or abruptly stopping medication without notifying my Provider.
19. I understand that mixing these medications with alcohol or recreational drugs is dangerous and I will avoid doing so.
20. I understand these medications can potentially lead to addiction/substance abuse problems in all persons. I will be truthful about my personal or family history of substance abuse to assist my Provider in protecting my safety.
21. I will not be involved in any activity that may be dangerous to me or someone else if I feel drowsy or not thinking clearly. I am aware that even if I don't notice it, my reflexes and reaction time might still be slowed. Such activities include using heavy equipment or driving a motor vehicle, working in unprotected heights or being responsible for another individual who is unable to care for him or herself.
22. (For Women) I understand that if I become pregnant while taking these medications, my child may be born dependent on the medication and other health risks to my child may exist. I agree to contact my Provider immediately if I become pregnant.
23. I understand that my provider may perform a dose count to determine my actual use of these medications. Significant discrepancies in this count may result in a dose adjustment or refusal to refill the medication. Additionally I understand that I may be required to bring my unused medication (in their original labeled pill bottle or container) to my scheduled appointment.

Appendix G3

Long-Term Risk Agreement Page 3

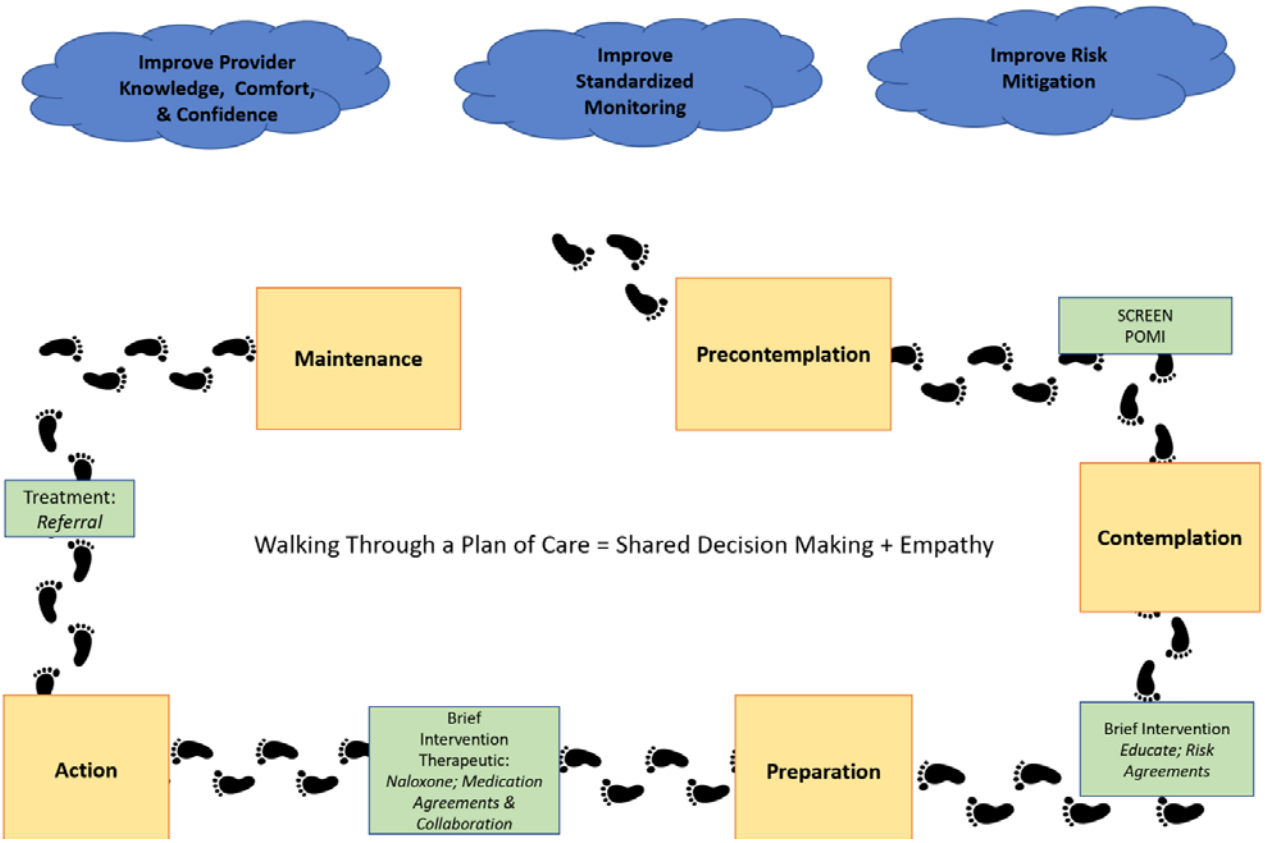
24. I understand that these medications are only one aspect of my care. Non-compliance with other care plan recommendations is a violation of this agreement and may lead to discontinuation of the prescription and my treatment relationship with this Provider and Group.
25. I understand my medication (s) can be changed or stopped at any point in my treatment at my Providers discretion.
26. I will keep all appointments with my Provider.
27. I understand this agreement is specific between me and my Provider and may not be continued in the event another provider takes over my care.

I understand this agreement is effective for the entire time I am a patient in this practice. I also understand it needs to be renewed annually. I am aware that violation of any part of the agreement will lead to discontinuation of the prescription and may lead to discontinuation of my treatment relationship with the Provider and Group.

Signature_____Date_____
Witness_____Date_____

Appendix H

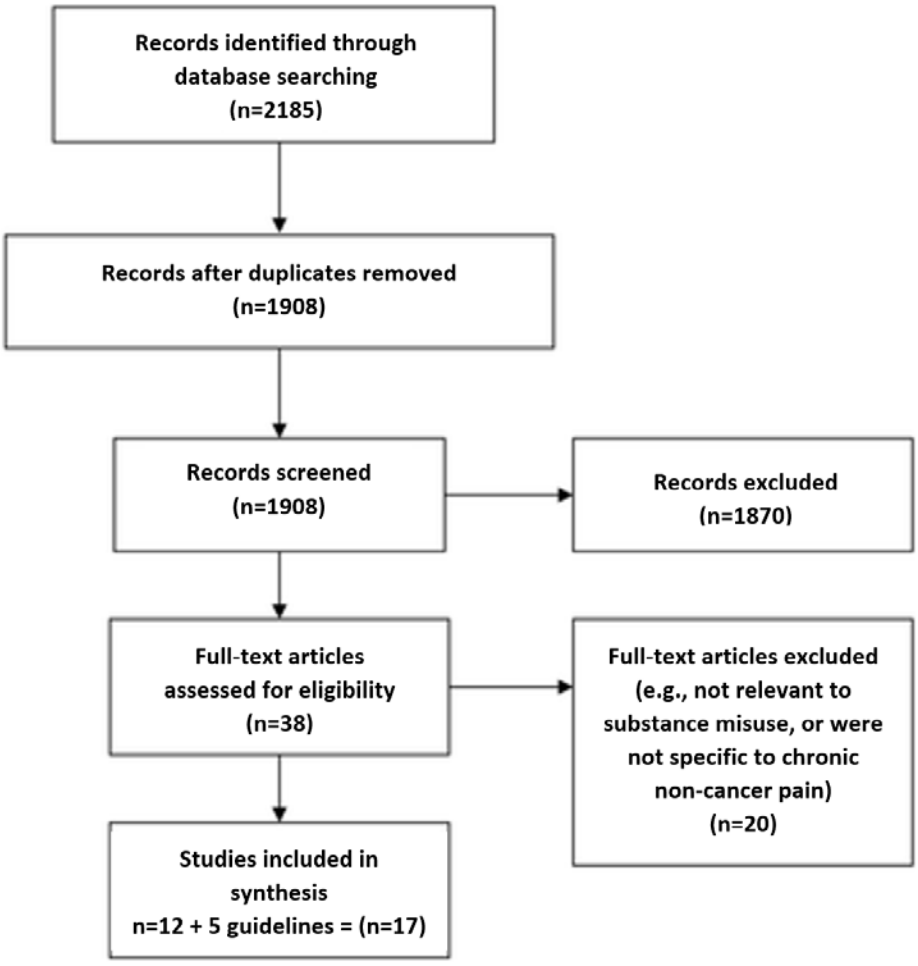
Opioid Prescribing Guideline Adherence Initiative Concept Map



Note. Concept map for the opioid prescribing guideline adherence initiative demonstrating the integration of project goals, transtheoretical change statge concepts, S-BiRt, and shared decision making. Copyright 2020 Stechschulte, A.

Appendix I

Literature Search Results



Note. The literature search results, inclusion, exclusion, and final articles identified 2019.

Appendix J

Level of Evidence Synthesis

Evidence Synthesis			
Level of Evidence	**Number of Sources**	**Overall Rating**	**Evidence**
Level 1 Systematic Reviews RCT, RCT, experimental study	0	N/A	N/A
Level 2 Quasi-experimental studies, Systematic Review of combination studies RCT/quasi-experimental	2	High	Supports screening for opioid misuse as beneficial.
Level 3 Non-experimental study, Systematic Review of nonexperimental study, qualitative studies	4	High	Supports among orthopedic patients to monitor for overdose risks and unhealthy medication use.
Level 4 Clinical Practice Guidelines, Consensus statements	7	High	Supports adherence to opioid prescribing guidelines and early education strategies improve care and reduce risks with opioid therapy.
Level 5 Opinions of respected authors, expert opinion, case reports, & literature reviews	4	Good to High	Supports screening and brief intervention (S-Bi-Rt) as primary prevention for unhealthy medication use and overdose

Note. The synthesis process and recommendation tool. Adapted from Dearholt, S. & Dang, D. 2017. *John Hopkins of Nursing Evidenced-Based Practice Model & Guidelines*. John Hopkins Hospital, p. 304-305. Copyright 2017 Sigma Theta Tau International.

Appendix K

Estimated Project Timeline

Estimated Project Timeline: Opioid Guideline Adherence Initiative																	
DNP Project Development	2019					2020											
	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
PHASE 1 PRACTICE: Plan and PICOTdevelopment																	
Literature Review																	
Select Project Committee																	
Identify Stakeholders/Resources																	
Meet with planning team																	
Meet with Trauma																	
PHASE 2 EVIDENCE: Appraisal & Sythesis																	
Internal Audit																	
Site Assessment: SWAT analysis																	
Barriers, limits and faciliators																	
Create Strategic Plan																	
Project Write up																	
IRB Submission																	
Project Proposal Defense																	
PHASE 3 TRANSLATION: Implementation & Dissemination																	
Create Education & Promotion material																	
GO LIVE: 4 wk Provider Education																	
GO LIVE: 8 wk Patient implementation																	
Outcome analysis																	
Final Project Write up																	
Disseminate Outcomes																	
Final Project Defense																	GRAD

Note. The estimated project timeline for Doctoral of Nursing Practice project 2019-2020. Copyright 2019 Stechschulte, A.

Appendix L

Budget Analysis for Opioid Prescribing Guideline Adherence Initiative

COST ANALYSIS				
EXPENSES			**REIMBURSEMENT**	
Resources			Reimbursement Code 99408: 100 x $33.41	$ 3,341.00
Paper/Print-POMI screen	$ 20.00		RVU 0.65: 100 x 0.65	65 RVU
Reminder screening fliers	$ 5.00		compare to typical 99213 office visit 0.97 RVU	97 RVU
Staff Training				
space: meetings	$ -			**40% increase**
reimbursement time: Lead-OM, Secretary, LPN, MA				
5 offices(4personsx16.00)	$ 300.00			
Refreshments meet. X4 initial every 1 month	$ 10.00			
3 ($10.00) monthly lounge treats x3	$ 30.00			
Provider gift card $25 x 5	$ 125.00			
Time involved each visit				
~5 min/visit: $1.50 wages (MA)/visit x ~100 visits	$ 150.00			
TOTAL	**$ 510.00**		**Potential**	**$ 3,341.00**

Note. The budget analysis for screening adults in orthopedic trauma clinic. 2019.

Appendix M

Provider Informed Consent Cover Letter

Study Title: Orthopedic-Trauma Opioid Prescribing Guideline Adherence Initiative

Principal Investigator: Linda Lewandowski PhD, RN, FAAN; Anita M. Stechschulte APRN-CNP, MSN, DNP candidate

Dear Participant
Dr. Linda Lewandowski and Anita M. Stechschulte are conducting a study to learn whether an opioid screening tool helps detect those with substance use disorder and gain early referral to treatment if necessary. By allowing us to collect data, it will help us to determine how to better meet the needs of patients like you in the future.

Procedures
If you choose to participate, you will be asked to complete a pre- and post-education survey with questions pertaining to prescription pain medications and the current nationwide opioid crisis. Each survey is estimated to take approximately 5-10 minutes to complete. Weekly education will be given via Healthstream, taking less than 1 hour. Your basic demographical information will not be accessed (age, gender, race, etc.). We anticipate a random selection of 200 patients charts to review documentation and adherence, on adults 18-65 years of age.

Safeguarding Privacy/Rights
Participation in this study is voluntary and there are no costs to participate. All responses will be kept confidential and all research records will be maintained in accordance with federal and state laws. Only the authorized research staff and the targeted Health System Institutional Review Board will have access to the survey information. It has been planned for this study to be published and presented at scientific meetings.

If you have any questions regarding your rights as a research subject, you may contact the Institutional Review Board, at (419) 291-5362. If you have any questions about this study, please contact Anita M. Stechschulte, Doctoral Nurse Practitioner Candidate, at astechs6@rockets.utoledo.edu. You may call the ProMedica Institutional Review Board at (419) 291-5362. If you have any further questions about your privacy, you may contact the *confidential ProMedica Hotline at* (419) 824-1815 or (800) 807-2693.

Respondent Agreement
PARTICIPATION IN RESEARCH IS VOLUNTARY. This letter serves to inform you of your rights as a research subject. By completing the surveys and education, you are agreeing to participate in the study.

Thank you in advance for your participation.

Kind regards,
Anita M. Stechschulte
Anita M. Stechschulte APRN-CNP, MSN, CEN
Doctoral Nurse Practitioner Candidate University of Toledo

Appendix N

Patient Informed Consent Cover Letter

Dear Participant:

You are being asked to complete a brief screening regarding the use of your current prescription pain medications to ensure safe patient care. The information gained will provide insight regarding whether the current opioid crisis has an effect on the quality of care delivered to our patients. In addition, the screening might support the need for additional resources and education for the patients, to ensure that we deliver the highest quality of safe care.

What will happen if you take part in this study?
You will be asked to complete a screening via I-pad with questions pertaining to your current prescription pain medications, to compare to current nationwide statistics. The survey is estimated to take approximately 3 to 5 minutes to complete. The screening itself will not include details that directly identifies you, such as your name or address. The completed screenings will be kept secure and separate from information that identifies you. You may experience direct benefits from this screening, if you have been identified as a person at risk for any opioid related harms, you will be given additional interventions including but not limited to brief education, naloxone prescription, and/or referral. These interventions will be given for all participants based on screening results.

Will your medical information be kept private?
Participation will not affect your current relationship with any ProMedica health system institution, personnel, or providers. Your plan of care might be updated to include initial opioid risk agreements, medication agreements for long term use of opioids, and referral to pain management if needed. All screening responses will be collected in an anonymous fashion. The information collected will be shared with your provider and will only be used to complete the purpose of this project. All responses will be kept confidential and all research records will be maintained in accordance with federal and state laws. Only the authorized research staff and the ProMedica Health System Institutional Review Board will have access to the screening information. All screening responses will be stored in a secured location with limited access to research and clinical staff. It has been planned for this study to be published and presented at scientific meetings. However, all patient identifiers including names and protected health information that might identify you, will not be used.

Questions?
If you have any questions regarding your rights, you may contact the Institutional Review Board, at (419) 291-5362. If you have any questions about this study, please contact Anita M. Stechschulte, Doctoral Nursing Practice Candidate, astechs6@rockets.utoledo.edu

Statement of Consent: PARTICIPATION IS VOLUNTARY and there are no costs to participate. This letter serves to inform you of your rights as a research subject. By completing the screening, you are agreeing to participate. **Once the screening has been completed, please exit out of the I-Pad and give the I-Pad back to the nursing staff.**

Thank you in advance for your participation.

Kind regards,

Anita M. Stechschulte DNP candidate

Anita M. Stechschulte APRN-CNP, MSN, CEN
Doctoral Nursing Practice Candidate, University of Toledo

Appendix O

Completed Project Goals and Outcomes

Goal	*Outcome*	*Analysis*	*Sample Rate & P-value*	*Project Goal*
Goal 1				
Improve Provider Knowledge, Comfort & Confidence With Monitoring Opioid Therapy	1: Improve Provider Knowledge of Adverse Events Factors	A change occurred-improvement	3 pre & 1 post responses	MET
	2: Improve Provider Comfort With Monitoring Opioid Therapy	A change occurred-improvement	3 pre & 1 post responses	MET
	3: Improved Provider Confidence With Management Strategies	A change occurred-worsening	3 pre & 1 post responses	NOT MET
Goal 2				
Improve Use of Standardized Opioid Monitoring Practices by at least 75%	1: Improve Screening for Unhealthy Medication Use	73.91%	34/46, p-value 0.8648	MET
	2: Improve Patient Education	0%	all given, 0/46 documented	NOT MET
	3: Improve PDMP Access	20.59%	7/34, 0/7 documented	NOT MET
Goal 3				
Improve Use of Risk Mitigation Strategies by at least 75%	1: Improve Naloxone Access to those At-Risk for Overdose	45.5% (MED) & 66.7% (ORS)	5/11, p-value 0.0236 ; 8/12, p-value 0.505	NOTMET/MET
	2: Improve Use of Opioid Risk Agreements	13% % (short-term) 33.3% (long-term)	6/46, p-value 0.0001; 6/18, p-value 0.0001	NOT MET/NOT MET
	3: Improve Interprofessional Collaboration	67.4% (PCP) 0% (Referral)	31/46, p-value 0.2334	MET