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Evidence-based Toolkit for Reduction of Overdose Risk in Primary Care Patients on Opioid Therapy

Katelin A. Aris
Grand Valley State University

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Katelin A. Aris

Kirkhof College of Nursing

Grand Valley State University

Advisor: Dr. Tricia Thomas, PhD, RN, FAAN, FNAP, NEA-BC, ACNS-BC, CNL

Advisory Team: Caroline Ring, DNP, RN and Dr. Karen Burritt, PhD, RN, FNP-BC

Abstract

Introduction: Opioids are powerful pain killing medications that can be highly addictive and can cause risk for overdose and even death (Michigan Prescription Drug and Opioid Task Force, 2015). Many primary care providers treat patients with acute and chronic pain, although it is recognized that many receive inadequate training in pain management and feel unprepared in the complexities of caring for these patients (Becker, Bair, Picchioni, Starrels, and Frank, 2018). To treat these patients safely, provider education and adherence to guidelines put forward by these initiatives is essential. **Methods**: An evidence-based prescribing toolkit was devised using guidance from the literature and was presented to prescribers in two northern Michigan primary care offices. The goal was to increase provider comfort level with opioid prescribing in primary care, as well as to increase adherence to organizational policy, using several metrics. Discussion, survey, and chart audits were used for evaluation. **Results:** Compliance with the Opioid Start Talking Documentation and Medication Contract use increased post implementation ($p < 0.05$, ; $x^2=3.95$, $p<0.05$). Total morphine milliequivalents decreased from a mean of 42mmEQ/day to a 37mmEQ/day, which provided clinical relevance but was not statistically significant ($S=757$, $p > 0.05$). In addition, benzodiazepine co-prescription rates did not statistically differ pre- and post-implementation ($p >0.05$). Provider comfort level increased slightly but was not significant. **Conclusion:** The evidence-based toolkit was effective at increasing organizational adherence but not provider comfort level. Reduction of morphine milliequivalents and co-prescribing are promising concepts that will likely improve over time.

Keywords: opioid, opioid guidelines, risk reduction, primary care

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Introduction and Background

Appriss Health (2018) indicates more than 7.8 million patients received over 103 million opioid prescriptions over the course of a five-year data review in Michigan, resulting in over 5,000 patient deaths attributed to opioid prescriptions. According to the Michigan Prescription Drug and Opioid Task Force (2015), the increased availability of prescription drugs along with misconceptions around safety of prescribed medications has led to an exponential growth of prescription drug users and mis-users. Further, drug overdose deaths have tripled since 1999, with the majority being related to prescription drugs (Trust for America's Health, 2015; as cited in Snyder & Calley, 2015). The state of Michigan is ranked 7th in the nation for opioid prescriptions and there was a 30% increase in overdose deaths from 2013 to 2015 (Appriss Health, 2018).

This problem is significant because of considerations of the legitimate needs of patients who require pain medication and the indistinct difference between safe and unsafe opioid prescribing. Chronic pain remains a significant issue for millions of Americans and attempts to reform opioid prescribing must have consideration for patients on existing opioid therapy and those that have future needs for pain medication (Snyder & Calley, 2015). However, there must be consideration of how to safely prescribe opioid pain medications through use of evidence-based guidelines that can help guide prescribing habits, regardless of whether the therapy is for patients with acute or chronic pain conditions.

The 2015 State of the State Address by Michigan governor Rick Snyder called for a comprehensive plan to address prescription drug and opioid abuse in Michigan (Snyder &

Calley, 2015). Since this publishing, there have been varied attempts at reducing risk related to opioid prescribing and additionally promoting use of tools in health care to reduce opioid overdose rates. At the site for the project implementation, there were wide variations of practice between providers in the prescribing and managing of pain with opioid therapies. With development of an evidence-based toolkit, opioid prescribers have these tools at their fingertips to safely and effectively prescribe for high risk patients. There also created the opportunity to provide patient education that is recognized by the Centers for Disease Control and other top agencies as a priority in this epidemic. The purpose of this paper is to describe an evidence-based improvement in two rural northern Michigan primary care offices, within the realm of safe opioid prescribing.

Evidence-Based Literature Review

A literature review is important and was conducted to identify familiarity with available evidence on a topic. With a thorough review of the literature, it was determined how to aggregate best evidence for translation and application in practice. The purpose of the literature review was to synthesize the opioid prescribing best practice literature to generate a toolkit and guidelines for implementation in primary care practices in rural northern Michigan.

Methods and PRISMA

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline served as the framework for this review (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009). A comprehensive electronic search was conducted in the CINAHL and PubMed databases and was limited to reviews in the English language during the period of 2008 to 2018. Keywords included opioid, opioid guidelines, risk reduction, and primary care. Similar

search terms were used by application of Boolean operators (OR, AND) to both broaden the search and include all relevant articles (see Appendix A).

For the purposes of the literature review, studies were identified if they pertained to physicians. Any patient outcome data was included for patients 18 and older. The studies centered on opioid prescribing and excluded other pain management strategies. Samples were limited to applicability in primary care and other specialties were excluded. Studies pertaining to palliative care, cancer and pediatrics/neonates were excluded.

For the intervention studies, an evidence-based opioid prescribing guideline had to be implemented in a primary care setting. Outcome data related to the prescriber and/or patient had to be generated to be included in the analysis, with the intended goal being identification of whether implementation of the prescribing guideline was effective. Included were outcomes on either the primary care provider's adherence to the guideline or patient outcomes related to application of the guideline in primary care practice. Also included was identification of the effectiveness of education to promote the evidence-based guideline for prescribers in primary care. A systematic review and quality initiative study were included to facilitate a well-rounded approach to the literature review.

The search yielded 180 CINHAL reviews. One duplicate was found and eliminated from the retrieved articles. Each article was screened using inclusion and exclusion criteria according to PRISMA criteria (Moher et al., 2009). Review of titles and abstracts resulted in removal of 137 articles that did not meet the inclusion criteria. The remaining 43 articles were reviewed for an in-depth examination of content, and all but six were excluded because they did not meet inclusion criteria. The remaining six articles were included in this review (see Appendix B).

Six CIHAHL and PubMed reviews met the inclusion criteria and are included. Three studies were randomized controlled trials, one was a systematic review, one was quasi-experimental, and the final study included was a quality intervention. All studies included patient outcome data related to quality and safety of opioid use following provider education intervention or related to primary care provider outcomes. The quality intervention looked at implementation of the Centers for Disease Control (CDC) 2016 guidelines for chronic pain management and opioid prescribing.

All articles evaluated primary care prescribers who treat chronic pain with opioids. The target was prescribers rather than patients, although some studies did put limitations around the patient population being treated. For instance, all patients included in the prescriber's panel needed to be older than the age of 18 and needed to be undergoing opioid pain management for non-cancer, non-palliative care pain. The focus was related to outcomes generated by changes in prescriber habits and did not account for patient characteristics, such as duration of opioid pain medication use, overdose risk, diagnoses specific criteria, specific age or gender or co-morbidities.

All samples looked to identify implementation of a strategy to increase provider knowledge and adherence for safer opioid prescribing techniques. Quanbeck et al. (2018) used a variety of implementation strategies and a framework to put forward evidence prescribing information to their providers. This study utilized audit and feedback, academic detailing and external facilitation as methods to deliver the information to the prescriber. This study compares four intervention clinics to four control clinics in a randomized matched pairs design (Quanbeck et al., 2018). McCracken et al. (2012) utilized two different training experiences for comparison to educate prescribers on opioid guidelines for chronic pain. One training looked to increase

psychological flexibility and the other included training in practical knowledge and skills related to pain management. Liebschutz et al. (2017) compared nurse care management, an electronic registry, one-on-one academic detailing, and electronic decision tools for better adherence to prescriber opioid prescribing.

Gaiennie and Dols (2018) utilized an information fair, training sessions, several quality meetings and one-on-one information sessions to increase provider knowledge and adherence. Finally, Von Korff et al. (2016) utilized statewide change education versus that of statewide and group practice change education to impact provider prescribing knowledge.

There were various measures used in the samples reviewed. McCracken et al. (2012) looked at provider prescribing practices, concerns about analgesic prescription, general well-being, the Acceptance and Action Questionnaire, the Mindful Attention Awareness Scale, and a test of opioid knowledge. The providers completed the instruments, including surveys, tools, and questionnaires and were again given these instruments pre-and post-intervention.

Several of the other samples looked at patient characteristics to account for the measures. Liebschutz et al. (2017) utilized documentation of guideline concordant care using patient provider agreement in the electronic health record (EHR), opioid refills and at least one urine drug test in the corresponding twelve months' post intervention. Quanbeck et al. (2018) utilized several measures for outcome data, including overall opioid prescribing rates, average morphine-equivalent daily dose for patients on long term therapy, rates of use of treatment agreements, urine drug testing and opioid/benzodiazepine co-prescribing. These factors were evaluated at both six and twelve months. Von Korff et al. (2016) utilized opioid days and total opioid equivalency for pre-and post-measurements following intervention. Finally, Gaienne and Dols

(2018) utilized number of opioid prescriptions and referral to pain management as outcome measures.

Tournebize et al. (2015) used a systematic review of current evidence to identify whether physicians in primary care are using safe approaches for prescribing opioids for chronic pain. Each guideline was reviewed for risk associated with opioid analgesics, initial medical evaluation, risk mitigation tools such as written treatment agreements, drug screening tests, dose limits of opioid analgesics, periodic medical evaluation, opioid formulation and drug to drug interactions.

Summary of Results and Evidence for Project

Five sources reported the outcome measures as improvement in provider knowledge and adherence to guidelines and therefore positively influenced prescriber habits. Quanbeck et al. (2018) identified cost savings with implementation of targeted education of over $7000. At a year post implementation, there was a statistically significant reduction in morphine-equivalent daily dose observed compared to the control. There was an increase in adherence to recommended urine drug testing, use of treatment agreements, and opioid-benzodiazepine co-prescribing rates (Quanbeck et al., 2018). McCracken et al. (2016) did not find a statistically significant change in provider prescribing habits following training but did find that there was an increase in intention to use prescribing methods as well as increase in provider well-being.

Liebschutz et al. (2017) identified a successful intervention related to reduction of total opioid prescriptions and a 10% reduction in daily morphine-equivalent daily dosing. In one sample, there was a 7% increase in patients referred to pain management and a 10% overall reduction in number of opioid prescriptions (Gaiennie and Dols, 2018). In a systematic review, it was identified that over 70% of physicians do adhere to opioid risk reduction strategies. There

are opportunities regarding more regular assessment and re-assessment of pain scores as well as with utilization of screening. Further, there is an opportunity to reduce risk of prescribing fentanyl patches to opioid naive patients (Tournebize et al., 2015).

All articles examined in the literature review provide evidence for the proposed project. The five articles concisely demonstrate the abilities for the DNP student to apply principles of the literature review to the project. All articles provided relevance for evidence to be used to guide the implementation of this project.

Organizational Assessment

An organizational assessment (OA) is a process for obtaining valid and useful information on the factors that affect the performance, culture, capacity and motivation of a specific organization (Lusthaus, Adrien, Anderson, Carden & Montalvan, 2002). Understanding baseline performance before enacting change creates the ability to recognize the patterns, linkages and philosophies of the organization for the change to be successful.

Burke and Litwin Model

The Causal Model of Organization Performance and Change, otherwise known as the Burke & Litwin Model, uses several key principles to suggest how an organization may be affected by a change (see Appendix C). According to Burke and Litwin (1992), change must be well strategized to fit an organization before it can be successful. Change comes with a significant impact on many factors that influence an organization, including strategy, leadership and culture (Burke and Litwin, 1992). The model is an important initial step conducted in the DNP student project.

Burke and Litwin first discus transformational factors, which are initially examined with relevance to the DNP project. The transformational dynamics of the model are defined as the

areas of an organization "in which alteration is likely caused by interaction with environmental forces (both within and without) and will require entirely new behavior sets from organizational members" (Burke and Litwin, 1992, p. 529). This encompasses the external environment, organizational culture, mission and strategy, individual and organizational performance and leadership (Burke and Litwin, 1992).

Burke and Litwin (1992) indicate any outside condition or situation that influences the performance of an organization is referred to in the model as the external environment. This is how things like governmental circumstances or political influences are endured by an organization. While there are many external factors that are relevant in healthcare, the most pivotal changes have recently been deployed by the state of Michigan in a legislative overhaul of opioid prescribing. Appriss Health (2018) did a statewide opioid assessment to understand the current state in Michigan regarding overdose data. The need for increased awareness and attention to opioid prescribing led to several pivotal legislations, including mandated use of prescription monitoring systems and limitations on the number of days written for acute pain (Cavitt, 2017). There are also local endeavors to combat the opioid crisis, including community efforts to increase awareness and knowledge of addiction, treatment for opioid use disorder and disposal of medications in a safe and effective way.

Culture is defined by Burke and Litwin (1992) as the collection of overt rules and values that guide organizational behavior. This is specific to the values and customs of the organization and provides a sense of meaning to the members of the organization. These statements provide meaning to be a member within the organization and include the concepts of "own it, patient impact, resources and relationships, high performance, one team, and financial health" (XXI, 2018). Additionally, the larger organization has a set of values that are shared by all the

organization, and these include the values of integrity, respect, teamwork, excellence, compassion and accountability (XXII, 2018).

The culture of the primary care practice is also in support of the lived values of the organization, both on a macro and micro level. The practice has adopted a primary care process that includes a concept called "Kaizen Culture" in which the employees are able to bring forth change from all levels. The goal is engagement from all staff and encouragement for change by communication in a way that reduces confusion and allows for collaboration on behalf of the practice.

According to Burke and Litwin (1992), leadership encompasses the overall organizational direction and serves as the role model for all employees. Not only is leadership evaluated as necessary and valued commodity, but it also includes the evaluation and perceptions of followers when it comes to executive practices and values (Burke and Litwin, 1992). The practice has a chain of command system that serves as a way of problem solving and raising concerns. The larger organization holds office to a president, followed by an organizational structure that leads down to the micro level. The practice has a director, manager and newly appointed supervisor. All three of these roles are shared among other primary care offices in the area. These leaders strive to embody the values of the organization and provide timely and appropriate decision making and problem solving that helps the practice with day to day operations.

Mission and strategy are defined as what the organization's top management believes is the forward-thinking approach that is central to the organization's success, including how the organization intends to achieve purpose over time (Burke and Litwin, 1992). As indicated previously, the primary care practice functions under an umbrella of leadership that includes a

larger organization, whose mission is to improve the health of the communities that are served (XXIII, 2018). There are several key initiatives that are aimed at this goal, including a recent large-scale change of the EHR and overall strategic goal to improve the organization's approach to patient care, with a "one patient story" approach.

The outcome or result as an indicator of effort and achievement allows for understanding of the individual and organizational performance of an organization (Burke and Litwin, 1992). This includes productivity, customer satisfaction, profits and quality of an organization. The primary care practice strives to identify and utilize these factors and utilizes a team of specialists that are devoted to using data productively.

Next, Burke and Litwin (1992) identify transactional factors, which are combined with transformational factors that allow for recognition of the way an organization thinks about a change. According to Burke and Litwin (1992), transactional factors are defined as the primary way of alteration that affects people and groups. Included in transactional factors are management practices, policies and procedures, structure, work unit climate, tasks and individual skills, motivation, individual needs and values and individual and organizational performance (Burke and Litwin, 1992). Each of these factors is described in greater detail in the following paragraphs.

Burke and Litwin (1992) identify management practices as the way leaders use human and material resources to carry out to the organization's strategy. This is carried out at the practice using the Kaizen culture that was introduced earlier. There is a process where employees are able to put forward a problem using a process improvement method of 'golden tickets' which can be a way to encourage staff to identify an innovative approach to tasks and projects to improve the healthcare delivery at the practice. Additionally, there is a concept called the clinical

practice model, or CPM, that allows for employee led change. There are monthly meetings where staff lead a group of fellow peers, with oversight by the supervisor or manager, and changes are promoted and enacted. The influences of peers on change can be an important structure for staff to feel comfortable.

The structure is the arrangement of people into specific areas to carry out the functions and responsibilities of an organization, including decision making authority, communication and relationships (Burke and Litwin, 1992). Good communication by leadership to employees is the key to assure effective implementation of strategies to align with the organization's mission. While the providers are ultimately responsible for the care of the patient regarding opioid prescribing and pain management, the medical assistant and registered nurse communicate and assess patients on a routine basis. Therefore, their understanding of the legislation around the pain management initiatives is important, as well as their closed loop communication with the provider.

Standardized policies are seen by Burke and Litwin (1992) as the mechanisms that facilitate the work in the organization and controls systems such as performance appraisal, goal and budget development and human resource allocation. There are many different policies and procedures that guide pain management at the organization. These are the driving force for how staff care for patients who present with pain complaints. The policies and procedures are informed by the accrediting body, The Joint Commission, as well as driven by organizational management to align with the key strategies of the organization.

A collective set of current impressions, expectations and feelings that staff members have that affect their relationships with one another, their leader and other practices is known as climate (Burke and Litwin, 1992). The climate within the primary care office is positive. There

are ways to promote change and for employees to have their voices heard. The CPM group, as mentioned previously is a way for culture to be promoted through staff-led change.

Motivation is thought to be aroused by behavioral tendencies with movement toward goals, taking needed action and persistence until satisfaction is attained (Burke and Litwin, 1992). Burke and Litwin (1992) indicate there are many attributes rolled into this phenomenon, including the energy that is generated by the sum of achievement, power, affection, discovery and other human motives. This is the driving force for employees in their work environment and urges their ability or inability to get things done in the work place. The staff are goal oriented and motivated by their daily work. This is evidenced by their vigor and attention to the recent opioid legislation change and adoption of standard work.

Required behaviors for certain tasks, including specific skills and knowledge required of people is described by Burke and Litwin as the skills necessary to possess to accomplish the work for which a person has been assigned (1992). Staff members take their roles very seriously, and practice with the best of their ability to attain the values of the organization. Some of the staff are licensed for their role, including providers and registered nurses. Medical assistants are certified, non-licensed personnel but must adhere to the job description and complete various competencies to demonstrate abilities pertinent to the functions of the role.

Psychological factors that provide desire and worth is known by Burke and Litwin as individual needs and values (1992). This creates job satisfaction and generates the work-related needs and values of an organization. The need to understand differences among people's needs and values is important, and recognition is a vital part of what makes the organization successful in recruitment and retention.

Burke and Litwin (1992) identify individual and organizational performance as the outcome or result at the organizational level. This is a way to identify productivity, customer satisfaction, profit and quality.

Strengths, Weaknesses, Opportunities and Threats (SWOT)

The identification of the strengths, weaknesses, opportunities and threats (SWOT) provides a platform for the project planning (Moran, Burson and Conrad, 2017). The purpose of a SWOT analysis is to identify key areas in contingency planning, help to identify trigger points and provide data for a gap analysis. According to Moran et al. (2017), the SWOT analysis looks at both the internal and external attributes and threats to the phenomenon (see Appendix D).

The site for implementation had many strengths. The primary strength is that there is engagement at the leadership level from the supervisor, manager, director and up through the chain of command. The onsite manager and supervisor have an open-door policy and allow time for staff to bring questions and concerns. There is low provider and staff turnover in the office, which allows for consistent practice over time. There are also consistent provider/medical assistant relationships. There are also golden tickets, clinical practice councils and a high attendance monthly staff meeting.

Rural health is plagued by long distances for patients to travel, as well as fewer providers per capita than in urban communities (Rural Health Information Hub, 2018). Unfortunately, this is the case in the counties in and immediately surrounding the clinic. Each provider has a high panel load, which creates challenges for patients to access their primary care provider. Appointment times are short, producing additional challenges to cover the items a patient may wish or need to discuss. Additionally, there are many other mandatory screening tools used due to various other projects and initiatives aimed at quality and safety, which takes time during the

visit. Finally, there have been system wide changes with the EHR, so there has been a myriad of change in recent times. This can lead to burnout staff and providers.

Consumer demographics in the area make the opportunity to impact health on a big scale more important. The counties surrounding the clinic have high opioid prescribing rates and statistics indicate at least one patient per month presents to the area emergency departments for overdose (XXIV). There have been recent state policy changes in the state of Michigan regarding opioid prescribing. To match this, the system is producing a policy that will provide guidance and oversite for prescribing and will be adopted based on the recent state and national legislation. Finally, the clinics are part of a larger organization that help to move initiatives along and provide a good climate for change.

Pain management has always been a topic of discussion with patient satisfaction. This provides a threat, given patient satisfaction scores for pain management have an opportunity to decline with new changes in prescribing. Patients who are on long-term regimens for pain management are less likely to feel empowerment with changes to their dosing and care plan if it has been "working for them." As mentioned previously, there are legitimate pain concerns to consider for patients presenting with painful conditions. According to the Rural Health Information Hub (2018), there are limitations in health literacy in rural communities, which is likely evident within the surrounding counties and during the clinical rotations at the site by the DNP student.

Stakeholders

There is significance in inclusion of key stakeholders for any change, as the stakeholders are those who are most affected by the change. Key attributes of successful interventions are the perception of key stakeholders, including how well the project is presented (Greenhalgh, Robert,

Macfarlane, Bate, Kyriakidou, 2004). This was investigated prior to enacting the project. A letter of support was provided for the DNP student to enact the project at the site prior to the student attending the site (see Appendix E).

Key stakeholders for this project included the providers prescribing and assessing patients in primary care, the medical assistants and registered nurses who interact with the patients both in the office and on the phone, as well as office leadership (supervisor, manager, director). Additionally, guidance from the pain management clinical nurse specialist, and key mentors for the project serve as stakeholders. Patients also serve as a stakeholder in the project. Finally, there are several key mentors guiding this work, including several physicians, professors and additional site resources.

Phenomenon Conceptual Models

Chronic Care Model

A phenomenon conceptual model served as a guide for the project. The Chronic Care Model is one that can be applied to the project, as it is an organizational approach to caring for people with chronic disease in the primary care setting (Improving Chronic Illness Care, 2018). According to Moore et al. (2016), successful organizational improvement processes depend on application of metrics that are reliable as a goal to set targets and to monitor progress for the intervention. It has been demonstrated that improvement in the management of guidelines for pain can have better adherence when guided by an implementation model (Dorflinger, Moore, Goulet, Becker, Heapy, Sellinger & Kerns, 2014; Moore et al., 2016;). This model applies because of the need for patient preference and needs, improvement in available clinical information for providers and developing a safe healthcare culture both inside the facility as well

as in the community (Levenson, 2017). There are six key aspects of this model, better explained below (see Appendix F).

Community resources. The goal of the community resources aspect of the Chronic Care Model is to mobilize community resources to keep chronically ill patients supported, involved and active (Improving Chronic Illness Care, 2018). There is encouragement for patients to participate in community programs, form partnerships with organizations to support and develop interventions that fill gaps in needed services and advocate for policies that improve patient care.

The healthcare system. The goal of the healthcare system concept within the Chronic Care Model is to create a process that provides safe, high quality care. The healthcare system works to support improvement at all levels of the organization and promote effective improvement strategies aimed at comprehensives system change (Improving Chronic Illness Care, 2018). The healthcare system encourages incentives based on quality of care and identifies and engages agreements to facilitate care coordination within and across the organization (Improving Chronic Illness Care, 2018).

Patient self-management. Patient engagement is a large part of the Chronic Care Model as is important for prevention and detection, management of the disease by the provider and self-management by the patient (Levenson, 2017). There is importance in this aspect of the model to empower and prepare patients to manage their health care delivery, set goals, identify barriers and challenges and to monitor their own conditions. There are support strategies involving the provider, that include assessment, goal setting with the patient, action planning, problem solving and follow up (Improving Chronic Illness Care, 2018).

Delivery system design. According to Improving Chronic Illness Care (2018), the decision support initiative within the Chronic Care Model is to assure effective, efficient care

and self-management support. This helps to define roles and distribute tasks among team members, use planned interactions to support evidence-based care, ensure regular follow-up by the healthcare team and give care to patients that is both holistic and culturally competent (Improving Chronic Illness Care, 2018). The site for implementation reports through a structure of governance for delivery system design and are supported in this way.

Decision support. To promote care consistent with data and patient preferences, clinicians must have convenient access to the latest, evidence-based guidelines for care of patients with chronic pain. There should be continued educational outreach to prescribers that reinforces utilization of these standards (Improving Chronic Illness Care, 2018). The goal is to embed evidence-based guidelines into daily clinical practice, share guidelines and information with patients and encourage their participation, and integrate specialist expertise to educate prescribers effectively.

Clinical information. Finally, the concept of clinical information systems is to organize data to facilitate efficient and effective care. Healthcare systems harness technology to provide clinicians with information they need at the point of care, to give the most necessary and important information possible. These allows for evidence-based guidelines to be embedded into daily clinical practice, with timely reminders, identification of specific populations of patients for proactive care, facilitation of individual care planning, and monitoring the performance of a care team (Improving Chronic Illness Care, 2018).

Kotter's Eight Step Change Model for Leading Change

John Kotter (1996) developed an 8-step Model of Change, which was created utilizing research of over 100 organizations going through organizational change (Kotter, 2018). The steps in the model allow for clearly defined steps to managing large scale change in the

organization and assist with the transition through varied points of challenge that come with change management. The eight steps to change are outlined in the following section and applied to the DNP project (see Appendix G).

The goal of the first step in Kotter's model is to help others see the need for change, through creation of a sense of urgency, which can be a powerful tool for change management (Kotter, 1996). This is done through involvement and support of the key stakeholders and customers on the issue of the change, as well as in honest dialogue and discussion that makes people think about the prevalence of the issue, as well as convincing argument to why the change is necessary. Finally, this step can be accomplished by examining the potential threats that may come up through implementation of change (Management Study Guide, 2018).

The second step in Kotter's 8-Step Model includes identification of effective people for the proposed change, who can help guide, coordinate and communicate change activities (Management Study Guide, 2018). Kotter identifies the third step as identification of how the future will be different from the past and how the change initiative may make the future a reality through interventions linked to the vision. Communication is a key during processes creating change. It is critical that the vision is powerfully and convincingly managed. This vision should connect with all crucial aspects like performance, training and the project steps themselves (Kotter, 1996).

Removal of barriers is an essential part of processes enacting large scale change. Inefficient processes and hierarchies can provide barriers to projects and removing these can assist with forward motion of the project (Kotter, 1996). The DNP student worked to understand and identify barriers to assist in barrier removal.

According to Kotter (1996), wins should be recognized, collected and communicated early and often both to track progress and to energize participants through the stages of the project. Short-term wins along the way should be numerous and attempt to create forward traction in the provider buy in for the work. Following the first success, Kotter suggests increasing the pace to press harder (1996). This will increase credibility to improve systems, structures and policies. Until the vision is reality, change after change should be accelerated. In the final stage, instituting change, Kotter states there should be articulation between the new behaviors and organizational success, ensuring there are strong enough connections for the new behaviors to push out old habits (2016). This is the final state of Kotter's model and accounts for the learned behaviors that become new practice.

Clinical Practice Question

At the organization, there were wide variation of practices between providers in the prescribing and managing of opioid therapies. The toolkit approach has been taken by the Centers for Disease Control and Prevention for other topics related to pain control in a way to help reduce rates of overdose. Currently, there are many toolkits published that provide access to relevant prescribing information for providers but there is not a toolkit available that bundles relevant evidence-based practices to all essential elements of the proposed project in a consistent, concise way that can be of benefit specific to primary care providers. The goal of this evidence-based opioid prescribing implementation was to provide information to prescribers in primary care to reduce risk of overdose in patients on opioid therapy. Toolkits have been used to assist in change management in a variety of ways and provide guidance and evidence to team members (Clancy, 2013). The toolkit includes the expected actions of each of the team members, establishes role accountability, documentation and monitoring. Each of these factors supports

team effectiveness and use of evidence-based guidelines to help deliver care. Accordingly, an evidence-based project to answer the following practice question is proposed: Does implementation of opioid guidelines increase provider awareness of opioid prescribing best practice, reduce risk of unintentional overdose and increase adherence to organizational policy?

Project Plan

Purpose of Project and Objectives

The overarching goal of the project was to assist primary care providers in their care of patients on opioid therapy, for acute or chronic pain management. This project aimed to assist with provider education of the new Michigan Legislation changes regarding opioid prescribing, worked to help reduce risk of overdose in high risk patients and had a goal of assisting in identification of ideal candidates for naloxone prescription. It also looked to delineate expected prescribing practices and processes supported by the clinical team member roles and documentation support.

The toolkit was aimed at allowing providers to have a concise set of standards that follows both national and Michigan laws and adheres to the policies set forth by the organization. The project was one that was deeply desired by the organization and will provide value in aligning with their key objectives of “healing the whole person.” The toolkit contents were driven by a new guideline put forward by the organization as well as evidence outlined by the several different national prescribing guidelines that are highly recognized by the organization.

The goal objectives for measure included increases in provider awareness and comfort with adherence to opioid laws and policies, increased adherence to organizational policy (utilization of contracts and Michigan Start Talking Document), reductions in total morphine milliequivalents in patients on opioids, higher rates of naloxone co-prescription, and reduction in

patients with commitment benzodiazepine and opioid prescriptions and finally. As a separate tier to the work, an informatics initiative was requested for easier identification of high-risk patients and ease of ordering naloxone, when suggested. Each of the objectives were measured and assessed pre- and post-implementation of the toolkit.

Design for the Evidence-based Initiative

The design for this evidence-based initiative was a quality improvement project and translation of evidence into practice. A quality improvement project consists of a systematic action that leads to measureable improvement in health care services for a targeted group (U.S. Department of Health and Human Services Health Resources and Services Administration [HRSA], 2011). The Institute of Medicine, a recognized leader of improving the nation's healthcare, defines quality in health care as "correlation between the level of improved health services and the desired health outcomes of individuals and populations" (HRSA, 2011, p. 1).

Setting and Participants

The setting for this project was two small primary care locations in rural northern Michigan. The services provided at the primary care offices includes health and wellness visits, prevention, sick visits and chronic care for patients across the continuum, from birth to geriatrics. These clinics provide care in the Northern counties of Michigan, connected to a larger organization and strives to create parity in healthcare access for rural county populations. The highest volume diagnoses in the primary care clinics are diabetes and hypertension. Joint/limb pain and neck/back pain are within the top four diagnoses. Between both clinics, there are eight providers, including three physicians, two nurse practitioners and three physician assistants. Additionally, there are ten medical assistants, one triage phone nurse and the number of patient visits per year is approximately 28,000. The DNP student sought and obtained administrative

approval to conduct the project at these sites, including support from office director, manager and the medical director for both sites. The executive approval came from the chief nurse of the overseeing affiliated hospital and was supported by administration at the site.

The target population included provider prescribers at the site, as well as medical assistants and registered nurses who provide care to patients. While the toolkit is aimed at assisting with habits of opioid prescribers, it was also utilized by front line staff who interact with patients and who were expected to also adhere to state law and office policy related to documentation. Front desk and clerical staff were excluded from the initiative. Only clinical staff were included in the intervention.

Ethics and Protection of Human Subjects

An application for review and approval for the project was submitted to the XXX Institutional Review Board (IRB) as well as the Grand Valley State University (GVSU) IRB (see Appendices H and I). The purpose and scope of this project was limited to evidence-based practice improvement or quality improvement. No intended physical, social, psychological, legal, or economic threats to patients were associated with this project. As such, it was anticipated that the impact of the project will pose minimal or no risk to participants. All members of the team have completed human subjects' protection training via the Collaborative Institute Training Initiative and their interactions with patients will be guided accordingly. The DNP student has also signed all forms required by the site to maintain confidentiality and to uphold requirements requested by the site.

The DNP student recognized the need for additional data permissions that were sought and obtained during the project. The data review was challenging in terms of discrete data details for reports to pull reports desired by the organization and student for analysis. Therefore, the

DNP student sent an email to the site's IRB to obtain additional data permissions for the project (see Appendix J). This was granted and discussed with the site mentor, GVSU mentor and the quality lead for the project site.

Data Collection Procedures and Management

The DNP Student did the primary data collection for the project and utilized assistance from a data analyst at the site. The data elements collected were primarily associated with the project variables and were carefully selected to provide relevance to the project (see Appendix K). While the goal of data analysis was to be completed prior to the rollout of the toolkit, additional IRB permissions were needed and delayed access to data. Therefore, the data was collected from the EHR following the implementation of the toolkit, with retrospective review. Data was again collected at the cessation of one month's time, post implementation. The sample size of data included a total of 61 patients for review for the retrospective review and a total of 20 after a month's time. The site provided very explicit guidelines regarding use of data and therefore, all EHR data utilized the processes enacted by the site for both privacy and confidentiality.

A data collection tool utilized to understand provider prescribing awareness and comfort level pre- and post intervention. This data was gathered prior to enacting the toolkit and was provided after implementation. The survey used a Likert style format, with ratings from 1 (strongly disagree) to 5 (strongly agree). See a sample in Appendix L.

Guided by evidence from the literature and site stakeholders and experts, the survey tool was created utilizing questions geared to reduce time spent completing the survey while still capturing the most critical data elements. There was no need to obtain copyright for this uniquely created tool. The goal was to identify whether providers felt comfortable about opioid

prescribing and had awareness of the state and legislative changes in opioid prescribing practice. This was assessed pre-implementation and post-implementation.

The organization had very specific data collection and management policies, and it was the student's responsibility to follow procedures explicitly. The data was collected by the data analyst for the site. This was completed by running a report for patients from the EHR. Once the report was generated, the data analyst placed this information on a secure, password secured m: drive that will be also secured using password encryption. The data was then evaluated and organized by the student.

The data variables that were relevant to the project were reviewed in the EHR, de-identified by the DNP student and provided to the statistician for review. There was no ability to identify any patients or providers. The only person with access to the data for the project were the data analyst and the DNP student. All other parties, including the site mentor and faculty did not have accessibility by any means. Following the cessation of the project, all data was destroyed.

Steps for Implementation

The following steps outline the DNP student's activities used to complete this quality improvement work (see Appendix M for timeline).

1). Create Urgency

- Completed the literature review and organizational assessment to understand current state of the problem and the organization's unique needs.
- Presented the topic across various forums to gain support and traction about the need for the work.

2. Formed a coalition prior to implementation.

- Met with the medical director to discuss the project's anticipated direction and evidence for the project. The medical director is a local addiction specialist and is assisting in providing the foundational approach for the go live.
- Met with the site's executive leadership and guiding members, including the pain management CNS, site director and director of operations to establish the content for the toolkit.
- Attended clinical practice steering meetings
- Cultivation of relationships with provider and medical assistant staff members.

3). Created a vision for change with creation of the toolkit, using the following as a guide.

- Evidence-based guidelines
- Organizational policy
- Requests by site leadership and provider staff

4). Communication of the vision through education and information around the toolkit to all involved.

- Presentations
- Emails
- 1:1 discussion and education sessions
    - This included education around the evidence from the literature and the toolkit itself.

5). Empowered action: go-live with the evidence-based toolkit.

- Provided weekly rounding times for updates and discussion
- Provided additional support and tools as needed.

6). Create quick wins

- Creation and embedding a best practice advisory for morphine mill-equivalency within the EHR. This required several presentations by the DNP student to the ambulatory informatics steering committee and required executive approval at this level.
- Several meetings took place to determine and understand the existing functionality of the EHR and the future upgrade regarding the informatics request.

7). Build on the change

- Weekly feedback to providers and staff
- Report provided on progress
- Discussion of key points and reinforcement of concepts.

8). Make it Stick

- Delivery of final report to leadership, prescribers and staff.
- Presented sustainability plan and next steps

Process Mapping/Timeline

Process mapping is a quality improvement tool commonly used to better understand the health care process within the practice system (HRSA, 2011). This provided a visual diagram of the sequence of events that result in an outcome. This was particularly helpful as the DNP student worked to objectively determine the timeline and outcomes for the project. Further, this was also used as a guide for the intervention. In primary care, there are many different interactions with the patient for opioid prescribing and the process map helps to clarify who has what role in the process. According to the HRSA (2011), this is a helpful tool to assist in creating change for quality improvement projects.

Project Evaluation and Measures

According to the HRSA (2011), data is the cornerstone of a quality improvement project. It is important to understand how well the current system supports the provider's workflow regarding patients who may be on opioid therapies. The goal of data collection was to separate what is thought to be happening with what is known based on data, as well as to establish a baseline for practice. It also reduces placement of ineffective solutions or those that do not address a tangible problem. Data collection helps with monitoring change and ensuring improvements were effective and sustained. Improvements can be identified using data when compared to baseline (HRSA, 2011). Data collection was through surveys and chart review in the EHR.

Each objective must be measurable as defined by the HRSA (2011). To assist with implementation, a pre-knowledge survey for opioid proscribing was developed and given to all available prescribers. The DNP student also attended goal setting education about opioids and prescribing, an initiative that the health system implemented in December 2018. This gathering of system-stakeholders and prescribers was strongly encouraged for providers to attend and provided additional direction for the project.

The toolkit was developed using an evidence-based approach and included information guided by best practice and literature. The organization had several resources that were most utilized when evidence-based information is desired, including the CDC references, UpToDate, the Lazarus Project and others. This was paired with the organization's guideline put in place to assist with opioid prescribing (see Appendix O). These resources proved to be the primary source of collection for information included in the toolkit. Several checklists were created to assist in provider, RN, and MA staff in adherence to the guidelines by the organization and state of Michigan for opioid prescribing and this was included in the toolkit (see Appendix S).

Additional resources in the toolkit provided increased awareness of responsibilities, expected documentation in the EHR, expected communication to patients, criteria for referrals to other providers, psychosocial support resources, screening recommendations and other clinical care interventions. Screenshots were provided for screening tools (see Appendix P). Finally, naloxone resources were provided with the CDC patient education materials (see Appendix Q).

Analysis Plan

The data was analyzed by the DNP student. The pre-implementation data was exploratory data and provided an understanding of current state practices at the site. Ultimately, this data was not readily available until after the proper permissions were granted through the IRB and was retrieved and reviewed after implementation of the project. Once available, the student compiled the chart review and presented results to key stakeholders.

The post-implementation data was again gathered by the student. This was then analyzed using suggested statistical methods for the data presented to the statistician. The DNP student collaborated with the GVSU statistician to determine the appropriate statistical methods and level of significance. Output for each of the measures was included and given to the student. This data was then displayed using graphs, tables and charts (see Appendices, as outlined in the results section of the paper).

Resources and Budget

The budget was important part of the DNP student project because of the need to enact a project that is sustainable and valued by the organization. Most of the costs for the project were donated by the DNP student, who served as the data collector and the project manager for the project (see Appendix Q). The time creating the educational plan and toolkit was calculated, and this included primarily the review of the literature and evidence-based recommendations, pulling

together the organization's desire opioid recommendations, printing materials and putting together the binders for presentation. The educational initiatives were varied, including email, and attendance with the providers one on one. There were several times that the DNP student needed to be at the project site for support around the implementation, totaling around six hours. The hours associated with the DNP student's time includes that at an RN rate (approximately $30 per hour).

The DNP student also donated printing and one binder for each provider to have in their own office for the intervention. Additionally, there was time required for the data analyst to pull and supply data to the DNP student for the project, as well as time spent by the statistician placing the information into a workable format. Average salaries were calculated using data from US Bureau of Labor Statistics in 2018. All monies are described in a table format in Appendix R.

According to Mack (2018), the overdose rate in Mecosta, Osceola and Lake counties was 10 patients in 2016. White et al. published an article in 2005 that indicated that for each overdose death, there were 33 related emergency department visits and 11 substance abuse treatment related admissions (Journal of Managed Care 2005). Additional sources indicate this information is still relevant. Therefore, most the revenue generation is targeting the average of ten overdose deaths and preventing those emergency department and substance abuse inpatient admissions.

Results

The evidence-based intervention took place in rural northern Michigan at two primary care sites. The current practices of opioid prescribing were assessed. The goal of the analysis was the determine how the evidence-based toolkit could be used to drive practice and to identify the variability among prescribing habits between various providers at the two sites. To do this, a report from the data analyst was generated following approval from the site's Institutional

Review Board (IRB). This report contained data over a year's period, calendar year 2018. The report included all opioid prescriptions generated out of each practice during that timeframe. Both short and long acting opioid medications were included in this report. The DNP student then did complete chart reviews to isolate the discrete data points to be reviewed for the project. During this analysis, it was assumed that the patient picked up their prescription and was taking the medication as prescribed.

Over the calendar year 2019, between the two practices there were 428 total opioid prescriptions generated. Each unique prescription was associated with a patient, although some of the data reflected more than one prescription to the same patient. Duplicates were removed, and methods were used to isolate the charts to be examined. These are discussed in more detail further in the results section. A manual EHR review of 26 charts (site A) and 39 charts (site B) were assessed at each site. Variables collected were age, gender, short acting opioid, long acting opioid, total daily morphine milliequivalents (mmEQ) prescribed, compliance with urine drug screen, presence of the Michigan Start Talking document and pain management contract, whether naloxone had been prescribed, presence or absence of a benzodiazepine at the time of opioid prescription, existing pain management referral, and whether there was a diagnosis related to opioid use or overdose. Finally, it was assessed whether there was use of screening tools to assist in assessment of patient function and goals. The data was reviewed to assist in description of the population of patients at the practices who were receiving opioid prescriptions.

Pre/Post Implementation Prescribing Characteristics

Site A: Pre-implementation. The data analyst was able to pull an entire year's worth of data, including duplicates. This entire data set was also analyzed for use patterns for pre-implementation data. At site A, the average age of patients receiving opioids was 56 years old

and there were ten female patients and twelve male patients. at site A, there were 48 total prescriptions for opioids in calendar year 2018. Of these, the primary medication prescribed was hydrocodone-acetaminophen 5-325mg, with a total of 32 prescriptions written. Hydrocodone-acetaminophen 10mg-325mg was prescribed eleven times, while hydrocodone-acetaminophen 7.5mg-325 and hydrocodone polistirex-chlorpheniramine was prescribed a total of three times. Of these 48 prescriptions, there was a total of 22 unique patients, with four patients receiving more than one prescription. These duplicates were removed for the analysis, leaving a total of 22 patient charts reviewed at site A.

Of these unique patients, fifteen had a prescription for hydrocodone-acetaminophen 5-325mg, three patients had a prescription written for hydrocodone-acetaminophen 10-325mg, 2 patients had been prescribed hydrocodone-acetaminophen 7.5-325mg, and two patients were prescribed the hydrocodone polistirex-chlorpheniramine. As hydrocodone-acetaminophen 5, 7.5 and 10mg doses are noted to be short acting medications, this was the primary type of medication prescribed, while hydrocodone polistirex chlorphenirmaine as the only long acting medication prescribed at site A. There were no instances where patients had both a long and short acting opioid prescribed.

Site A: Post-implementation. Post implementation at site A, there were a total of six prescriptions written from February 18-March 18, 2019. The average age of patients receiving opioids in the calendar month was 62. There were four male patients and two female patients. The primary medication prescribed was hydrocodone-acetaminophen 5-325mg, with a total of 4 prescriptions written. There was one prescription for a fentanyl patch (24mcg/24 hours) and one prescription written for hydrocodone-acetaminophen 7.5-325mg. These were all unique patients,

with no duplicates. There were no instances where patients had both a long and short acting opioid prescribed.

Site B: Pre-implementation. At site B, a total of 379 prescriptions were written for opioids in calendar year 2018. Of these, there were 142 prescriptions for hydrocodone-acetaminophen 10-325mg, 84 prescriptions for hydrocodone-acetaminophen 5-325mg, and 34 for hydrocodone-acetaminophen 7.5-325mg. Additionally, there were 31 prescriptions for methadone 10mg, 19 prescriptions for methadone 5mg and 17 prescriptions for morphine 60mg extended release. Other medications ordered included various formulations of both short and long acting oxycodone, oxycodone-acetaminophen, and morphine. There were two instances of fentanyl patch prescriptions and one prescription for codeine.

As there were many opioid prescriptions written at site B, a review of the first patient and then every 10th patient listed was performed to ensure randomization, and a total number of 39 patients were reviewed. There were 24 female patients and fifteen male patients. The only exception was one patient with cancer-related pain, who was excluded, and the next patient was picked from the report. None of the patients using every tenth patient were duplicate patient prescriptions. Of these patients, eighteen were prescribed hydrocodone-acetaminophen 10-325mg, eight were prescribed hydrocodone-acetaminophen 5-325mg, and five were prescribed hydrocodone-acetaminophen 7.5mg. Three patients were prescribed methadone 10mg, methadone 5mg and morphine 60mg extended release. There was one prescription for morphine 100mg extended release, oxycodone-acetaminophen 10mg, morphine 15mg, oxycodone 30mg immediate release, and a fentanyl patch (37.5mg/hr). There were six patients of the 39, or 15%, who had a prescription for both a long acting and short acting opioid medications. On the report, each of these six patients was coded to only one prescription but it was discovered on chart

review that an additional opioid was present on the current medication list, thus accounting for both a long and short acting preparation.

Site B: Post-implementation. Post implementation at site B, a total of 27 prescriptions were written from February 19-March 19. Of these, there were nine prescriptions written for hydrocodone-acetaminophen 5-325mg, four prescriptions written for hydrocodone-acetaminophen 10-325mg, oxycodone 15mg, and morphine 15mg. There were two prescriptions written for oxycodone 10mg, morphine 60mg and methadone 5mg. Of the 27 prescriptions, there were several duplicates. These were removed and the first chart listing per patient reviewed. On analysis, three patients were excluded due to cancer related pain. This left a total of fourteen patients included in review. The average age of those receiving opioids at site B was noted to be 58 years old. There were ten males and four females included in analysis.

Of these patients, eight received a prescription for hydrocodone-acetaminophen 5-325mg, three received a prescription for hydrocodone-acetaminophen 10-325mg, two received a prescription for methadone 5mg and one patient received a prescription for morphine 60mg extended release. There were no instances where patients were on both long and short acting opioids.

Pre/Post Morphine Milliequivalents

Site A pre/post implementation. An online calculator was utilized to assist in calculation of morphine milliequivalents, as this is not identified as a discrete data field in the electronic health record. Therefore, the total was calculated at the time of new prescription written and it was assumed that the patient was taking the medication as prescribed. For instance, if the prescription was written as 1-2 tablets, it was assumed that the patient was taking both

tablets. If it was written as every six or every eight hours, it was assumed the patient was taking as such.

Site A pre/post implementation. At site A, the pre-implementation total daily morphine milliequivalents was noted to be seventeen among the 22 patients on the report. There was only one patient above 50 mmEQ. Post implementation of the evidence-based toolkit, the average daily morphine milliequivalents was noted to be twenty-five among the six patients reviewed. Again, only one patient was noted to be above 50 mmEQ.

Site B pre/post implementation. At site B, the average daily morphine milliequivalents was noted to be 85mmEQ/day among the 39 patients reviewed in the pre-implementation data. There were fourteen total patients (36%) who were prescribed over 50 mmEQ/day and of these, ten patients were prescribed over 100mmEQ/day. Post implementation, the average daily morphine milliequivalents was noted to be 39mmEQ. Only two patients (14%) were prescribed greater than 50mmEQ/day, with only one of these patients over 100mmEQ/day.

Co-Prescribed Benzodiazepine

During chart review, the DNP student reviewed the patient's current medication list for evidence of a prescription for benzodiazepine concurrent to the opioid medication prescribed. This was noted regardless of name, strength, dose or indication. It was assumed with this review and presence of benzodiazepine on the patient's current medication list that the patient was taking the medication as prescribed.

Site A pre/post implementation. At site A, pre-implementation data showed that three out of 22 patients, or 14%, had a co-prescribed benzodiazepine concurrent to opioid prescription. Post-implementation data showed a total of 1/6 (17%) patients received a co-prescribed benzodiazepine.

Site B pre/post implementation. At site B, a total of fourteen patients out of 39, or 36%, had a co-prescribed benzodiazepine at the time of opioid prescription. Following implementation of the evidence-based toolkit, a total of 1/14, or 7%, patients had a co-prescribed a benzodiazepine.

Urine Drug Screen

During chart review of patients receiving prescriptions for opioids, presence or absence of urine drug screen within the last calendar year on file was reviewed to measure adherence to organizational policy. This drug screen had to be present and could have been ordered at any point during the duration of opioid therapy. The actual contents of the urine drug screen report were not reviewed.

Site A pre/post implementation. Pre-implementation data showed there was a total of twelve patients of the 22, or 55%, with a urine drug screen present. Post Implementation data revealed that all but one patient (5/6) had a urine drug screen present (83%).

Site B pre/post implementation. There was a total of 25/39 patients, or 64% of patients with a urine drug screen present in the pre-implementation data review. Post Implementation data showed a total of 5/14 patients, or 36% of patients with a urine drug screen present on chart review.

Medication Contract

Presence of a medication contract on file was another way to measure adherence to organizational policy. This was reviewed both pre- and post-implementation to identify presence or absence of the signed contract. This needed to be signed with the specific office, and not necessarily the provider prescribing as the contract is applicable to all prescribers at the office location.

Site A pre/post implementation. It was noted at site A, twenty patients out of 22, or 91%, had a medication contract on file. Following implementation of the evidence-based toolkit, all patients, or 100% had a medication contract on file.

Site B pre/post implementation. Pre-implementation data showed 53% of patients had a medication contract on file for the 39 patients reviewed. After implementation, all but two out of fourteen patients, or 88%, had a prescribing contract on file.

Opioid Start Talking Document

The state of Michigan implemented the Opioid Start Talking document to assist in ensuring educated conversations are happening between patients and prescribers when opioids are being issued. This was implemented in June of 2018 and is required for any patient receiving a new prescription for opioids from a prescriber they do not have a previous relationship with. For this measure, presence or absence of the opioid start talking document was identified. This had to be signed with association to the prescriber listed in the report. To note, some of the patients have long standing relationships with their prescriber and do not qualify under the need for this document and some of the pre-implementation data was captured prior to June 2018, which meant the providers would not have had this on file.

Site A pre/post implementation. For the Michigan Start Talking documentation, three patients out of 22 or 14% of patients had this conversation noted on file. Post implementation, of the six patients receiving opioids, two or 33% had a Michigan start talking form on file.

Site B pre/post implementation. At site B, two patients out of 39 or 5% had the conversation noted on file. After implementation, six patients out of fourteen, or 43% had this conversation on file.

Naloxone Co-Prescription

For both pre- and post-implementation data, it was noted on chart review whether the patient had been co-prescribed naloxone. This medication, which is the reversal for opioid overdose, has been recently promoted by the CDC if a patient meets high risk criteria, including total daily morphine milliequivalents over 50 seen as the suggested amount. Other risk factors increase the likelihood of accidental overdose and should be considered when identifying need for co-prescription, as well.

Site A pre/post implementation. There were no instances of co-prescribed naloxone pre- or post implementation. To note, at site A, only one patient was prescribed over 50mmeQ daily and would be considered as a suggested co-prescription, according to the CDC guidelines.

Site B pre/post implementation. At site B, there were no instances of co-prescribed naloxone pre-or post-implementation. Of the pre- implementation fourteen patients would qualify in the high-risk category suggesting co-prescription of naloxone, according to the CDC. Post-implementation, only two patients fell into this high-risk category.

Use of Screening Tools Available in Epic

Part of the implementation of the evidence-based toolkit was discussion around the documentation that should occur during the office visit to evaluate the patient's overall goals and function while prescribed opioids. There are several new tools the new EHR that make it easier for providers to do this assessment within the realm of prescribing. This was not well known or understood prior to implementation of the toolkit. Pre-implementation, it was expected that there would likely be no utilization of screening tools. Screenshots were provided within the toolkit and guidance was given in the opioid guideline on why these tools can be useful.

Post-implementation revealed no instances of these tools being utilized within the health record for the patients prescribed opioids at either site. This may be due to several factors, discussed later in the results section.

Pain Management Referral and Diagnosis Categories

Pain management referral and diagnosis categories was helpful in the retrospective chart review to see whether the prescriber had considered alternative or additional assistance in the patient's pain management. Current opioid overdose or diagnosis related conditions helped to clarify the patient's risk status, as the CDC indicates patients with history of opioid overdose are considered in the category of patients suggested to receive co-prescribed naloxone.

Pre/Post Provider Prescribing Comfort Level

Site A and B pre/post combined data. Regarding provider practices, there were a total of four providers who took the pre-comfort level survey at both sites and three providers returned this survey for 75% return rate. These were pooled due to the small amount of responses. This survey included a Likert scale to assist in determining a baseline of perceived knowledge of their own prescribing habits and comfort level around prescribing in general. For the analysis, the two sites were combined since the sample size of site A is small. A total of 35 points indicates the provider strongly agrees to all points listed. For the pre-implementation data, the average score was 28.75. The lowest ranked item was 'I feel confident in understanding the organization's policies for opioid prescribing.' The highest ranked item was an item that measured the provider's awareness of practice, which was 'most of my patients on opioids have at least one UDS per year,' and 'most of my patients are under a daily limit of 50 me.'

Three providers returned the post-analysis survey. The remaining provider was on vacation during the post-implementation survey timeframe. The average score was 29. The

highest ranked item was ‘most of my patients on opioids are under a daily limit of 50 mmEQ,’ which is an awareness of practice question. The lowest ranked item was ‘I find it easy to find how many morphine milliequivalents for my patients who are prescribed opioids,’ which is a confidence question.

Pre/Post Site A and Site B All Measures Comparisons

As each site had small sample sizes due to the short time frame post implementation, it was not considered statistically relevant and there were limitations when considering the site’s individually for statistical analysis. For the purposes of understanding whether the overall project was successful regardless of site, all data was combined to provide total analysis over the project. This is Pre-implementation, there were 61 total patients in review and 20 total patient’s post-implementation. Gender frequencies, short and long acting opioid frequencies for the entire data set evaluation are listed in appendices T through V.

Co-Prescribed Benzodiazepine

There is not sufficient evidence to say that the proportion of patients that had benzodiazepines differs pre- and post-implementation using Fischer’s Exact Test. ($p = 0.1339$). Appendix W outlines the presence and absence frequencies for co-prescribed benzodiazepines.

Morphine Milliequivalents

There is not sufficient evidence to say that the total distribution of morphine milliequivalents differs pre- and post-implementation using Wilcoxon Rank Sum test ($S = 757$, $p = 0.4954$). See Appendix X for the evaluation of mmEQ distributions.

Urine Drug Screen

There is not sufficient evidence to say that the proportion of patients that got a drug screen differs pre- and post-implementation using a Chi-square test ($x^2 = 0.2$, $p = 0.6551$).

Frequencies for both sites are listed in appendix Y. Pre- and post implementation comparisons are listed in appendix Z.

Medication Contract

There is sufficient evidence to say that proportion of patients that had a medical contract differs pre- and post-implementation using Chi Square test ($x^2 = 3.95$, $p = 0.0468$). There were 90% of patients who had a contract in place post implementation compared to 67.2% pre-implementation (see appendix AA and BB for medication contract frequencies and implementation characteristics).

Michigan Start Talking Document

There is sufficient evidence to say that proportion of patients that had a start talking document differs pre-and post-implementation using Fisher's Exact test ($p = 0.0022$). Following implementation, 40% of patients had a start talking document in place, compared to 8.2% prior to implementation (see appendix CC and DD for Michigan Opioid Start Talking Frequencies and implementation characteristics).

Naloxone and Screening Tools

There was no change in naloxone co-prescription or use of screening tools pre/post implementation and therefore, these measures could not be included in statistical analysis.

Discussion

The CDC considers what is known from epidemiology research about benefits and harms related to opioids in consideration of recommendations for prescribing patterns, including high dose therapy, co-prescription, and others. The CDC was the primary body of evidence used for the evidence-based toolkit and provided guidance for the measures in this project. Several key

points were considered when looking at the relevance to the purpose of this project and with evaluation of the association between the interventions and outcomes.

Morphine Milliequivalents

In most studies, higher dose opioid therapies are associated with increased overdose risk (Dowell, Haegerich, and Chow, 2016). In several studies reviewed by the CDC, fatal overdose was associated with opioid mmEQs that were higher, including those above 50mmEQ. The results of this implementation indication there is risk for unintentional overdose associated with patients at both practices, and this was recognized and mitigated with the evidence-based toolkit. The post implementation data for combined practices was not statistically significant for reduction in total mmEQ. However, with combining of both sites, there was a reduction of mmEQ/day of 26.4 and at site B, there was a reduction in mmEQ/day by 46. While this is not statistically significant, it is clinically relevant in reduction of harm by risk of unintentional overdose to patients in these practices.

Additionally, not included in the metrics but notable was the consideration of importance around formulation of opioids, with extended release/long acting (ER/LA) and short acting prescription. The FDA agrees that there are several serious risks associated with ER/LA opioids and documents the indication or this class of medication being pain management severe enough to require long term, daily opioid treatment for whom other options are not effective (US Department of Health and Human Services Food and Drug Administration, 2013). Site A did not assume this risk for any patients reviewed either pre- or post-implementation, but site B did have 15% of patients reviewed on both ER and short acting medications pre-implementation. After implementation of the evidence-based toolkit, which included literature on the risk for long acting opioids, there were no patients prescribed both long and short acting medications at either

site, which is again considered very clinically relevant in reduction of overall risk status for patients on opioids.

Co-Prescribed Benzodiazepine

In epidemiologic studies, the CDC found that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose (Dowell et al., 2016). Within the chart review, it was noted whether the patient had a prescription for benzodiazepine on the medication list, but duration, dose or indication was not considered. In combined data, it was notable that there was not a statistically significant change in co-prescribed benzodiazepine but both sites had a reduction of 18% of co-prescribed benzodiazepines. Like mmEQ/day, site B provided what appeared to be a large practice change regarding this measure, with an overall reduction of 29% of patients on co-prescribed benzodiazepines. Site A did have an increase in the percentage of patients on benzodiazepine therapy, but the small sample size was likely the cause for this finding.

Start Talking and Medication Contracts

The Opioid Start Talking Document and medication contract were enacted to assist in a patient's increased understanding of the risks of opioid therapies. These factors are part of the organization's suggested guideline for opioid prescribing and were included in this project to assist in increased adherence to this measure. Both the Start Talking Document and Medication Contract saw statistically significant change post intervention. The Start Talking document, as indicated previously, was enacted after the period of review for some patients. There were several considerations for use of this document, as well, as patients on long-term therapies with the same provider would not fall into the legislation of need to have the document.

Urine Drug Screen

There are benefits of urine drug screen testing including the ability to identify patients who might be at higher risk for opioid overdose or opioid use disorder (Powell et al., 2013). The use of urine drug screen was highly compliant at site A both pre-and post-implementation. The use of urine drug screen decreased in compliance at site B post implementation. This could be due to a variety of factors, including consideration of whether reduced mmEQ and less patients with ER/LA and short acting combinations had an influence on this factor. Further, as discussed previously, duration of drug was not part of the review, so if a patient was started on short duration (<7 days) opioids, it is unlikely to be associated with a urine drug screen.

Naloxone and Screening Tools

As noted in the results section, there was no change in naloxone prescribing or screening tools post intervention. There are several limiting factors to the implementation of both measures. Risk mitigation with co-prescription of naloxone provides limited evidence in the literature surrounding primary care. However, there is success through distribution through community-based programs offering prevention services for substance users and there has been an association with decreased risk for opioid overdose death at the community level.

The concepts around co-prescribing in primary care are new for most providers. This generated the most questions regarding the toolkit discussions. There was information in the toolkit on the importance of naloxone and patient education was included. However, there was not information included on pharmacy or insurance information for obtaining the medication within a reasonable cost. Additionally, at time of implementation there were not quick, patient friendly videos on naloxone administration targeted for patient and families. It takes time for the provider and/or medical assistant to properly educate the patient on identification of overdose

and how to appropriately administer the medication. With limited time during the primary care visit, this poses a challenge. Continued work is planned for this education and standard work.

Screening tools are identified by the CDC as useful but there were mixed results in the review of literature. The EHR provides availability to these tools and screen shots were given in the toolkit to providers but it was not physically shown to providers where or how these were accessed, assuming providers had the knowledge and use of epic to implement these on their own. This assumption may have led to no change in post-implementation data. Additionally, most of the opioid prescriptions in the post data period were not associated with an in-office visit and instead was with a phone call from the patient for a refill request. The message was sent via medical assistant or RN to the prescriber, who reviewed the chart data and refilled. Use of screening tools in these cases, would not be indicated.

Provider Comfort Level in Prescribing

The CDC identifies that many prescribers lack confidence in the ability to prescribe opioids safely, to predict or detect prescription drug abuse and to discuss this with their patients (Dowell et al., 2016). Further, according to Dowell et al. (2016), most clinicians are not consistently using practices intended to decrease the risk for misuse, including urine drug testing, opioid treatment agreements and Prescription Drug Monitoring Systems (PMPD's). It was identified that there was slight change pre- and post with provider comfort level and awareness of organizational policy, but this change was not significant. This Likert style survey was created by the DNP student and thus could have been subject to limitation by question strength and applicability to the desired outcome. See appendix EE for the survey characteristics.

Informatics Change

As mentioned previously, part of the implementation was an informatics change that was requested by the DNP student that would aid in provider use of tools in the EHR. This change is not discussed in detail in the project discussion, due to the challenges in implementation of this change. The student presented across several different leadership forums to discuss the idea, which was a best practice advisory (BPA) that would allow for provider recognition of high-risk patients in the EHR. This BPA would look across several factors and pull together the alert to the provider on the total daily mmEQ as well as recommendations for naloxone, as needed. Further, there would be ease of ordering this medication through a few clicks.

During implementation of the project, the DNP student was simultaneously working through this change. The BPA was approved through these several presentations, including to leadership, the Primary Care Informatics change management group, and with information services. However, it was decided by the organization that this request would be grouped together with other, similar EHR changes that would be taking place with the opioid initiatives across the organization. Therefore, progress was halted, and this could not go forward within the timeframe desired by the student. There will still be continued work toward finishing the initiative in the 'next steps' section of the paper.

Site 'A' Overall Learnings

There were several points of discussion following review of the results revealed in the current practices of opioid prescribing at the site. At site A, it was identified that there was generally good practice for opioid prescribing, with some overall suggestions for improvement. Opportunities included ensuring providers were considering use of a screening tool to assist with recognition of their patient's overall goals for pain and function. Annual drug screening and use

of the Michigan Start Talking document were additional suggestions for improvement of the individual practice.

The strengths of site A included the fact that only a small number of patients had a co-prescribed benzodiazepine, there was an overall low total daily morphine equivalence, there were use of referrals in place to assist with the patient's pain management related conditions and use of short acting medications rather than longer acting, which is recommended by the CDC's guidelines. There is also good compliance with medication contracts.

Site B Overall Learnings

At site B, there are also areas of strength and opportunity. Strengths include the high compliance with urine drug screen and compliance with medication contracts. There are several pain management referrals and referrals elsewhere to assist with pain. While there was significant improvement with prescribing practices with overall mmEQ and co-prescribed benzodiazepines, there is still some opportunity for improvement in this area. No patients had naloxone prescribed, which is recommended by the CDC if a total daily MMEQ is listed about 50, which still exists for some patients. Of significant relevance was that there was a complete reduction in instances with both long and short acting preparations post-intervention. Site B saw many different improvements clinically, though not statistically significant.

Barriers

There were several barriers hindering the success of the project implementation. First, the limitation in the epic EHR provided gaps in the provider's ability to quickly find morphine milliequivalents for their patients and to identify high risk patients for overdose. This was outlined in the post survey and apparent in the DNP student's review of patient charts.

Additional barriers included the challenges in implementation due to limited availability during the office day of providers, including vacation schedules and provider turn-over in the office.

The organization is working on another facet of the evidence-based toolkit which would have provided some relevance and assistance to the use of this project. An interdisciplinary committee is putting together intentional tools and algorithms to aid the provider in weaning, consideration for substance use treatment, and how best to navigate and approach different types of pain a patient presents with. The algorithms provide suggestions and treatment alternatives to pain management. This provided a barrier to the project because these tools were not yet available to prescribers. Therefore, they needed to navigate the complexities of weaning and referral, without prior guidance and this can prove to be an obstacle in rural primary care. There is continued work on this piece and is provided in the 'next steps' portion of the paper.

Limitations

Clinician and patient values are difficult to discern and are not captured in the data. Patients all have varying clinical presentation, history and indications for use. There are not discrete data fields in the EHR to evaluate the extent of this discussion or consideration for opioid prescription. There were not qualitative measures obtained to assist with the recognition of these factors and had these been present could have been a factor to assist in the understanding of the patient/provider values in opioid prescribing. Further, diagnosis, duration of therapy, co-morbidities and age were not accounted for in the design. Individualized factors prove to be important pieces in the opioid prescribing puzzle, so it is difficult to discern how these pieces of information would have contributed to the project outcomes.

Indications for opioid prescriptions were not considered regarding prescribing patterns. This is another important piece in understanding the overall picture of the patient's need for

opioids. The exception to this was the removal of cancer patients in the data review. Additional considerations that have been found to have considerable connections to opioid prescribing include mental health and substance use history and these factors were not assessed. Many people have been found to have a large emotional connection with their medications and while these conversations were likely happening during the visit, this was not addressed.

Among chart review findings, it was noted in the notes for refills that many patients were said to be weaning from their opioid medication, which was not captured in the data. Additionally, many patients had documentation that there were attempts at other pain modalities prior to starting opioids, which is an important concept to consider. For example, many patients had tried non-opioid alternatives such as anti-inflammatory medications, Tylenol, non-opioid pain patches, and medications such as tricyclic antidepressants and nerve pain medications to control pain and this was noted in the documentation. These alternatives were not captured in the data and could have been an important factor to understanding why opioids were the best alternative for the patient with significant pain, resistant to other therapies.

Tabulation of the total mmEQ for patients was challenging to include in the review. Many pain medications are listed as needed (PRN) or are written for one to two tablets for use, which makes it difficult to assess what the patient is taking when attempting to capture their total daily mmEQ. Therefore, the DNP student had to assume that the patient was taking the medication as prescribed, as there was no way to capture the amount taken in a discrete data field from the electronic record. This meant that the mmEQ described in the data was unlikely to be completely accurate.

Site B has a physician that specializes in pain management, addiction, and is a Buprenorphine provider for the community. He also serves as a palliative care and hospice

provider. While cancer and palliative care patients were excluded, there were no exclusions made for patients with pre-existing addiction concerns or any exclusions for chronic, longstanding pain. There was no Buprenorphine listed on the opioid report. Therefore, as a limitation of the study, it's likely expected that this provider would possibly have higher daily mmEQ tabulations due to the nature of the work he does and the patient population he sees.

Additional limitations included the recent provider turnover in the office, which meant that some providers were on the pre-implementation report but did not have any prescriptions listed after implementation. It was considered that many of the patients being prescribed medications are likely to remain with the practice after provider absence, so these provider's practices were not excluded from the pre-implementation report.

The Michigan Start Talking Document only became a requirement for the state middle of the audited year, leaving some patients to have decreased compliance in this, which was expected. Additionally, use of this document is not easy to understand with chart review as far as whether this is necessary during the specific patient's case. It would be a more detailed and extensive chart review to understand the patient/provider relationship and this was not completed. Therefore, presence or absence of this document was tabulated but more consideration should go into the significance of this document.

One of the most important factors is the fact that opioid practices have undergone large changes between the beginning of 2018 and 2019 because of state and organizational initiatives. There were several forums outside the work of this project where providers could learn about opioid legislation changes, CME offerings and opportunities where there was additional education provided. Therefore, the significance of their changes in opioid prescribing practices must take into considerations other opportunities for learning.

The project had a short implementation period and took place at rural locations with very few provider staff present. Additionally, there were transitions of providers before and during implementation of the toolkit, making consistency challenging. Another limitation included the small amount of data collected to reveal to 'pre-implementation' data and the fact that this retrospective review took place following the intervention. This was a limitation because providers could not see pre-prescribing trends and data to help drive the intervention. This was presented to them after implementation and results were available.

Finally, there was a limitation realized with the provider survey. Questions 1-6 on the survey are responses that are expected and/or desired to increase post implementation. It was discovered that question 7 is written in such a way that the responses would be expected to decrease following intervention. This was somewhat contradictory in the provider's view of the survey and made data analysis for this survey difficult. Further, the small amount of responses compared to eligible prescribers, as well as even smaller amount of responses post implementation created limitations.

Summary

According to the Centers for Disease Control and Statistics (2018), drug overdose deaths continue to rise in the United States. Every day, an average of 130 Americans die from opioid overdose, and the number of opioid overdose deaths is six times higher than in 1999 (CDC, 2018). The nature and significance of this problem is astounding and requires unique attention paid by all health care providers, including those in primary care. Unintentional overdose should be considered a factor and should not be ignored.

There are many relevant studies to how primary care providers fit into the puzzle of ensuring safe prescribing habits for patients. Many studies examine the impact of increased

provider knowledge of safe opioid practices, which can positively influence prescriber habits. Additional studies identify cost savings with implementation of targeted education to providers on opioid prescribing (Quanbeck et al., 2018). Relevant studies identify a statistically significant reduction in morphine-equivalent daily dose observed compared to control when a targeted implementation is put in place. There are also known increases in adherence to recommended urine drug testing, use of treatment agreements, and opioid-benzodiazepine co-prescribing rates with targeted interventions (Quanbeck et al., 2018). Additional relevant studies by McCracken et al. (2016), Liebschutz et al. (2017) and Gaiennie and Dols (2018), found increased intention to prescribe using safer habits, reduction in total opioid prescriptions, a reduction in daily morphine-equivalent dosing, increased referral to pain management, as well as increased awareness of strategies to provide more regular assessment and re-assessment of pain scores and screening for patients on opioid therapies. Therefore, the literature does support such intervention.

There were several models used to guide the intervention, including the Chronic Care Model and Kotter's Eight Step Model for Leading Change. The intervention utilizes the principles of each model to assist in the understanding of how the intervention will be successful at the chosen site for implementation. Several assumptions were used to develop the intervention, including the idea that the organization is moving in the way of improving opioid prescribing practices leading to desired changes among providers, the idea that most providers could benefit from increased knowledge and awareness of safe opioid prescribing practices and there are needed changes in the EHR to make the work of the provider more efficient.

The intervention was expected to work because of the use of evidence to drive practice change. Providers use evidence every day to guide the care of their patients in the care they

provide in other ways. This is not a new concept in primary care medicine and is a driving force in the care of patients. Due to the extensive nature of the changes in the state of Michigan regarding opioid prescribing as well as the desire of the organization to match these changes, it is assumed that the intervention will only help drive providers to become more aware of organizational and state/national policy. Specific aims of this project include identifying ways the literature and best practice can guide evidence-based care at the bedside, ensuring there is opportunity to have the needed resources available for providers at their fingertips. The purpose of this project and of this paper is to outline the project, including a description of the methods, intervention, approach, measures and analysis of the project.

Implications for Practice and Further Study in the Field

The topic of opioids is one that has wide relevance in primary care practice. This ability for a primary care prescriber to care for patients holistically is a well understood role of the DNP prepared nurse. It was the goal of the DNP student to learn more about safe opioid prescribing through this evidence-based project. While there are many varied practices in primary care for caring for patients, and there is individualized care that requires unique attention to a patient's specific needs. Further, there is a desire and need to understand the part of the practitioner in keeping a patient safe from harm, including risk for unintentional overdose.

While not statistically significant, there were many lessons learned by the reduction in overall mmEQs and benzodiazepine co-prescribing habits and these provide clinical relevance in the reduction of overall risk for overdose in patients of the primary care practices. Clinical relevance in the DNP student's project prove of exceptional value in what the project can provide to patients and the unique care that is provided.

Support, Sustainability and Next Steps

Sustainability of the DNP project is also an important concept to consider, as after graduation, there should be a way for the project site to maintain the direction and momentum that has been gained by the student enacting the project. There are several next steps to consider for the project. First, the informatics change with the best practice advisory will continue and the checklist can be updated and used at the bedside whenever there is a legislative or organizational change that needs to be added. Additional work around opioid tools are also being vetted, with a dashboard in the works to assist providers.

Continued support and work on the algorithms mentioned previously will require some additional work related to this project. This will include, but is not limited to sample weaning schedules, opioid use disorder treatment options and referrals, and alternative pain management pathways with alternative medications and non-pharmacological strategies. This strategy should help immensely in provider comfort and awareness of care for patients on opioids.

The final results were presented in April 2019 to the site, as well as the Steering committee. The DNP student provided handoff to the director of operations at the site, who will continue work on implementation of the toolkit across the system. The information is valuable for the organization to continue forward so this formality will take place to ensure the organization has all materials desired to be put forward to providers.

Dissemination of Outcomes

Dissemination of the results included several presentations to key stakeholders across the organization and the university. The student has already had an opportunity to share portions of the project along the way. In October, a presentation to both the local newspaper and local news was conducted by the student to bring awareness to both the project and the opioid epidemic. Additionally, the student also presented at a local conference. The purpose of this presentation

was to engage the public and other health care professionals on the topic of opioids, including current and local trends on the topic.

The student participated in the DNP Defense, which is a presentation to faculty and peers and provides an opportunity for discussion and review of the overall scope and results of the project. Additionally, the student presented at the monthly all provider meeting at the organization, which prefaced spread of the materials to other providers in the practice. Additional presentations included to the Opioid Steering Committee at the site, as well as leadership committees that were requested. The results were shared both individually and collectively across the provider groups at the specific sites for implementation.

Reflection on DNP Essentials

While the focus of the DNP degree is expertise in clinical practice, there is additional emphasis placed on what are considered the Essentials for Doctoral Education for Advanced Nursing Practice by the AACN. These essentials include leadership, health policy and advocacy and information technology. The goal of the DNP prepared nurse is to identify those essentials as significant to the character of learning while completing the DNP degree. These essentials will aid in the overall ability of the DNP prepared nurse to enter clinical practice in a way that prepares them for the additional scope and provision of their role. It helps to formulate the type of practitioner the DNP prepared nurse wishes to become.

The goal of the DNP essential completion was to initially identify the essentials that were of lesser competency in the DNP student's personal abilities. This took place over a detailed review of each competency and how that specific competency could be achieved. Over the course of several semesters, the student worked to address and improve the ability to achieve each competency, including continued self-reflection at the beginning of each semester. The

student would seek opportunities that provided the ability to better knowledge and understanding of the principles of the DNP project, as well as those experiences that contributed to improving the ability to be a well-rounded DNP prepared nurse. The experiences ranged from working side by side with other providers and practitioners, to volunteerism, to seeking out lectures, conferences and webinars to broaden the knowledge base. The student worked with a clinical ethicist at a local health care organization to better assist in understanding the various ethical challenges associated with healthcare and how the DNP fit into the role of an ethically competent professional.

Additional experiences included frequent volunteerism with the Grand Rapids Red Project. This role was paramount to the student's project in the way of learning to reduce the stigma associated with care and assistance of people fighting addiction. This helped the student to change language and assumptions related to the care of patients who use and potentially mis-use opioids and other substances. The student provided several overdose prevention trainings to area inpatient and outpatient drug and alcohol rehab facilities, local universities and provided one on one training during walk-in hours across several counties in Michigan. Volunteerism at the Hall Street location in Grand Rapids provided the opportunity to work with and learn from people who have current and previous addiction, including how best to serve them and their needs. The DNP student learned to "meet people where they are at" which is a key strategy and vision of the Red Project and learned to discuss sensitive matters in ways that are more caring and non-judgmental. This carried over into the student's personal employment as an Emergency Room nurse and provided value in everyday interactions with patients that are often otherwise stigmatized in health care. This volunteerism provided some of the richest experiences the student encountered during the immersion opportunities.

Conclusion

The opioid crisis has reached epidemic proportions. Learning and understanding that addiction to opioids and unintentional overdose are a driving factor in this epidemic left the DNP student looking for ways to help reduce this risk. The evidence-based approach to creation of the toolkit helped the student to engage the literature and find best practice in opioid prescribing. It also assisted in recognizing the organization's desire and need for opioid prescribing guidelines that are centered around evidence. Entering practice with the knowledge that this project has created is instrumental in ensuring there is the ability to carefully and safely prescribe in the future.

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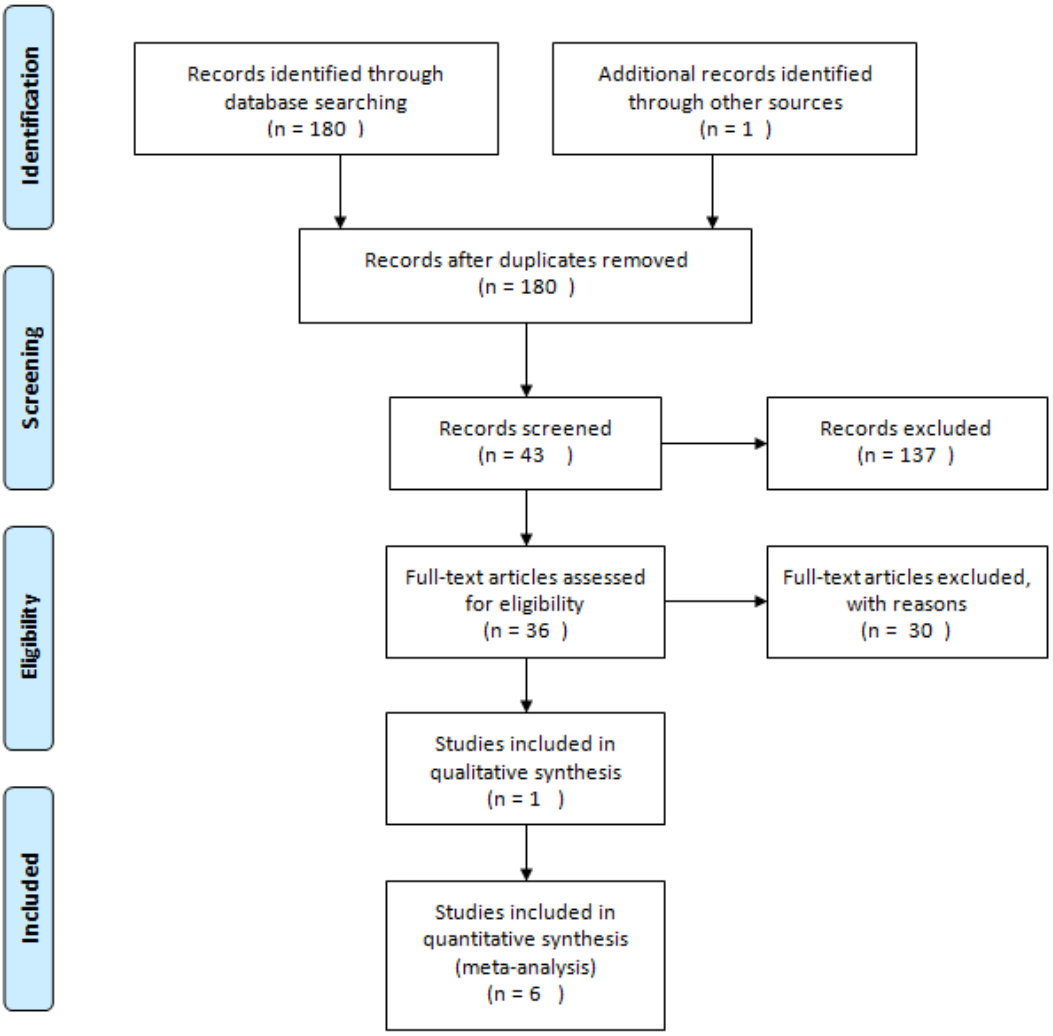
Appendix A

PRIMSA Flow diagram of search selection process



Appendix B

Table of Evidence

Author (Year) Purpose	Design (N)	Inclusion Criteria	Intervention vs Comparison	Results	Conclusion
Gaiennie and Dols (2018)	Quality intervention	Primary care NP and physicians in one practice	Pre-and post-implementation data was collected after an information fair, trainings and quality meetings. There were also 1:1 meetings with each provider.	Following intervention, there was a 10% reduction in opioid prescriptions written and 7% of patients referred to pain management for treatment.	Targeted education and guideline implementation can increase patient safety and influence outcomes.
Liebschutz et al. (2017) Intervention to identify provider adherence to guideline.	Randomized Controlled Trial	Physicians and Nurse Practitioners who had at least 4 patients 18 and older on opioid therapy.	4 interventions vs. control 1). Nurse care manager 2). Electronic education 3). Single academic session 4). Academic and online platform.	At 1 year, intervention patients were more likely than controls to receive guideline-concordant care, to have a patient provider agreement and to undergo at least 1 urine drug screen. Intervention patients were more likely than controls to have a 10% dose reduction or opioid treatment discontinuation.	A multicomponent education intervention improved guideline-concordant care but did not decrease early opioid refills.

				There was no difference in early fill of prescriptions between groups.	
McCracken et al., (2012)	Randomized Controlled Trial	General practitioners at Primary Care Research Network	All participants had a 1-hour training followed by either: 1). Training based on acceptance and commitment theory, or, 2), standard training	Overall, there was an increase in knowledge of opioid prescribing for chronic pain and decreased concerns related to prescribing following training. There were no changes in provider reported wellbeing. There was a greater increase in intention to use prescribing guidelines.	Well-designed training can increase knowledge of opioid prescribing.
Quanbeck et al. (2018)	Randomized controlled trial	Primary care providers with patients being treated for chronic pain	Four intervention clinics versus four control clinics that received one of several options: 1. Audit and feedback, 2. Academic detailing, external	At 6 months, statistically significant improvements were noted in intervention clinics in the percentage of patients with mental health screens, treatment agreements,	There is an opportunity to increase safety and efficiency of opioid prescribing with intervention versus none.

			facilitation	urine drug tests and opioid-benzodiazepine co-prescribing. At 12 months' morphine-equivalent daily dose was significantly reduced in intervention compared to control. There was a cost savings of $7345 per clinic.	
Tournebize, et. al (2016)	Systematic review	Prescribers with adherence to at least one opioid reduction strategy	N/A	Less than 50% of providers assess pain intensity using a pain scale and often consider transdermal fentanyl as a safe alternative in opioid naive patients. Further, providers do not always discontinue opioids if they are ineffective in relieving pain.	There are opportunities to increase provider adherence to safe opioid prescribing practices.
Von Korff et al. (2016)	Quasi-experimental design	Physicians part of health group in Washington state	Statewide guidelines for change in opioid prescribing versus health plan group practice changes and	Groups that received both guidelines had reduced opioid days and reduced morphine mmeQ versus	Additional information increases physician adherence to practice changes.

			statewide guidelines.	that of the statewide guidelines alone.	

Appendix C Burke Litwin Model

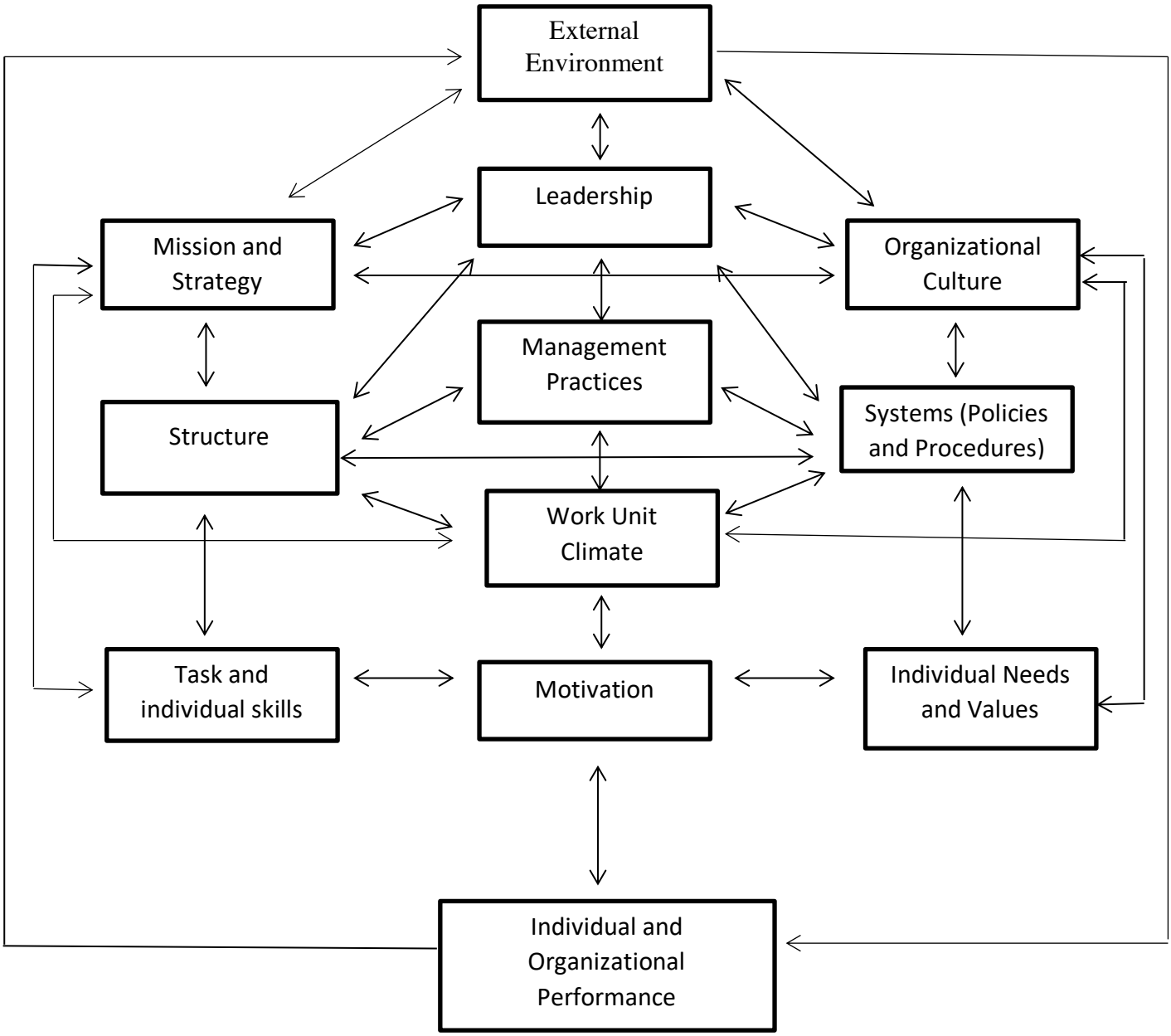


Figure 1. A model of organizational performance and change. Re-created from "A Casual Model of Organizational Performance and Change," by W. W. Burke and G. H Litwin, 1992, *Journal of Management, 18*, 528. Copyright 1992 by Southern Management Association

Appendix D

SWOT

Strengths	**Weaknesses**
• Engaged Leadership including supervisor, manager, director • Low provider and staff turnover • Consistent Medical assistant/prescriber relationship • Consistent providers in the practice • Process improvement in place • DNP prepared NP	• High panel load for each provider • Patients on long term opioid regimens • No current EHR notification for high MMEQ • Many screening tools already in place • Recent EHR change with large focus on recent big changes.
Opportunities	**Threats**
• Consumer demographics • Recent state policy changes • Organizational policy changes coming • Increase quality of care with evidence-based care solutions • Part of a larger health care organization • Reduce risk of overdose	• Patient satisfaction regarding pain management regimens and their satisfaction with pain control. • Patients unaccepting of changes in long term regimens. • Limitations in health literacy in the community • Limited transportation • High no show rate at the office • Staff and provider buy in to practice change.

Appendix E: Letter of Support from the Site

July 15, 2018

Regarding: Permission to conduct DNP Project at the [redacted] Office

To Whom It May Concern,

Katelin Aris is a Doctor of Nursing Practice (DNP) student at Grand Valley State University. As part of her DNP studies, she will be conducting a project at [redacted]. The project entails assessing current state for adult patients who are receiving one or more opioid pain medication from their primary care provider. She will work to identify risk for opioid overdose in this population and identify gaps between evidence-based care and current practice. An evidence based toolkit will be developed from the literature and will then be utilized to reduce overdose risk in patients who are at high risk based on various factors identified in chart review.

I will serve as a mentor for Katelin Aris in relation to this project. I will allow this student to conduct her project at this location.

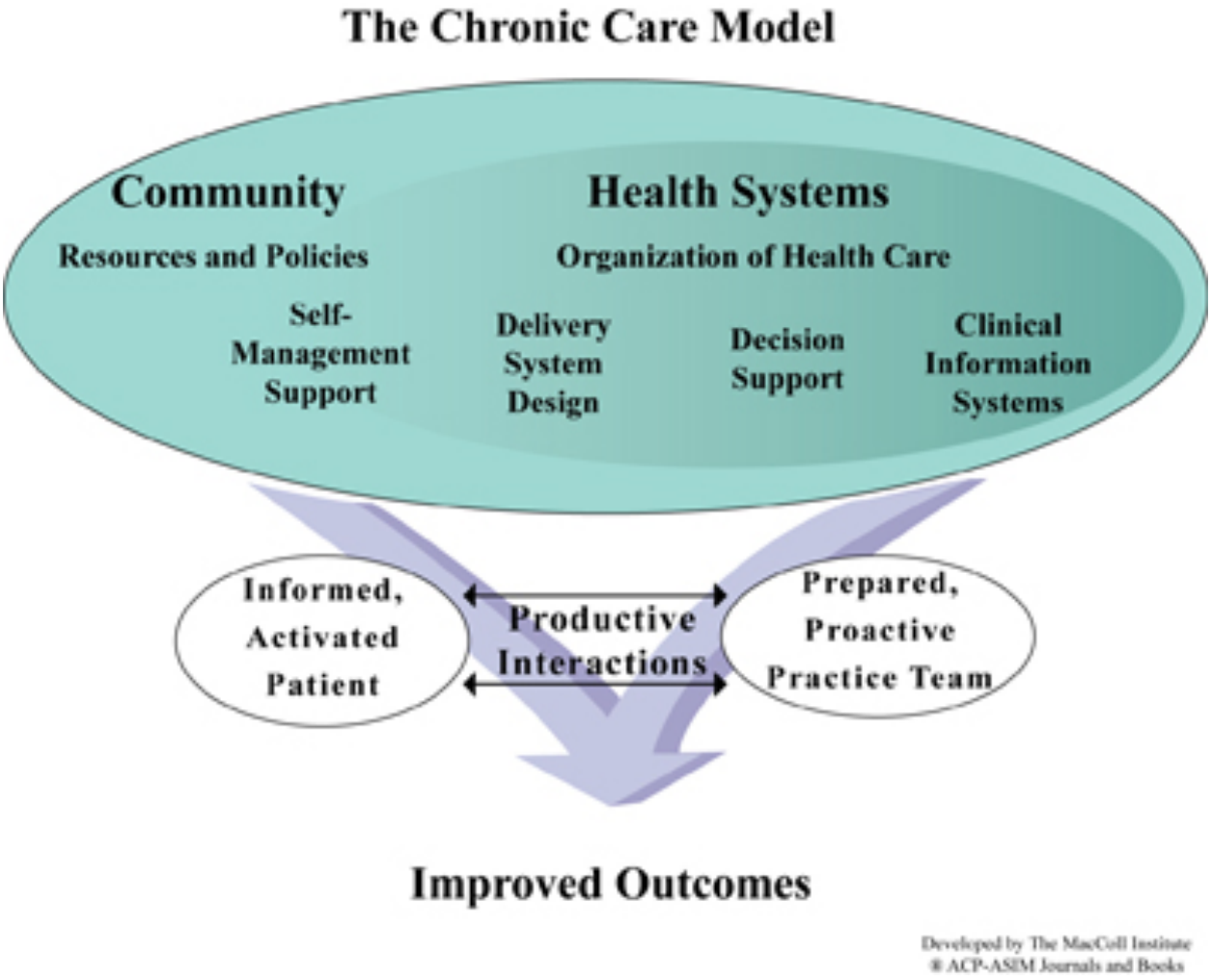
Sincerely,

Caroline Ring

Caroline Ring, DNP, MSN, RN

[redacted]

Appendix F: Chronic Care Model



Levenson, J. (2017). Behavioral health: moving to a chronic care model helps payers, providers and patients. *MAP Health Management.*

Appendix G: Kotter's 8 Step Model for Change

Appendix H: IRB Site Specific

NON HUMAN RESEARCH DETERMINATION

November 2, 2018

Katelin Aris, DNP

[redacted]

PROTOCOL TITLE: **Evidence Based Toolkit for reduction of overdose risk in primary care patients on opioid therapy**

SPONSOR: Investigator

Dear Ms. Aris ,

On November 2, 2018, the above referenced project was reviewed. It was determined that the proposed activity does not meet the definition of research as defined by DHHS or FDA.

Therefore, approval by [redacted] IRB is not required. This determination applies only to the activities described in the IRB submission and does not apply if changes are made. If changes are made and there are questions about whether these activities are research involving human subjects, please submit a new request to the IRB for a determination.

At this time, you must submit your data request to the Quality Department via their online request tool. Upon completion of this form, your request will be assigned to a quality analyst for processing. Any questions about this requirement should be directed to the Quality Department at datarequest@[redacted]

A quality improvement project may seek publication. Intent to publish alone is insufficient criterion for determining whether a quality improvement activity involves human subject research. However, please be aware when presenting or publishing the collected data that it is presented as a quality improvement project and not as research.

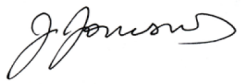
The IRB has made the following determination:

- **WAIVER OF HIPAA AUTHORIZATION**: A waiver of HIPAA authorization has been approved per 45 CFR 164.512(i)(2)(ii).

Please be advised, this determination letter is limited to IRB review. It is your responsibility to ensure all necessary institutional permissions are obtained prior to beginning this project. This includes, but is not limited to, ensuring all contracts have been executed, any necessary Data Use Agreements and Material Transfer Agreements have been signed, documentation of support from the Department Chief has been obtained, and any other outstanding items are completed (i.e. CMS device coverage approval letters, material shipment arrangements, etc.).

Your project will remain on file with the Office of the IRB, but only for purposes of tracking research efforts within the [redacted] system. If you should have questions regarding the status of your project, please contact the Office of the IRB at 616-486-2031 or email irb@[redacted]

Sincerely,



Appendix I: IRB Grand Valley State University

From: rci@gvsu.edu
Subject: HRRC Research Determination Form - Not Human Subjects Research [19-159-H]
Date: December 3, 2018 at 1:39:58 PM EST
To: <ARISK@MAIL.GVSU.EDU>, <THOMATR@GVSU.EDU>, <DAVIREBE@GVSU.EDU>

Dear Patricia Thomas,

An HRRC Research Determination Form has been reviewed for the following project.

Study Title: Implementation of an Evidence Based Toolkit to Reduce Risk of Overdose in High Risk Primary Care Patients
PI: Patricia Thomas
Study Number: 19-159-H

This study has been determined to NOT meet the federal regulations for Human Subjects Research. An official determination letter is attached to this email.

To view a copy of the submission in IRBManager, click here: HRRC Research Determination Form [Human Subjects Research]

If you have any questions, please contact the Office of Research Compliance and Integrity at rci@gvsu.edu or 616-331-3197.

Thank you,
Office of Research Compliance and Integrity

Appendix J: Additional IRB Approvals

Katelin Aris <arisk@mail.gvsu.edu> Fri, Jan 18, 2019 at 8:45 AM

[redacted]

Good morning,

Attached is my IRB determination from this fall. [redacted] has some additional data needs for my project so I would like to request additional permissions to review the data but I am not sure that it needs to come back through the IRB since it does not change my project to human subjects research. I have attached the data points already approved for the project, as well as revisions requested (there are only a few).

Please let me know if there is a need to do anything further.

Thank you,
Katie Aris

2 attachments

K ARiS DNP IRB Determination .pdf
52K

K ARIS IRB Data Points .docx
85K

[redacted] Fri, Jan 18, 2019 at 4:18 PM

Hello Katie,

Thanks for your question. Because your project has been deemed quality and these additional data points do not change the overall scope of your project, this does not need to come back to the IRB for review.

Thank you,

IRB Assist

Appendix K: Data Points

Data Variables to Be Collected for Project Before and After Toolkit Implementation

1. Age
2. Gender
3. Short acting opioid name, dose, strength, regimen and length of time on medication
4. Long acting opioid name, dose, strength, regimen and length of time on medication
5. Benzodiazepine (presence or absence on medication list at time of opioid prescription)
6. Screening tool-PEG, SOAPP, ORT (presence or absence on medication list at time of opioid prescription)
7. Morphine milliequivalents (calculated by me using online calculator)
8. Urine drug screen presence or absence
9. Medication contract presence or absence
10. Start talking document presence or absence
11. Referral to pain management
12. Diagnosis related to opioid use
13. Diagnosis of opioid overdose
14. Provider pre- and -post comfort level with guidelines.
15. Total provider prescriptions per month

Appendix L:

Sample pre- and post-survey for Prescribers/Office Staff

1 = strongly disagree 2 = disagree 3 = neutral 4 = agree 5 = strongly agree

Please rate the following on a scale of 1 to 5.

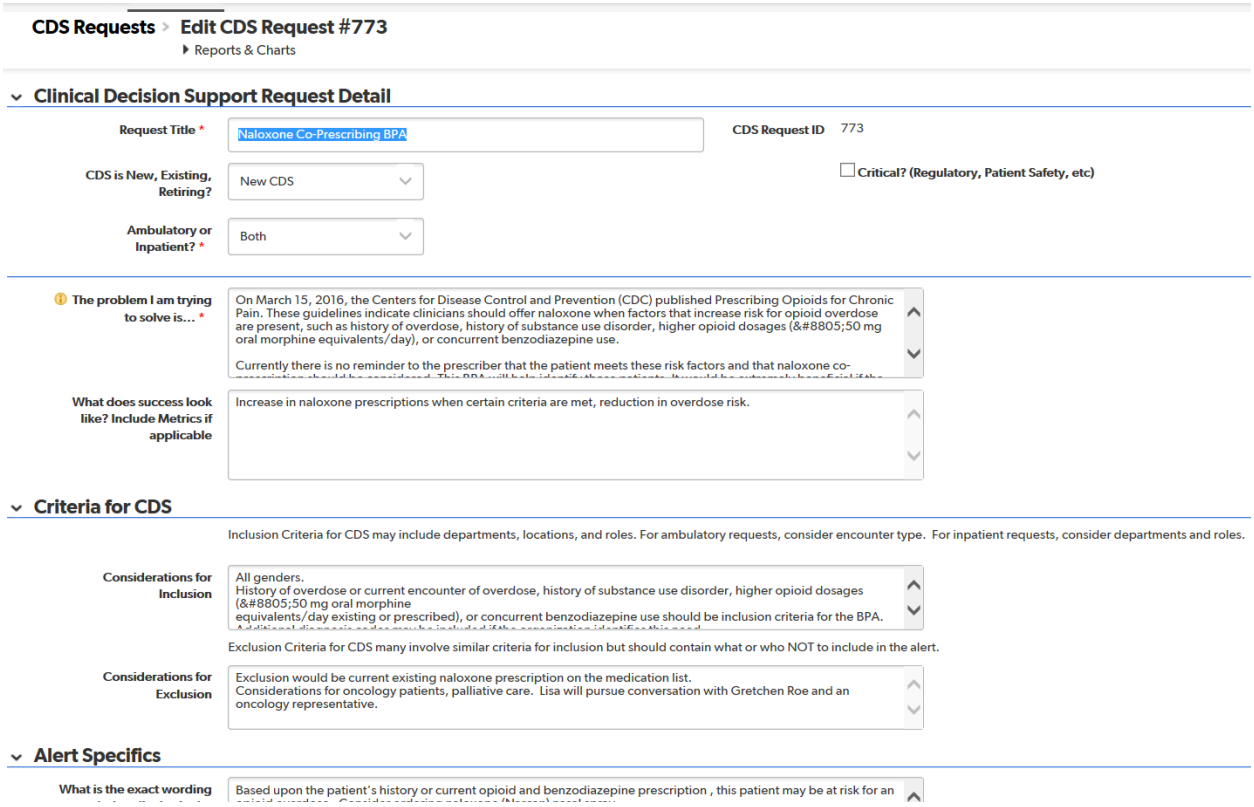
1. I feel confident in understanding the legislative changes in the state of Michigan with regard to opioid prescribing.
2. I feel confident in understanding the organization's policies for opioid prescribing.
3. Most of my patients on opioids have signed opioid prescribing contracts.
4. Most of my patients on opioids have at least one UDS per year.
5. Most of my patients on opioids are under a daily limit of 50 mmEQ.
6. I find it easy to know how many morphine milliequivalents for my patients who are prescribed opioids.
7. I think patients could use more education with regard to opioid prescribing changes.

Appendix M:

Timeline for Implementation

Item	**Projected Timeline**
IRB Determination	Granted December 3, 2018
Proposal Defense	November 5, 2018
Toolkit creation	12/15/2018-1/15/2019 *month long review of literature, approvals, putting together education.
Implementation date/education and support	February 18 (site A) February 19 (site B)
Pre-data review	Week of March 5, 2019
Return to site for provider updates and questions/feedback	Week of March 18, 2019
30-day implementation data	Week of March 18, 2019
Presentation of data to site	April 2019
Final Defense	April 1, 2019

Appendix N: Informatics Change Request



CDS Requests > Edit CDS Request #773

Reports & Charts

Clinical Decision Support Request Detail

Request Title * Naloxone Co-Prescribing BPA

CDS Request ID 773

CDS is New, Existing, Retiring? New CDS

Critical? (Regulatory, Patient Safety, etc)

Ambulatory or Inpatient? * Both

The problem I am trying to solve is... *

On March 15, 2016, the Centers for Disease Control and Prevention (CDC) published Prescribing Opioids for Chronic Pain. These guidelines indicate clinicians should offer naloxone when factors that increase risk for opioid overdose are present, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 mg oral morphine equivalents/day), or concurrent benzodiazepine use.

Currently there is no reminder to the prescriber that the patient meets these risk factors and that naloxone co-

What does success look like? Include Metrics if applicable

Increase in naloxone prescriptions when certain criteria are met, reduction in overdose risk.

Criteria for CDS

Inclusion Criteria for CDS may include departments, locations, and roles. For ambulatory requests, consider encounter type. For inpatient requests, consider departments and roles.

Considerations for Inclusion

All genders.
History of overdose or current encounter of overdose, history of substance use disorder, higher opioid dosages (≥50 mg oral morphine
equivalents/day existing or prescribed), or concurrent benzodiazepine use should be inclusion criteria for the BPA.

Exclusion Criteria for CDS many involve similar criteria for inclusion but should contain what or who NOT to include in the alert.

Considerations for Exclusion

Exclusion would be current existing naloxone prescription on the medication list.
Considerations for oncology patients, palliative care. Lisa will pursue conversation with Gretchen Roe and an oncology representative.

Alert Specifics

What is the exact wording

Based upon the patient's history or current opioid and benzodiazepine prescription , this patient may be at risk for an

Appendix O: Table of Evidence from Toolkit

Guideline Reference Number	Evidence
5.1 Providers will prescribe opioids based on evidence-based guidelines and in accordance to state law.	**State Law in Michigan** Public Act 246 of 2017 (June 1, 2018) ▪ Must discuss risks of opioids with parent or guardian of minors, including overdose, addiction, danger of mixing, and mental health connection with addiction. ▪ Obtain signature of parent or guardian. If not a parent or guardian, cannot prescribe more than single 72-hour supply to minor. ▪ For adult patients: Must discuss addiction risk, disposal information and that delivery of a controlled substance is a felony under Michigan law. ▪ If patient is pregnant, must disclose risk to fetus. Public Act 248 of 2017 (June 1, 2018) ▪ Before prescribing or dispensing a controlled substance to a patient, a licensed prescriber shall register with MAPS. ▪ Before prescribing or dispensing a patient a controlled substance in a quantity that exceeds a 3-day supply, a licensed prescriber shall obtain and review a MAPS report. Public Act 250 of 2017 (March 27, 2018) ▪ Requires a health professional licensee or registrant that treats a patient for an opioid-related overdose to provide the patient with information regarding substance use disorder services. Public Act 251 of 2017 (July 1, 2018) ▪ A prescriber treating for acute pain shall not prescribe more than a 7-day supply of an opioid within a 7-day period.
5.1.1 Providers should consider non-opioid alternatives prior to starting opioid therapy.	Considerations to be used include: ▪ NSAIDs, TCAs, SNRIs, anti-convulsant medications ▪ Physical therapy, exercise, weight loss ▪ CBT behavioral treatments ▪ Procedures such as intra-articular injections ▪ Ice or heat, elevation, immobilization, rest, relaxation ▪ Also consider treating sleep, depression, anxiety, or mood (avoiding benzodiazepines)
5.2.1. Providers prescribing should consider opioid therapy if the benefits for pain and function outweigh patient risk.	▪ Benefits of long-term opioid therapy for chronic pain is not well supported by the evidence. ▪ Short-term benefits are small to moderate for pain but inconsistent for function. ▪ Insufficient evidence for long-term benefits in lower back pain, headache and fibromyalgia.
5.1.3. Treatment goals should be established with patient prior to starting opioid therapy.	Not all acute pain requires treatment with opioids and it is important to consider that pain varies among patient demographics, cultural/ethnic factors, prior history of alcohol, drug or opioid use, and history of mental health conditions (anxiety and depression). ▪ Opioids should be prescribed in no greater quantity than required for

	expected duration of pain that is severe enough to require opioids. ▪ The goal for acute pain should not be zero pain, but rather tolerable that allows for optimal physical and emotional function.
5.1.4 The risks should be discussed with the patient or the patient's representative prior to and during opioid therapy.	See Michigan Public Health Law 246 of 2017 (above). This takes place in the form of the Start Talking Document at Spectrum Health. ▪ The form should contain the medication name and quantity prescribed. ▪ The consent form should be completed for each opioid medication prescribed and updated annually if the prescription is still active. ▪ Any licensed personnel can have the discussion around opioids with adult patients; pediatrics should be discussed directly with the provider.
5.1.5. Providers should start with the lowest effective dose of short-acting opioids when initiating opioid therapy.	Opioids should be prescribed in the lowest effective dose for the shortest duration necessary. ▪ Taking opioids for acute pain is associated with a greater likelihood of long-term opioid use. ▪ The greater the amount of initial opioid exposure (higher total dose, longer duration of prescription) is associated with risk of long-term use, misuse and overdose.
5.1.6. Before prescribing or dispensing an opioid to a patient, a licensed prescriber shall ask the patient about other controlled substances the patient may be using and document this in the medical record.	The provider should be equipped to deal with a patient presentation and how other medications interfere with the patient's current opioid therapy. Overdose risk is increased when medications are mixed. ▪ Some points to consider: some patients are under the impression that a stimulant medication will offset the effect of opioids but instead these tend to increase risk of overdose. ▪ Alcohol use should be assessed and risk factors of overdose with alcohol and opioids should be discussed. ▪ Having an open line of communication is key with patients who may be on other substances. Taking time to understand the reasons behind their additional substance use as well as their methods may clue the provider into whether this is illicit use or use to better control pain.
5.1.9. Careful assessment of individual benefit and risk should be considered before increasing dosage to >50MME/day and a provider should generally avoid increasing dosage to >90MME/day.	Use extra precautions when increasing to >50MME per day, such as: ▪ Monitor and assess pain and function more frequently ▪ Discuss reducing dose or tapering and discontinuing opioids if benefits do not outweigh the harms. ▪ Offer naloxone (see 5.1.10). **How much is 50 or 90 mmEQ/day for commonly prescribed opioids?** <u>50mmEQ/day</u> 50mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300). 33 mg of oxycodone 2 tablets of oxycodone sustained-release 15mg) 12 mg of methadone (<3 tablets of methadone 5mg) <u>90mmEQ/day</u> 90mg of hydrocodone (9 tablets of hydrocodone/acetaminophen 10/325) 60mg of oxycodone (2 tables of oxycodone sustained release 30mg) 20 mg of methadone (4 tablets of methadone 5mg)
5.1.10. Co-prescription of naloxone will	Project Lazarus reduced 80% of overdose deaths from prescription

be prescribed for any of the following patient situations: ▪ History of overdose ▪ SOAPP score >14 ▪ ORT Score >8 ▪ MME >50mmEQ/day	medication overdose in primary care sites of western North Carolina. The method used was to identify patients at high risk for overdose death and to provide them with access to naloxone education and a prescription for the medication. *Naloxone Priority Groups and Risk Factors for Opioid Overdose include (among others, see naloxone resources):* ▪ Recent medical care for opioid overdose/intoxication/poisoning ▪ High-dose opioid prescription
5.1.11. Concurrent use of benzodiazepines, sedative-hypnotics, or barbiturates should generally be discouraged. Every effort should be made to taper therapy.	According to the Lazarus project data, any patients concurrently using alcohol, benzodiazepines, or anti-depressants are included in the risk factor group for overdose. <u>Additional factors included</u>: smoking, COPD, lung disease, sleep apnea or respiratory system disease, renal or hepatic disease, and remoteness from or difficulty accessing medical care.
5.1.12. Patients with opioid use disorder should be treated using evidence-based medication assisted treatment in combination with behavioral therapies.	Approaching substance use disorder as a chronic illness can help providers deliver care that helps patients stabilize, achieve remission of symptoms and establish and maintain recovery.
5.2. Patients receiving >60 tablets of an opioid prescription in a 90-day period will require: ▪ Office visit at least every 3 months with the prescribing provider to assess pain and function using a validated tool. ▪ Clinically meaningful improvements in pain and function compared to start of treatment should be evident for continued prescribing. ▪ Provider should evaluate the benefits and risk of continuing therapy if meaningful improvements have not been seen in pain and/or function. ▪ If benefits do not out-weight the risk, the provider should consider a lower dose, taper to discontinue or seek alternative treatment option. ▪ Validation of patient risk of addiction to prescription opioids should occur at least annually using a validated tool. ▪ Routine urine drug screen based on patient risk category or	<u>Visit Quantity:</u> Regular visits allow the provider to assess for pain and function, as well as to review risk factors for misuse or diversion. <u>Screening Tools</u> ▪ Epic provides the ability to assess pain and function using some of the approved scales for documentation. Validation of specificity and validity of each scale has been validated in the literature and can be useful in discussion and goal setting with the patient. ▪ Discussion around meaningful improvement in therapy should be an ongoing discussion between the patient and provider. ▪ Signs that the patient may not be having meaningful improvement may be evidenced in the following: no attempts to increase in physical function, continually not meeting mutually set goals, missing clinic appointments, etc. The discussion over tapering medications and changes in therapy can be a gradual adjustment and discussion with the patient. Identifying goals with the patient ahead of time can help prepare them for the time that tapering, or discontinuation may occur. Identifying with the patient that there MUST be clinically evident improvement in their care before prescribing additional opioids should occur at the initial discussion around goals for pain and function. Both the patient and provider should be an active partner in ensuring safety for opioid prescribing, understanding and reducing risk for overdose and continued assessment of needs.

<table>
<tr><td>provider discretion (see suggested criteria).</td><td><u>Urine drug Screen Risk Categories</u>

<table><tr><td>Risk Category</td><td>Definition of Risk</td><td>Screening Frequency</td></tr><tr><td>Low</td><td>ORT Score 0-3
SOAPP 0-7</td><td>Annually</td></tr><tr><td>Medium</td><td>ORT Score 4-7
SOAPP 8-10</td><td>1-2 times per year</td></tr><tr><td>High</td><td>ORT Score 8+
SOAPP 11+</td><td>2-4 times per year</td></tr></table></td></tr>
<tr><td>5.3. Opioid therapy prescriptions are prescribed as a trial or test, where the decision to continue therapy is made at a minimum of every three months throughout treatment.</td><td>Just like prescribing medications for any condition, prescribing opioid medications should occur on a trial basis. Education to the patient should include how the trial will work, including expectations for use of the medications and goal setting should occur at the onset of the opioid prescription.</td></tr>
<tr><td>5.4.4. Active signed controlled substance agreement if patient received >60 tablets in a 90-day period.</td><td>Controlled substance agreements are documents that contain statements to ensure patients understand their role and responsibilities regarding their treatment, the conditions under which their treatment may be terminated, and the responsibilities of the health care provider.

They can help facilitate communication between patients and the provider. The provider should explain that the primary reason to start a pain contract is to keep the patient safe.</td></tr>
<tr><td>5.4.5. Opioid prescriptions will be written as a 28-day supply for ongoing opioid therapy. Three consecutive prescriptions, each for a 28-day supply may be prescribed. All three prescriptions must be dated with the date the prescriptions are written (i.e. no pre- or post-dating) and may include direction to not fill until a certain date).</td><td>Prescribing more opioid than necessary can result in leftover pills, which are then available for diversion and inappropriate use.
Among those who abuse opioids, over 70% obtain them through diversion and another 40-50% obtain them through family or friends with left over pills.
Per the opioid contract, a patient is not to fill their prescription early unless there is explicit discussion and validation from their provider.
The patient should be notified of these guidelines and every attempt should be made to address any concerns.</td></tr>
<tr><td>5.5. The prescribing provider can discontinue OR taper the opioid prescription if the patient violates the controlled substance agreement. Discontinuation should be carefully assessed by the prescribing provider to ensure the opioid therapy is discontinued safely based on evidence-based treatment. Violation of the</td><td>Physicians should be equipped to deal with patients who are found to be misusing opioid medications. Possible responses might include:
Education and discussion along with restatement of the written agreement
Review of the written opioid agreement
Discussion with others involved in the patient’s care
Change in the amount or type of medication dispensed
Discussion on whether the patient should seek consultation with pain and/or addiction specialist</td></tr>
</table>

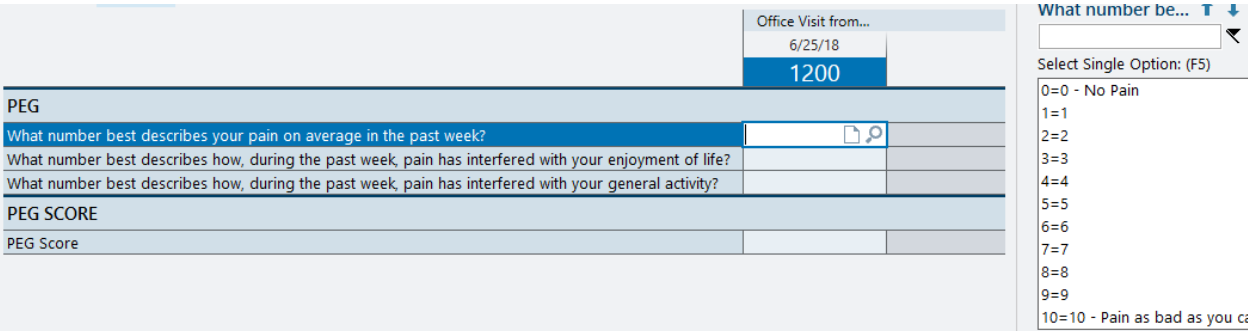
controlled substance agreement does not solely justify a discharge from the practice.	▪ More frequent clinic visits ▪ Instituting regular or random urine drug testing for prescription renewal

Appendix P: Screening Tools

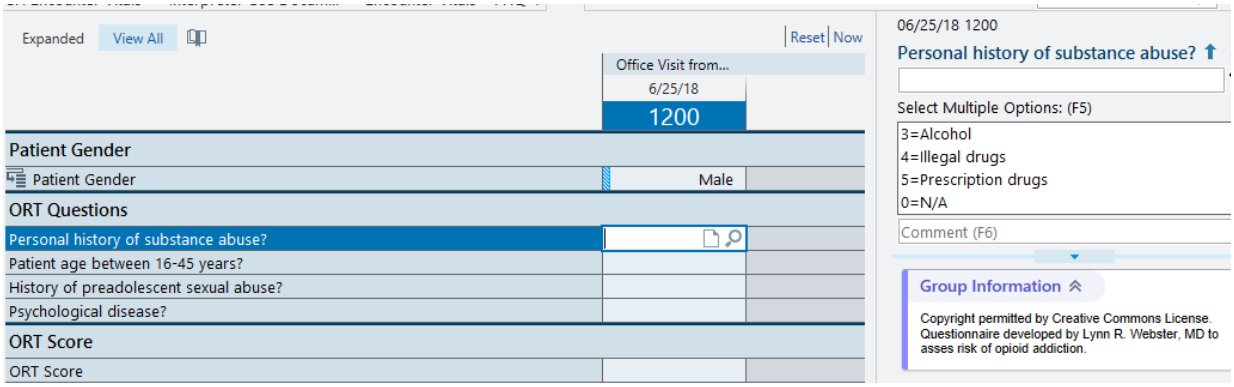
Patient Assessment Tools

The following tools have been adopted by the site and can be found in the EHR as flowsheets.

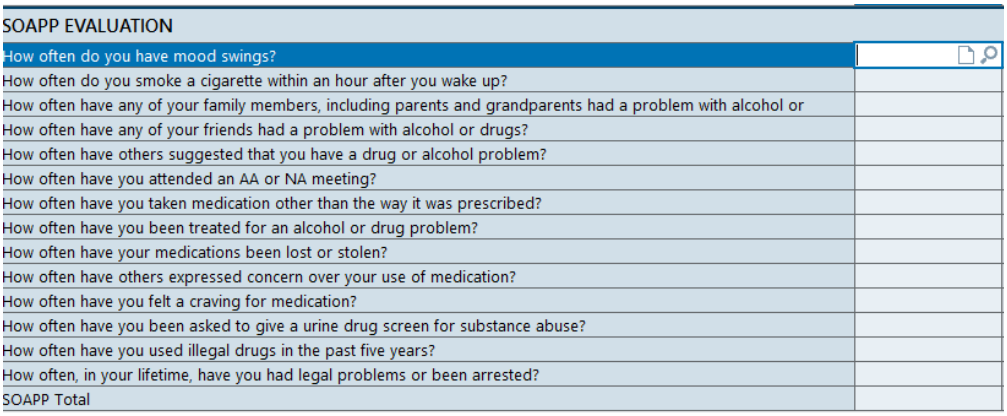
Pain Enjoyment and General Activity (PEG)



Opioid Risk Tool



SOAPP



Appendix Q: Naloxone Resources from Toolkit

PROJECT LAZARUS

Risk Factors for Opioid-Induced Respiratory Depression

If you are considering the possibility of prescribing or refilling an opioid prescription, please conduct a medical assessment that includes reviewing all potential risks to determine if the patient is at an increased risk of Opioid-Induced Respiratory Depression or overdose. Please also consider using the SBIRT-AUDIT and DAST-10 forms during the medical assessment. If you determine that your patient is at-risk, yet still needs to receive an opioid prescription, please provide the patient with a Naloxone Rescue Kit and a prescription for naloxone that can be filled at a local pharmacy.

Persons are at risk of Opioid-Induced Respiratory Depression if they have/had a(n):

1. Recent emergency medical situation for opioid poisoning and/or intoxication.
2. Suspected history of illicit or non-medical opioid use.
3. Prescription for a high dose opioid of greater than 100mg of morphine equivalent per day.
4. Methadone prescription (specifically, opioid naïve patients).
5. Recent release from incarceration.
6. Recent release from an opioid detox or mandatory abstinence program.
7. Enrolled in a methadone or buprenorphine detox and/or maintenance program for addiction or pain.
8. Voluntary request from patient or family member.
9. Difficulty accessing EMS due to distance, remoteness, etc.

Persons are at risk of overdose if there is a combination of prescription opioids with any of the following:

1. Smoking, COPD, emphysema, asthma, sleep apnea, or another respiratory diagnosis.
2. Renal dysfunction or hepatic disease.
3. Known or suspected concurrent alcohol use.
4. Concurrent benzodiazepine prescription.
5. Concurrent SSRI or TCA anti-depressant prescription.

Appendix R: Budget

Evidence Based Toolkit: Initial Budget	
Expenses	
Project Manager (RN) Donation for education and support	$1,230.00
Data Analyst (Donation)	$216.00
Statistician (Donation)	$122.00
Color Printed Educational Fliers	$25.00
Binder and paper	$25.00
RN education Time	$33.00
Medication Assistant Education Time	$130.00
Physician, NP and PA Education Time	$1,076.00
Clinical Nurse Specialist Time	$49.00
Project Mentor Time	$99.00
Total:	$3,005.00
Revenue	
Project Manager Donation for education and support	$1,230.00
Data Analyst (Donation)	$216.00
Statistician (Donation)	$216.00
Overdose death prevention	10 overdose patients in surrounding counties per year $1917.00 x33 (ED) = $63,261 =$632.610. $10,000 (inpatient) x10 =$110,000 per person x 10 1,100,000.00
Total	$1,101,662.00

Total Operating Income: $1,090,657.00.

Appendix S: Checklists and Pocket Cards from Toolkit

Check List for Prescribing Opioids for Primary Care Providers Treating Adult Patients with Chronic, non-cancer, non-palliative pain.

___ Set realistic goals for pain and function based on diagnosis

___ Check that non-opioid therapies have been tried and optimized

___ Discuss risk and benefits with Start Talking document concepts. Even if the patient is not a new opioid user, the discussion should still occur.

___ Initiate opioid use contract or start talking as needed.

___ Elevate risk of harm or misuse, including risk factors of overdose

___ Risk factors with the patient

___ Check PMPD data

___ Check urine drug screen

___ Set criteria for trial of medication and reassessment goals (1-4 weeks)

___ Assess baseline pain and function using scale (i.e. PEG)

___ Prescribe at lowest possible dose for shortest duration.

Centers for Disease Control Evidence

- Benefits of long-term opioid therapy for chronic pain is not well supported by the evidence
- Short-term benefits are small to moderate for pain but inconsistent for function.
- Insufficient evidence for long-term benefits in lower back pain, headache and fibromyalgia.

Non-Opioid therapies

*To be used alone or in combination with opioids, as indicated.

- NSAIDs, TCAs, SNRIs, anti-convulsants
- Physical therapy, exercise, weight loss
- CBT behavioral treatments
- Procedures such as intra-articular injections

Risk Factors for Misuse

- Illegal drug use including prescription drug use for nonmedical reasons
- History of SUD or overdose
- Mental health conditions
- Sleep disordered breathing
- Concurrent benzodiazepine use.

Tips for Re-Assessment During Return Visit

___ Assess pain and function using same scale as previous. Compare to baseline.

___ Evaluate for harm or misuse:

- Over-sedation: consider tapering dose
- PDMP data
- Discuss use of medications and assess for aberrant behaviors

___ Check that non-opioid therapies have been optimized

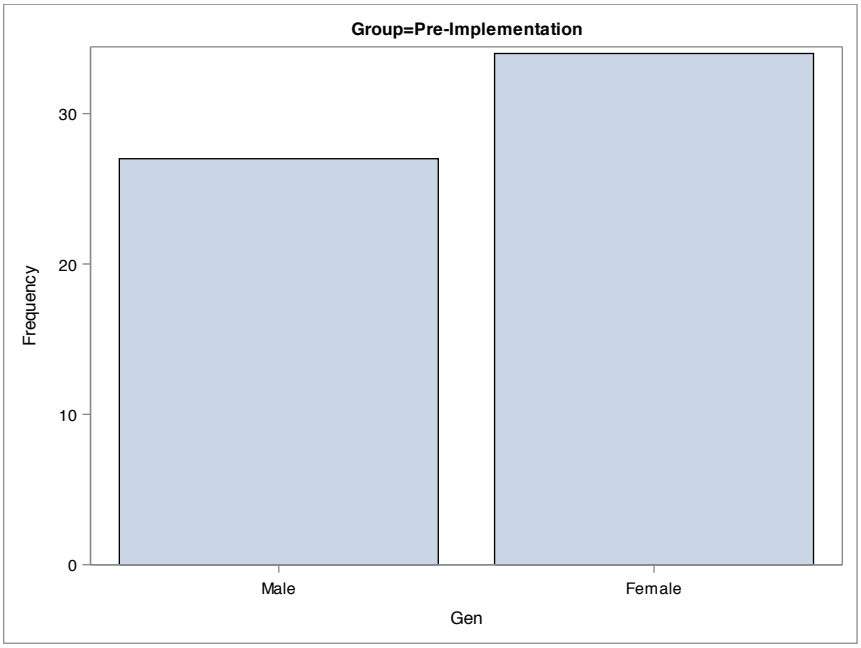
___ Calculate opioid dosage morphine milligram equivalent (MME)

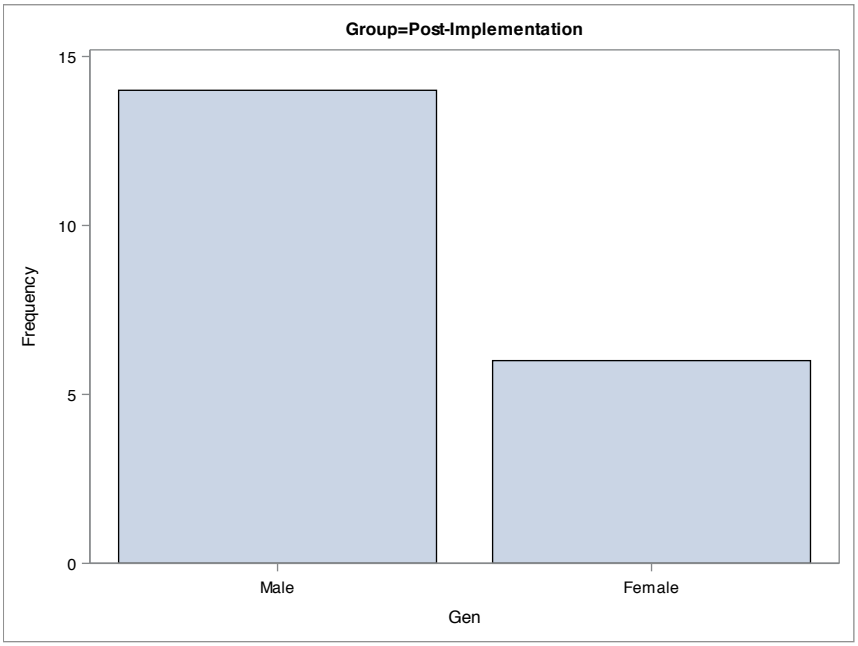
- If $\geq$ 50MME/day total, increase frequency of follow up and consider adding naloxone as a co-prescription
- If $\geq$90MME/day total, co-prescribe naloxone and justification is necessary along with consideration of specialist referral.

___ Determine next steps: continue, adjust, taper or stop opioids

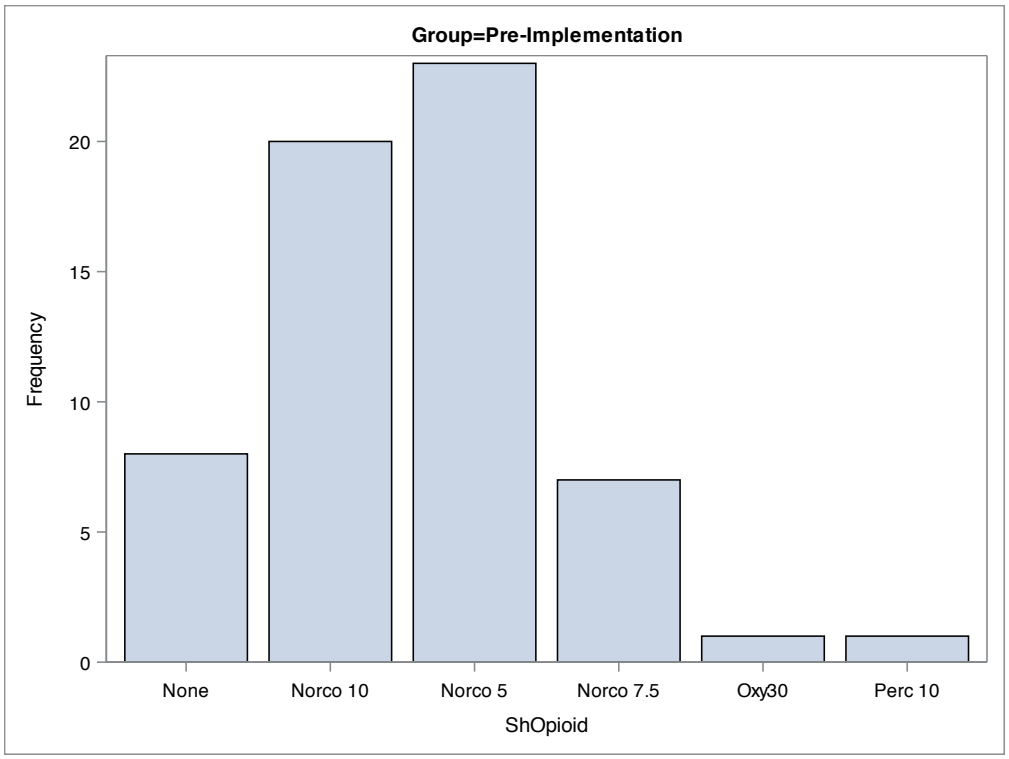
___ Schedule regular reassessment intervals ($\leq$3months)

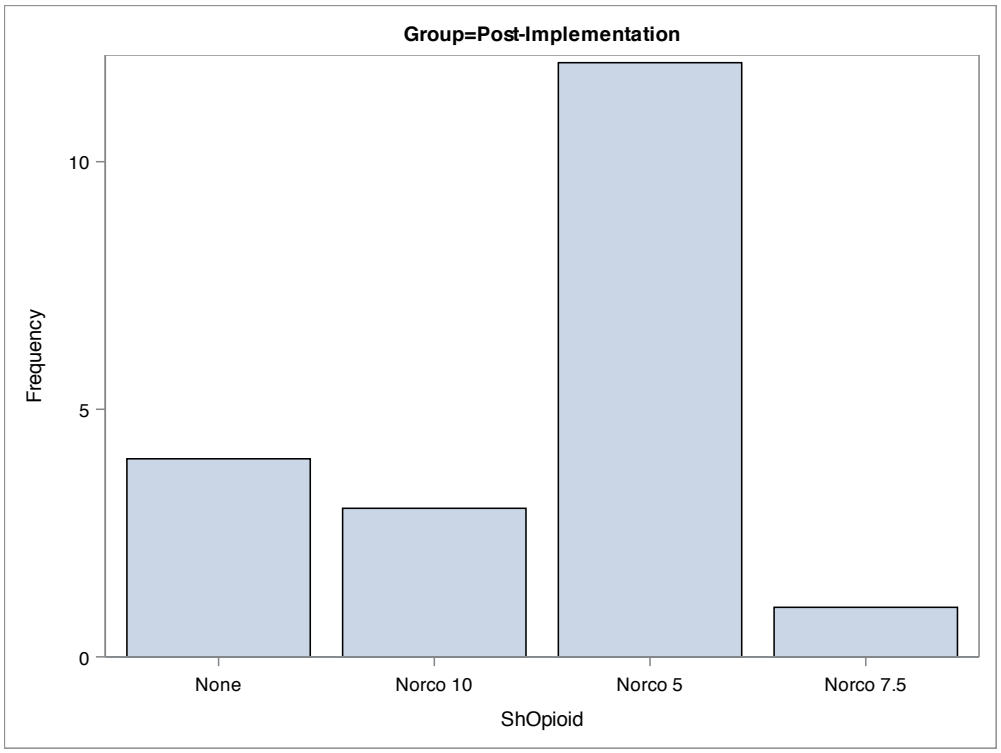
Appendix T: Gender Frequencies for Data Collection



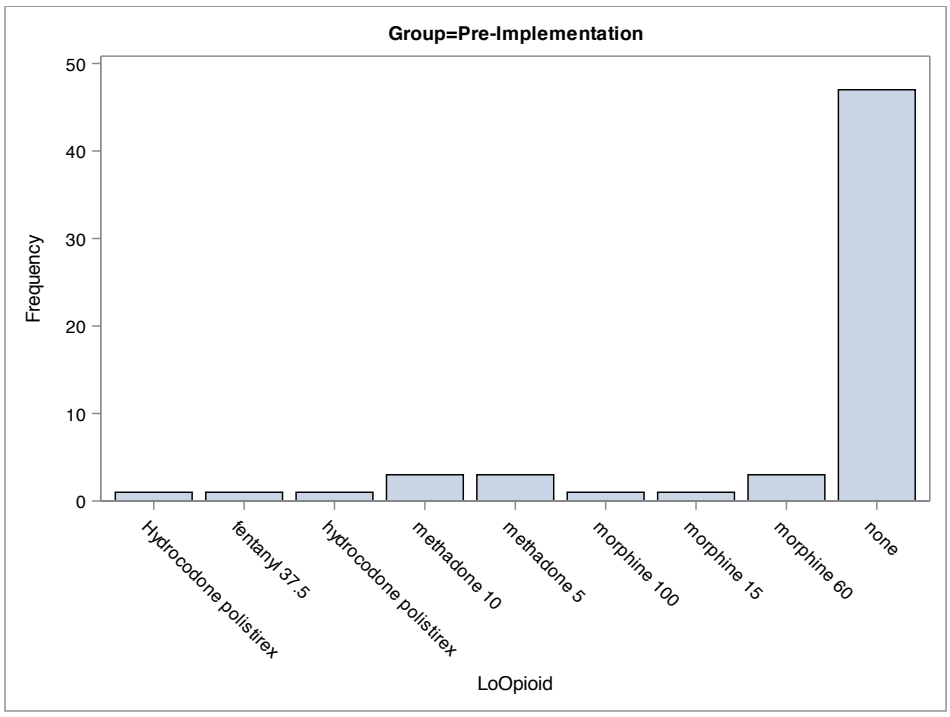


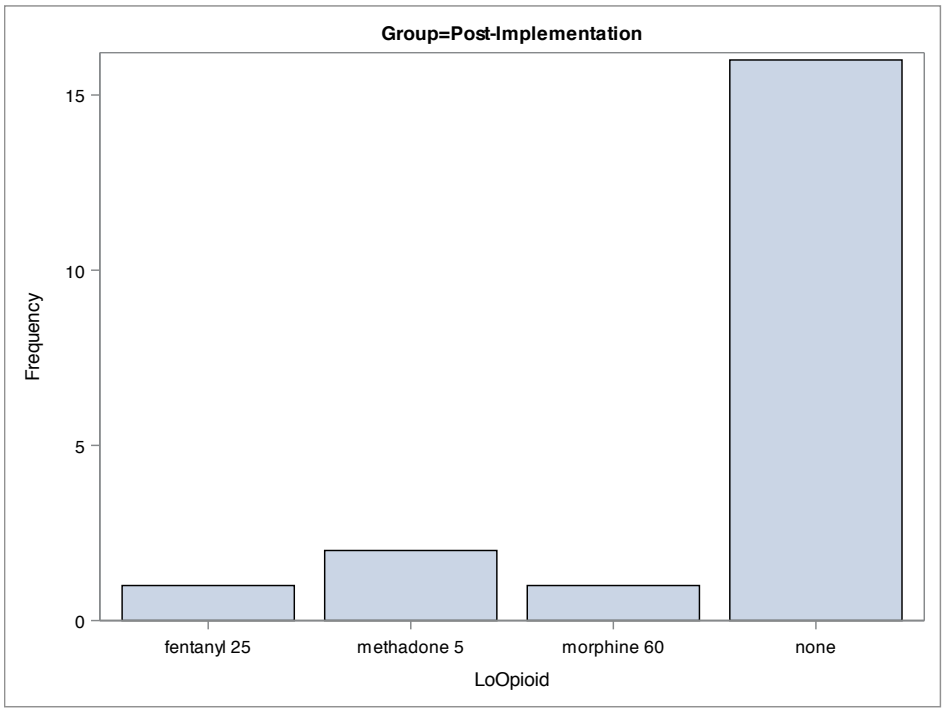
Appendix U: Short Acting Opioid Frequencies



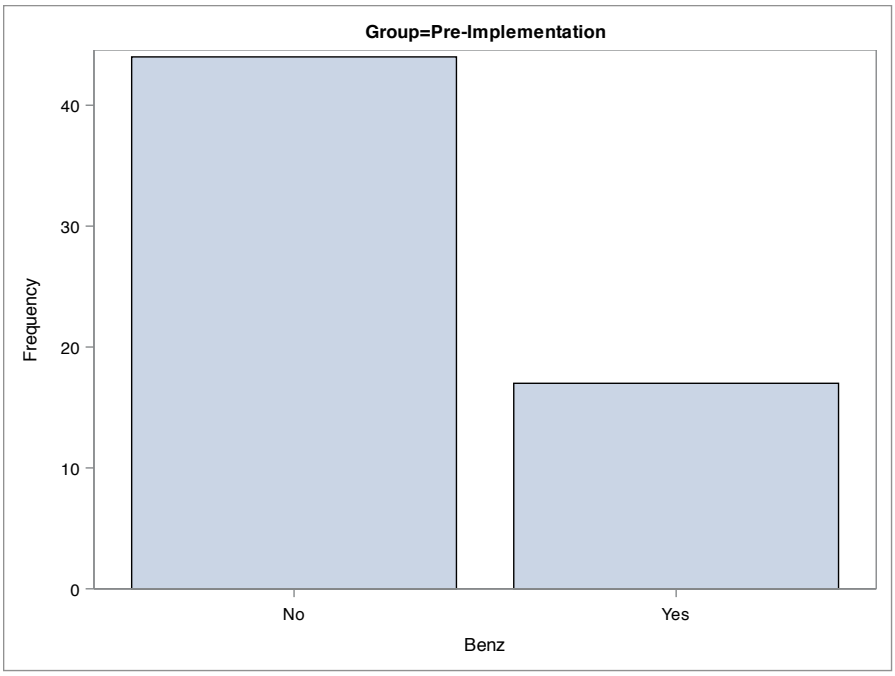


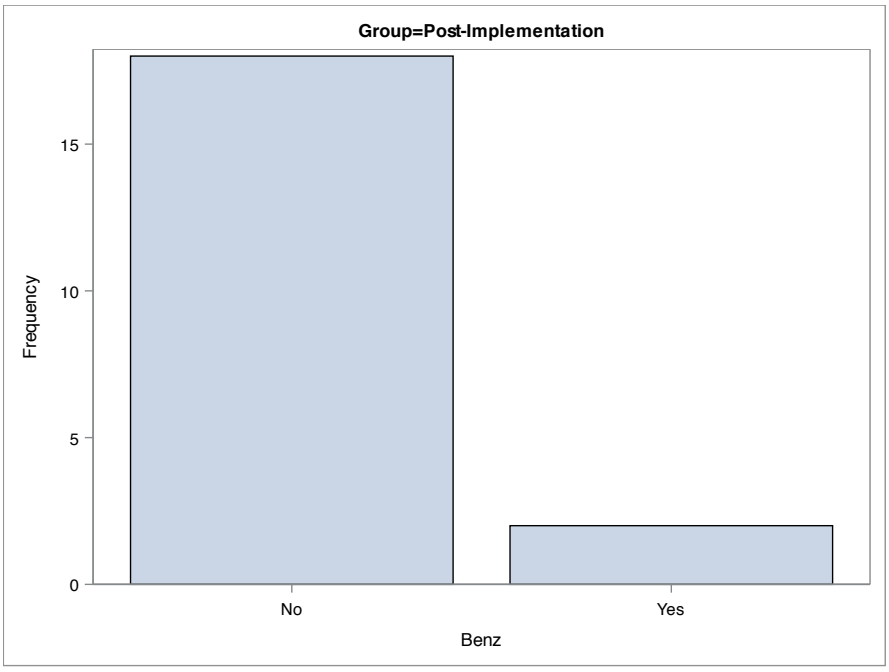
Appendix V: Long Acting Opioid Frequencies



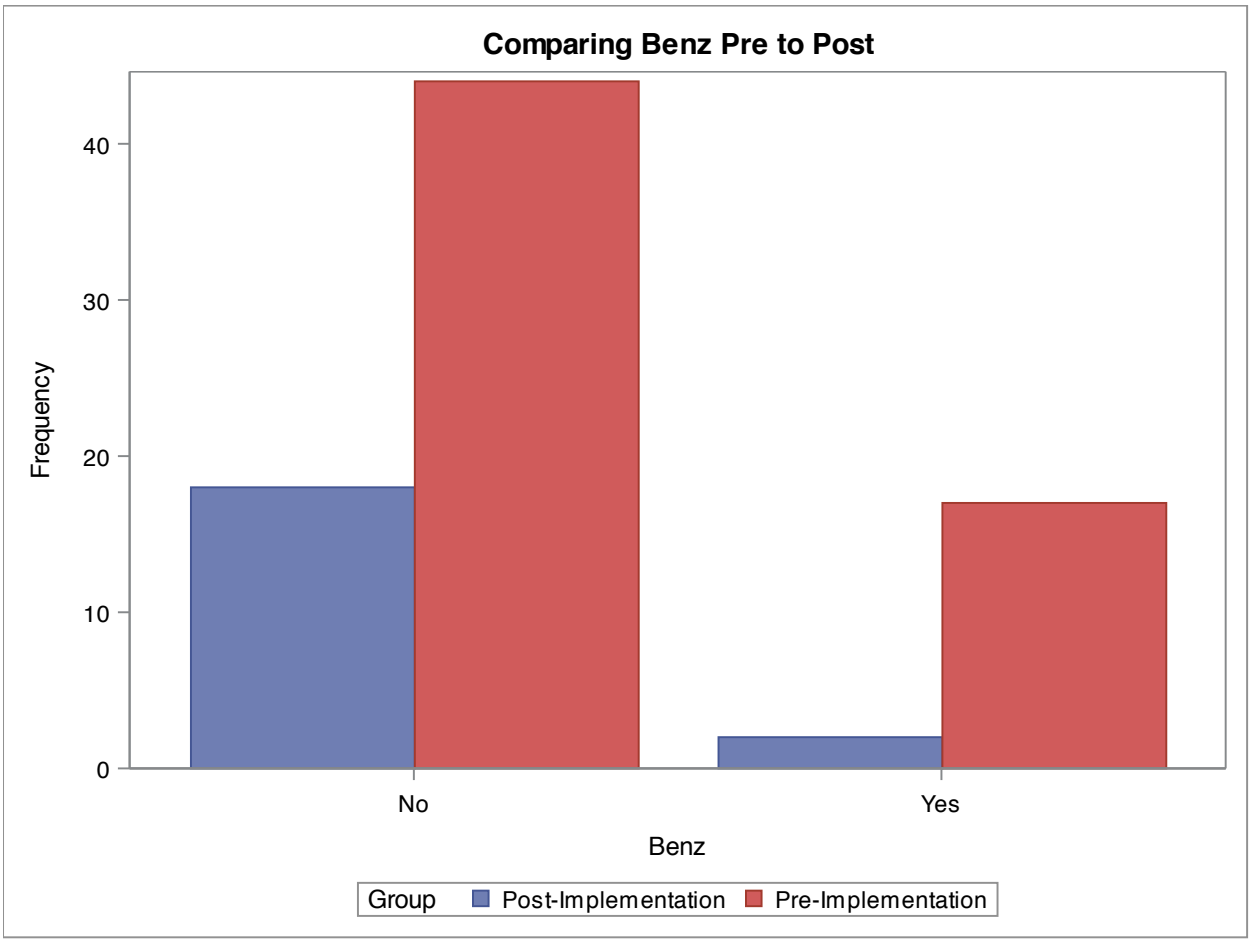


Appendix W: Benzodiazepine Presence Frequencies

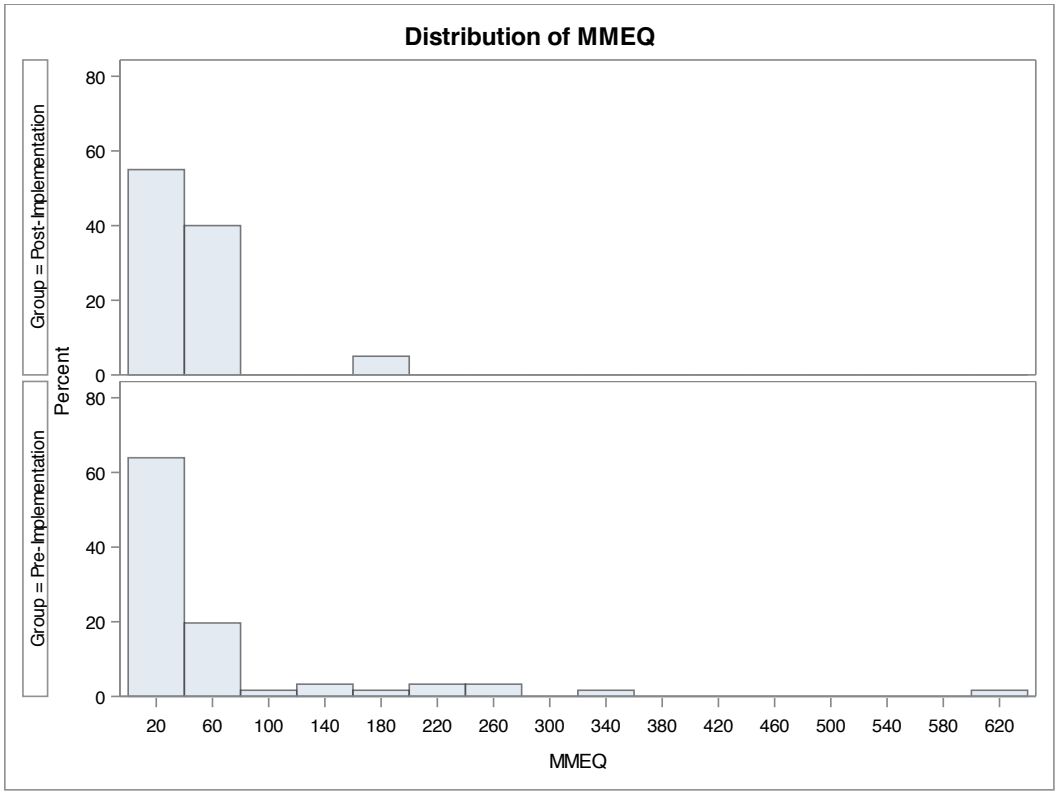


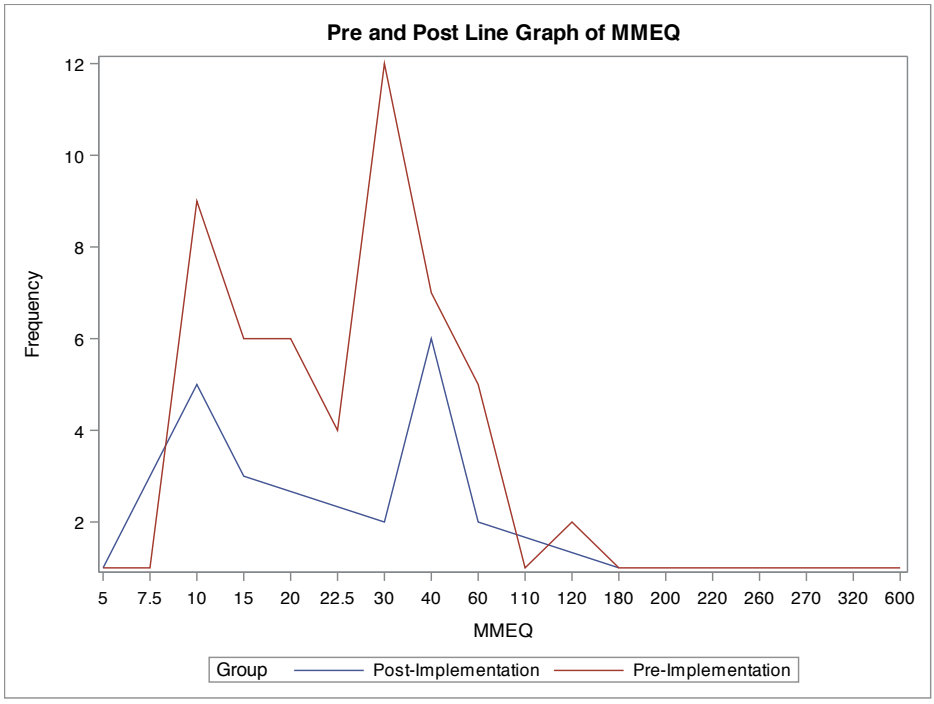


Appendix X: Benzodiazepine Pre-and Post-Comparisons

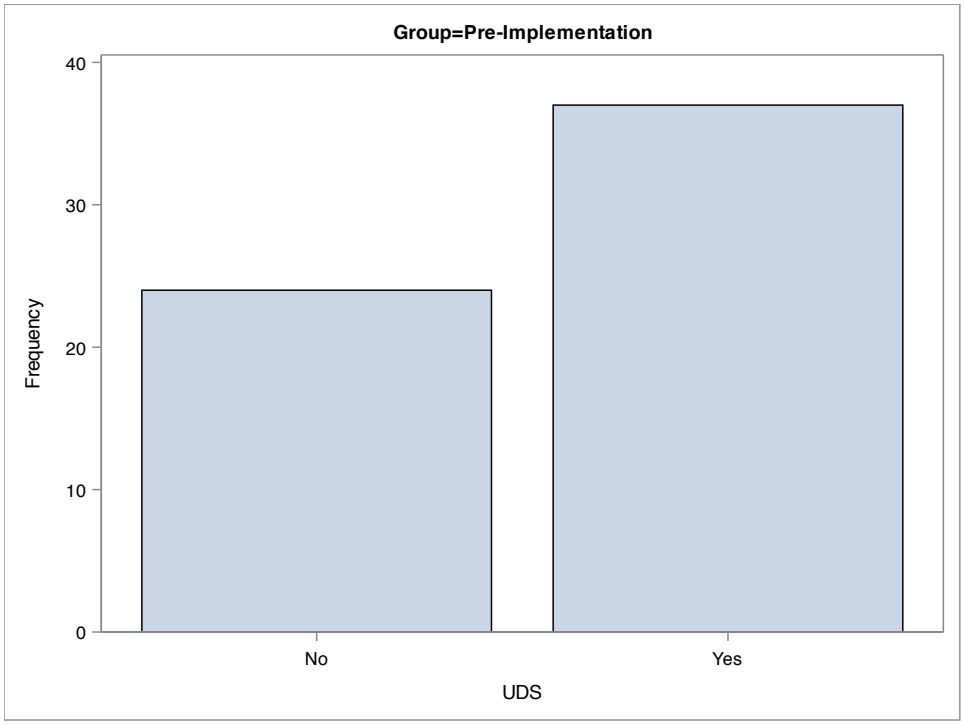


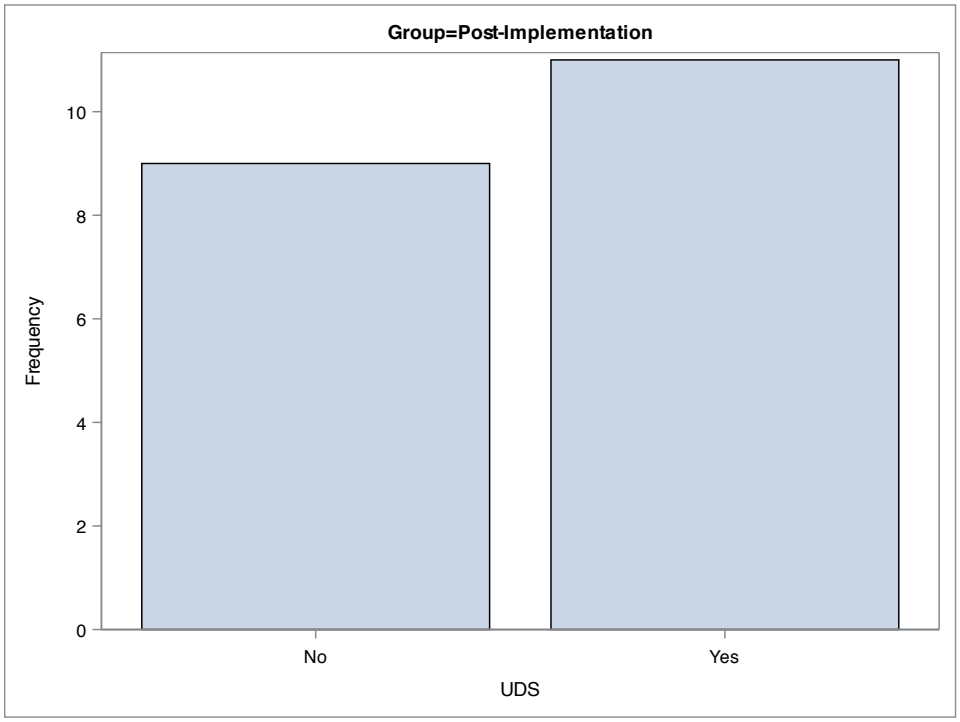
Appendix Y: Morphine Mill- Equivalence Pre-and Post-Distributions



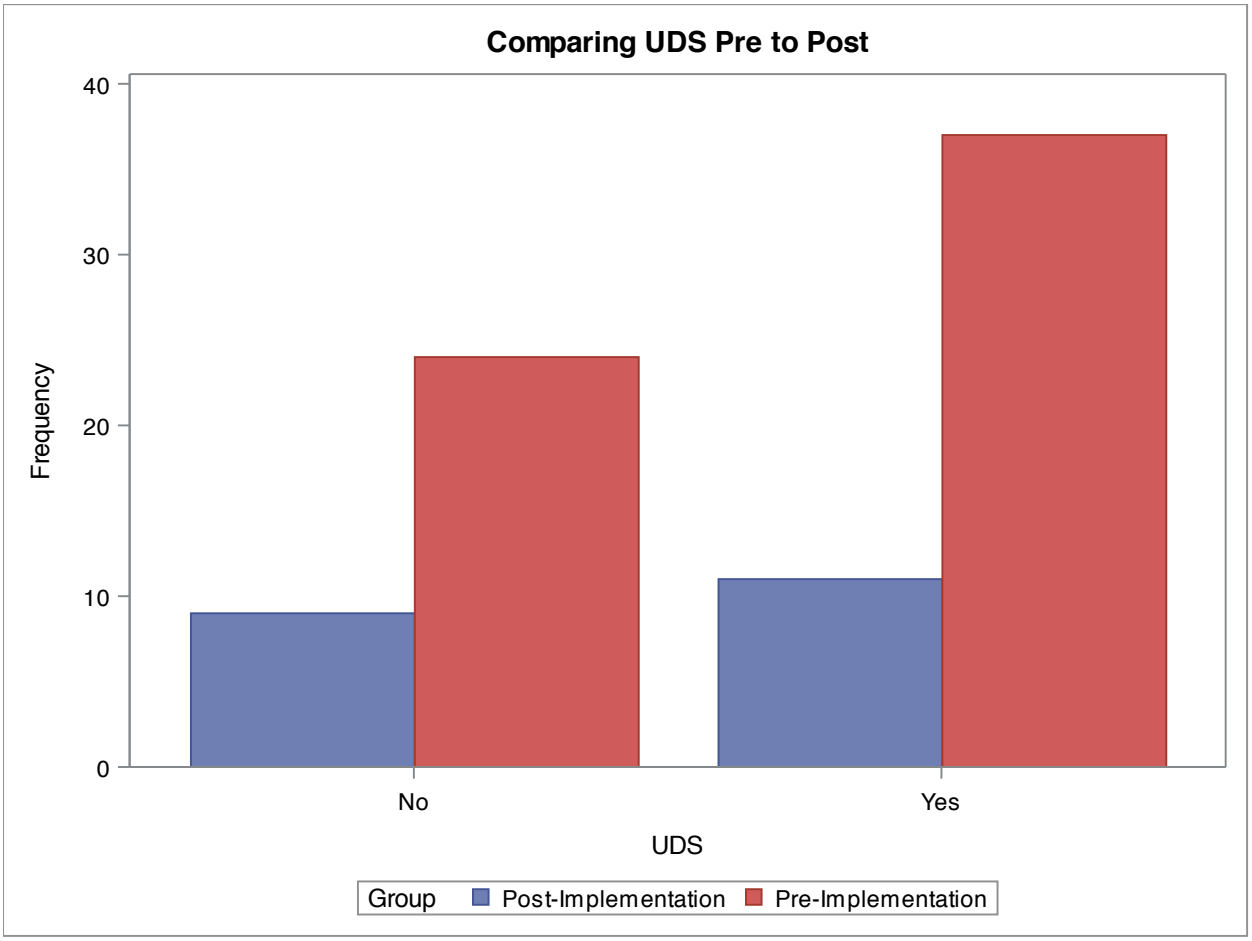


Appendix Y: Urine Drug Screen Frequencies

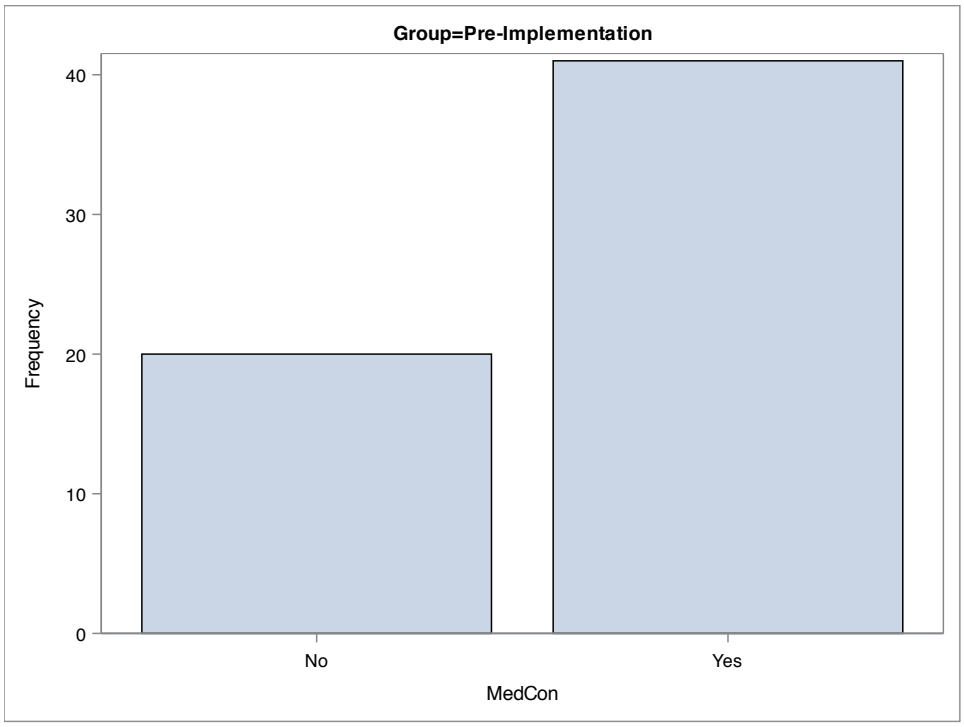


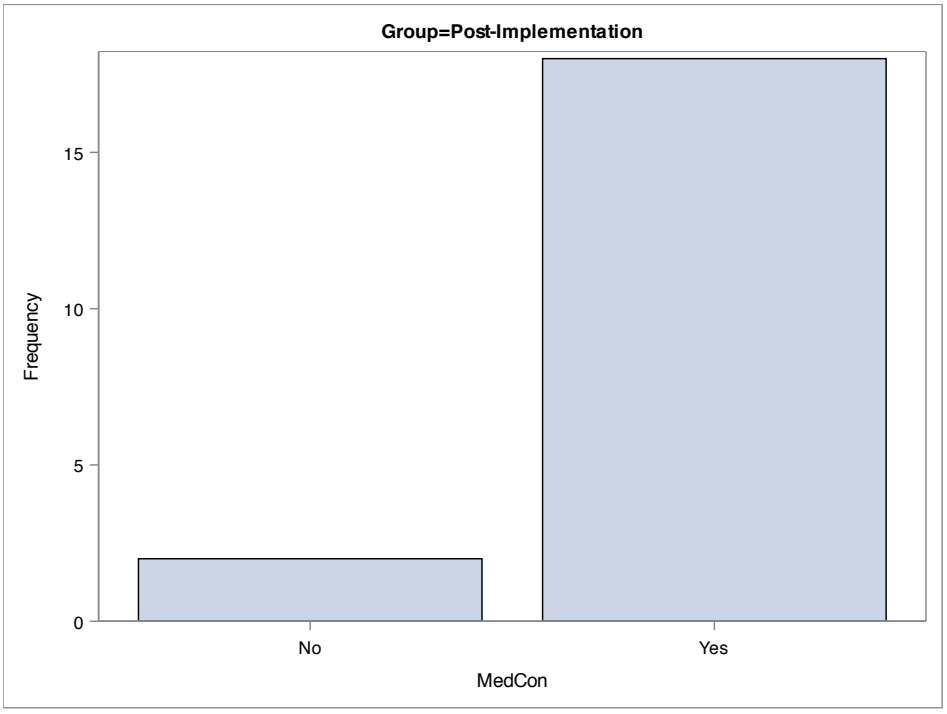


Appendix Z: Urine Drug Screen Pre- and Post Implementation Comparisons

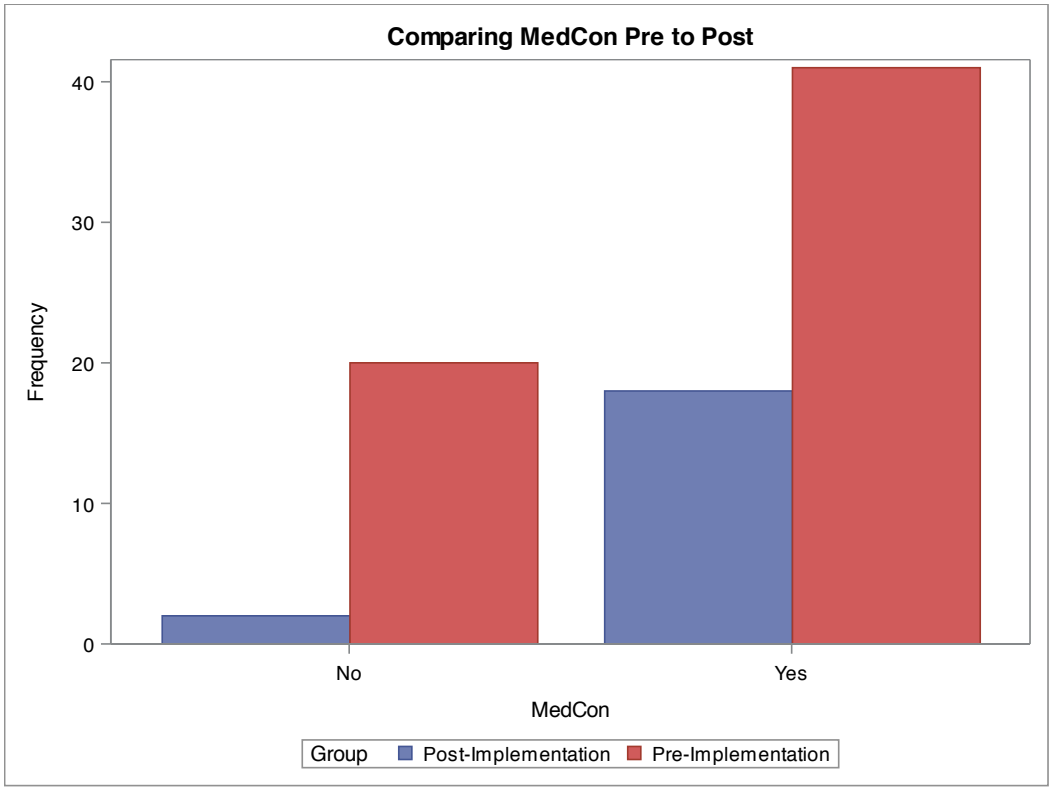


Appendix AA: Medication Contract Frequencies

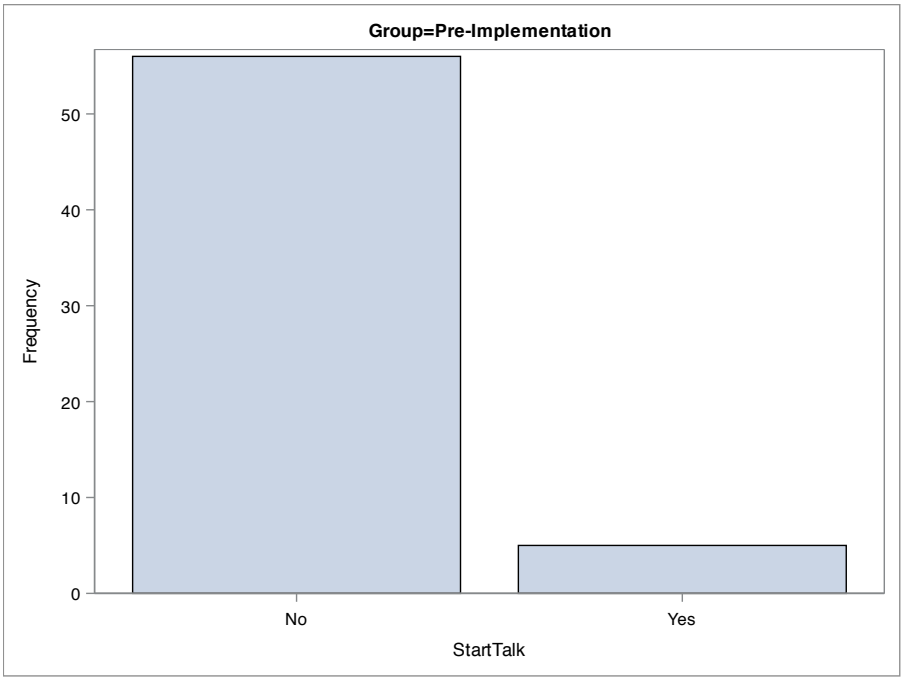


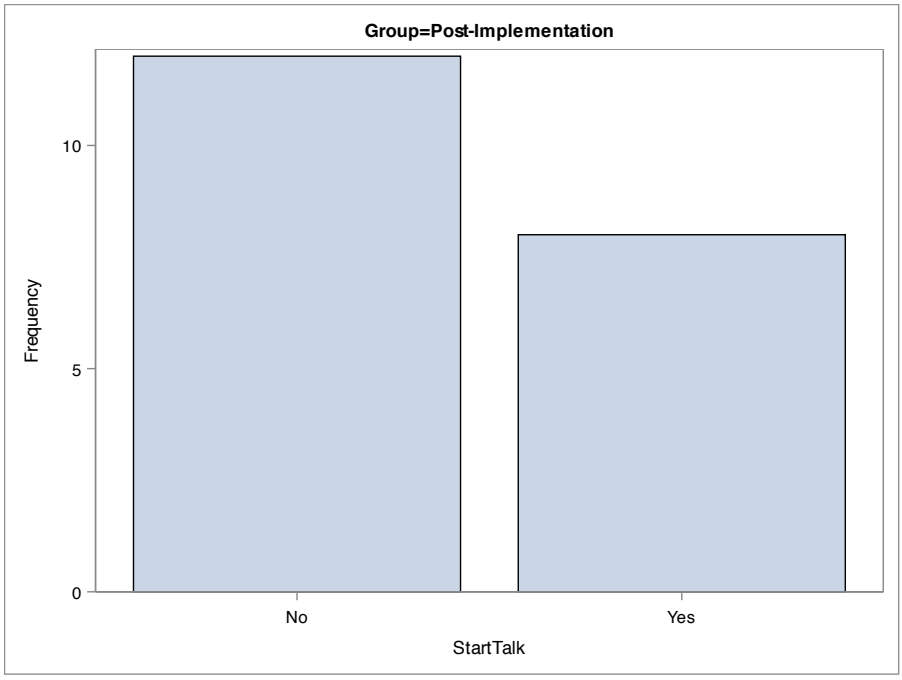


Appendix BB: Medication Contract Pre- and Post Implementation Comparisons

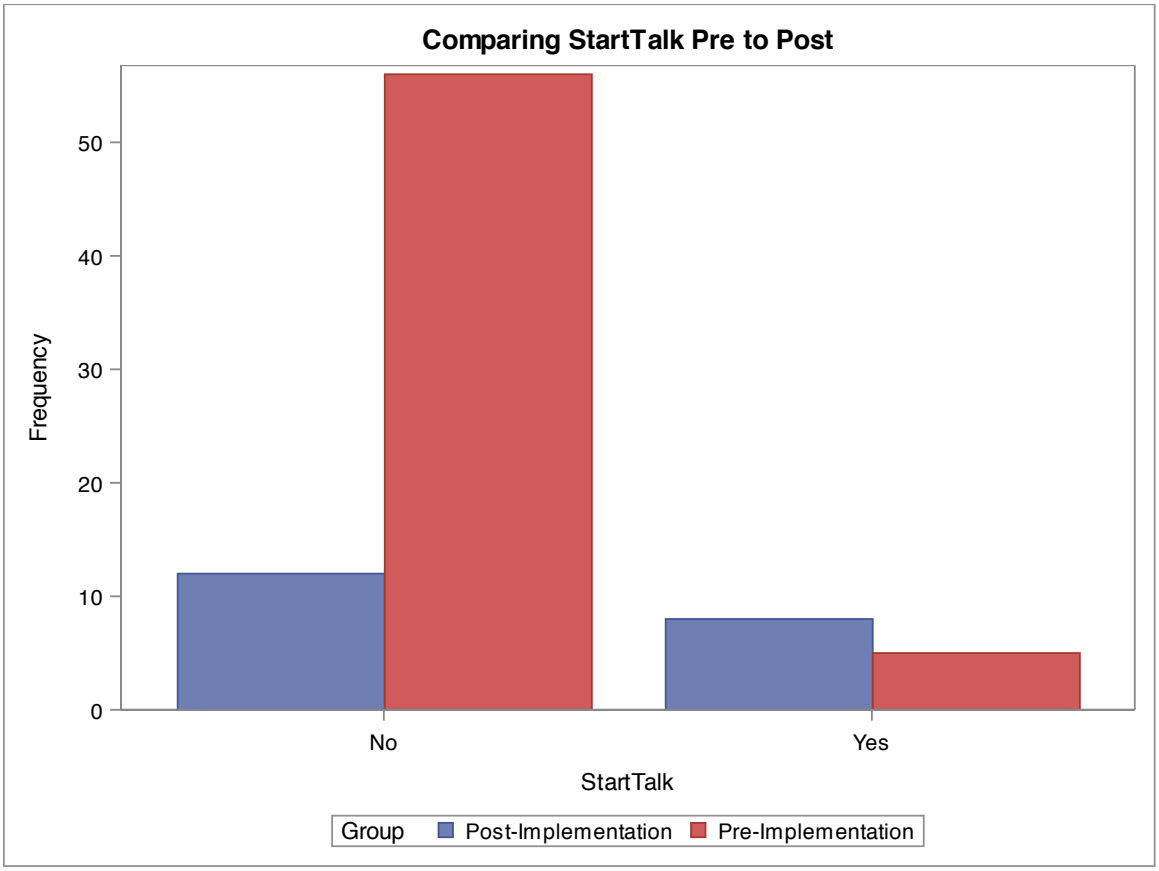


Appendix CC: Michigan Start Talking Form Frequencies

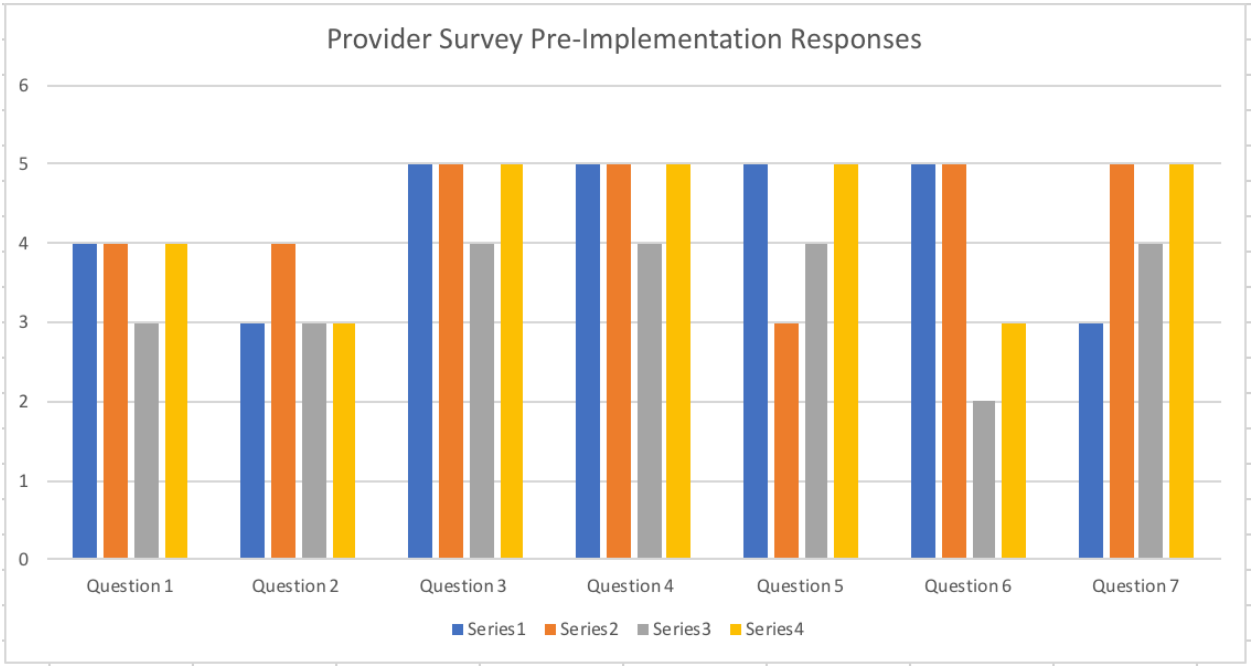


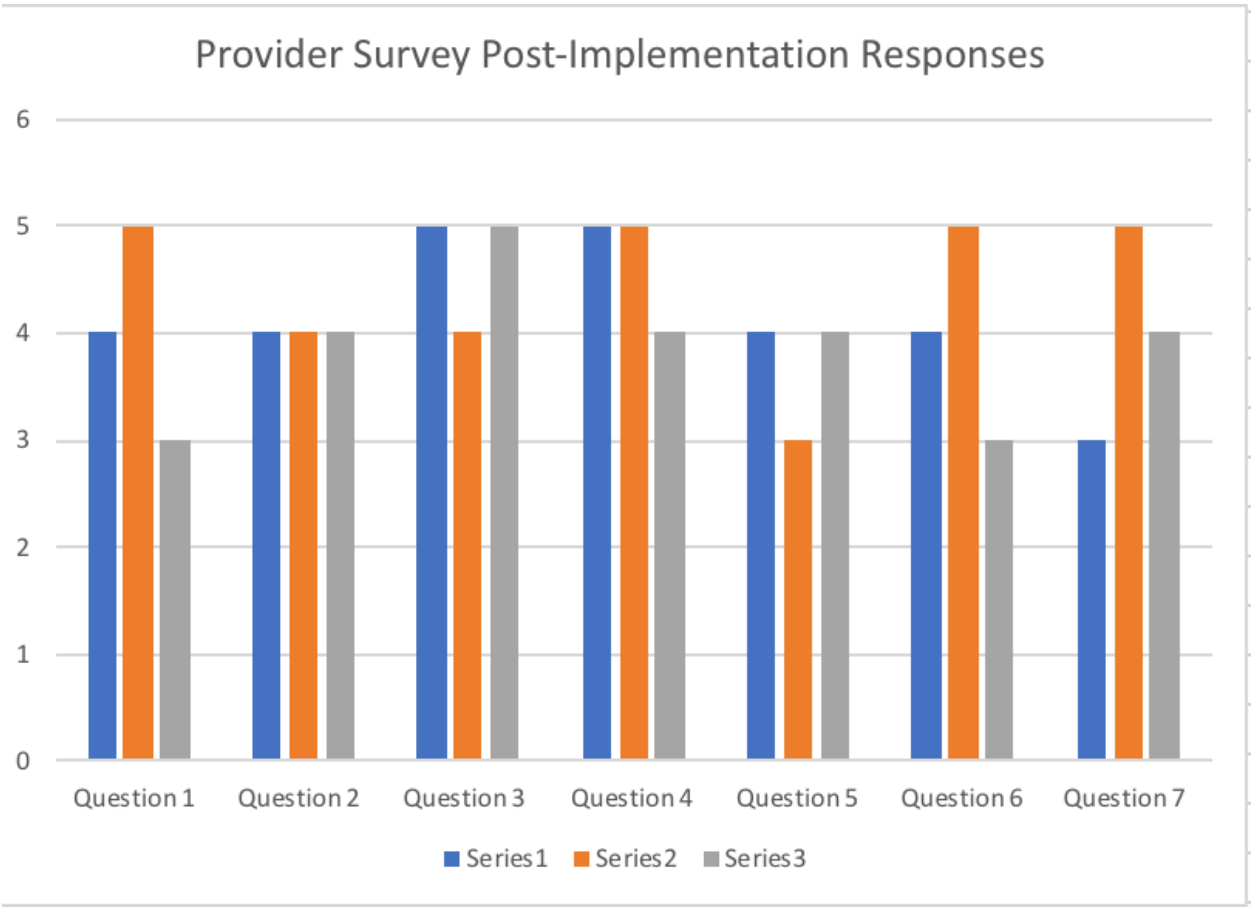


Appendix DD: Michigan Start Talking Form Pre-and Post-Implementation Comparisons



Appendix EE: Provider Survey





Evidence-based Toolkit for Reduction of Overdose Risk in Primary Care Patients on Opioid Therapy

Katelin Aris

DNP Project Proposal Defense

April 1, 2019

Acknowledgements

Primary Mentor: Dr. Tricia Thomas
Secondary Reader: Dr. Karen Burritt
Site Mentor: Dr. Caroline Ring

Objectives for Presentation

1. Introduce the background information and prevalence of opioid prescribing and overdose deaths in the state of Michigan.
2. Identify and examine the clinical problem.
3. Outline the quality improvement initiative and implementation plan that took place.
4. Discuss results and limitations.
5. Outline dissemination plan, sustainability and reflect on DNP essentials.

Introduction

- More than 7.8 million patients received over 103 million opioid prescriptions over the course of a 5-year review in Michigan
- Resulted in over 5,000 opioid overdose deaths.
- Increased availability of prescription drugs, along with misconceptions around safety of prescribed medications has led to growth of prescription drug users and mis-users.

Introduction

- Michigan is one of the highest ranked states in the nation for prescribing of opioid pain relievers.
- Almost 60% of opioid overdose deaths had a prescription filled for hydrocodone within the last 30 days.
- There has been a 100% increase in opioid deaths from 2010-2016 and Michigan is ranked 7th in the nation.

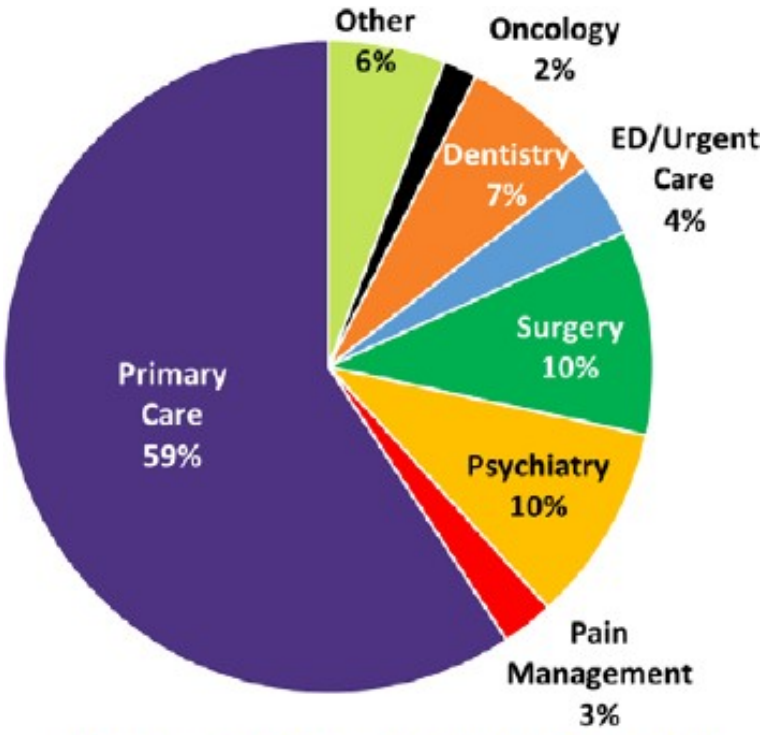
Introduction

1st Narcotic Prescription

- Primary Care: 42.9%
- Surgery: 15.8%
- ED/Urgent Care: 14.3%
- Dentistry: 16.1%

- Average age: 45.7 years
- 10.9% of patients had a narcotic prescription before the age of 20.

- Among patients whose ***first*** narcotic was written between 2014-2015, those who died of overdose death were prescribed narcotics only 8 months prior to death.



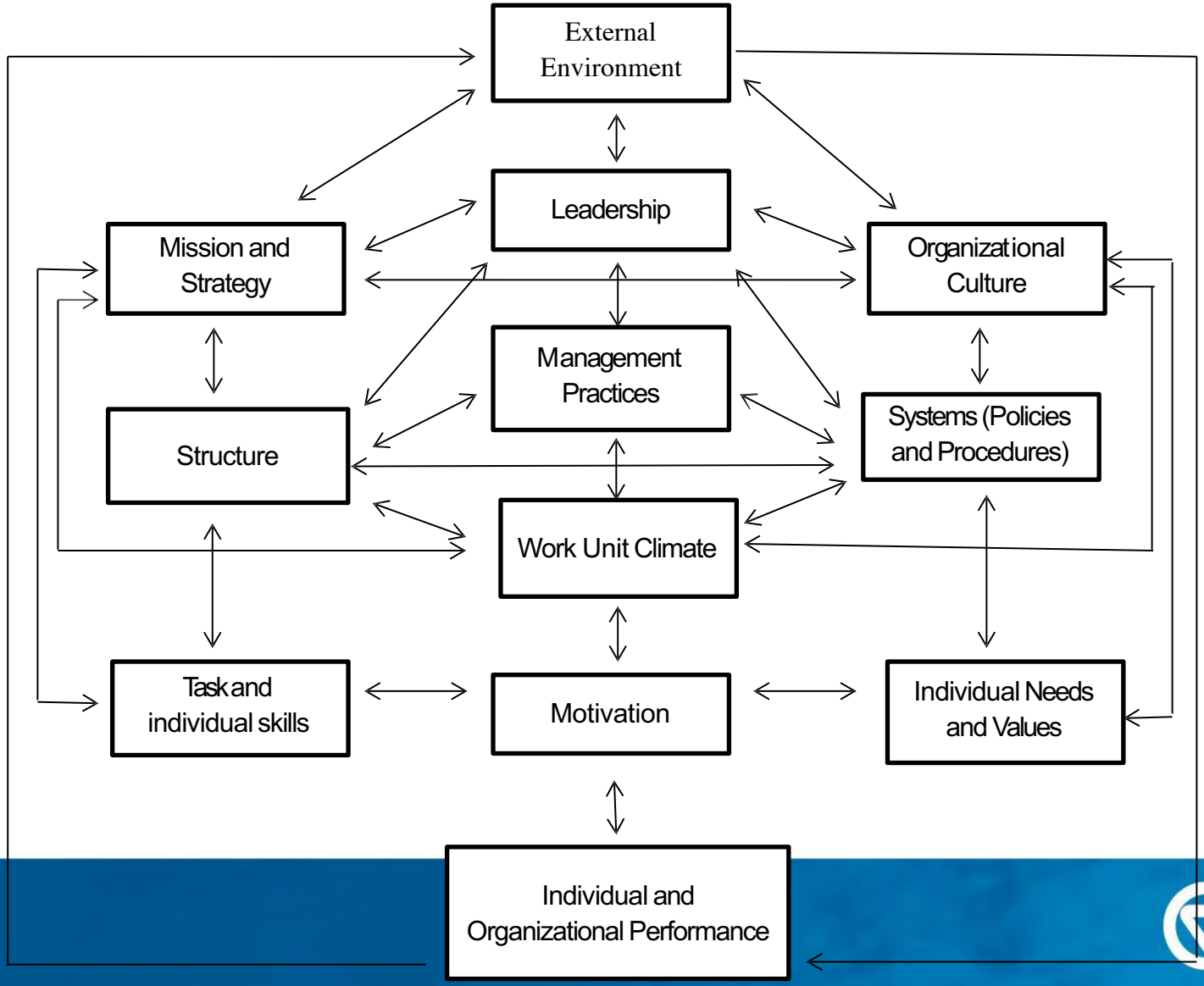
Number of Prescribers by Specialty

Michigan Prescription Drug & Opioid Abuse Task Force. (2015).

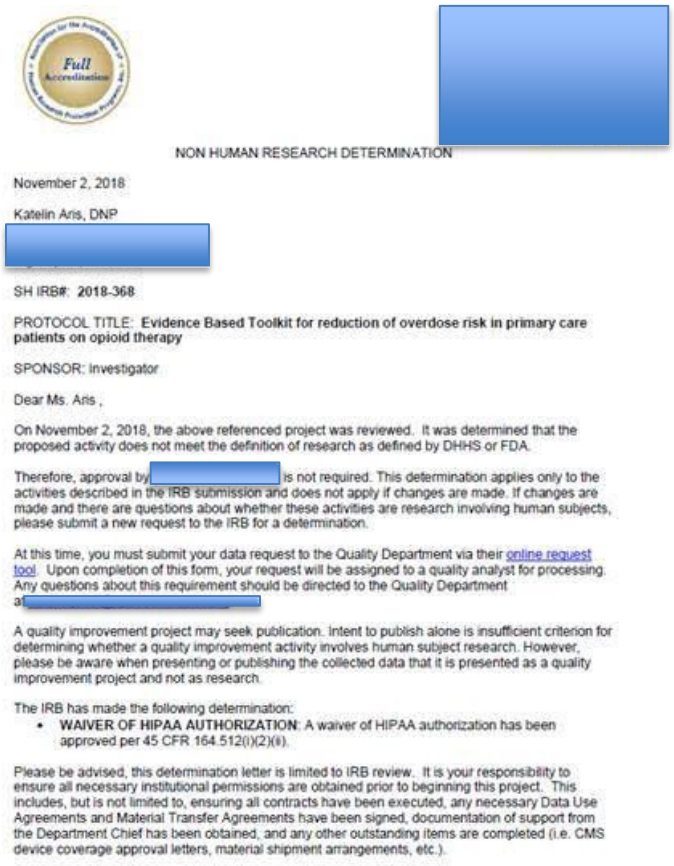
Assessment of the Organization

Framework: Burke & Litwin

Figure 1. A model of organizational performance and change. Re-created from "A Casual Model of Organizational Performance and Change," by W. W. Burke and G. H Litwin, 1992, *Journal of Management, 18*, 528. Copyright 1992 by Southern Management Association



IRB Approval



NON HUMAN RESEARCH DETERMINATION

November 2, 2018

Katelin Aris, DNP

[redacted]

SH IRB#: 2018-368

PROTOCOL TITLE: **Evidence Based Toolkit for reduction of overdose risk in primary care patients on opioid therapy**

SPONSOR: Investigator

Dear Ms. Aris ,

On November 2, 2018, the above referenced project was reviewed. It was determined that the proposed activity does not meet the definition of research as defined by DHHS or FDA.

Therefore, approval by [redacted] is not required. This determination applies only to the activities described in the IRB submission and does not apply if changes are made. If changes are made and there are questions about whether these activities are research involving human subjects, please submit a new request to the IRB for a determination.

At this time, you must submit your data request to the Quality Department via their online request tool. Upon completion of this form, your request will be assigned to a quality analyst for processing. Any questions about this requirement should be directed to the Quality Department a[redacted]

A quality improvement project may seek publication. Intent to publish alone is insufficient criterion for determining whether a quality improvement activity involves human subject research. However, please be aware when presenting or publishing the collected data that it is presented as a quality improvement project and not as research.

The IRB has made the following determination:

- **WAIVER OF HIPAA AUTHORIZATION**: A waiver of HIPAA authorization has been approved per 45 CFR 164.512(i)(2)(ii).

Please be advised, this determination letter is limited to IRB review. It is your responsibility to ensure all necessary institutional permissions are obtained prior to beginning this project. This includes, but is not limited to, ensuring all contracts have been executed, any necessary Data Use Agreements and Material Transfer Agreements have been signed, documentation of support from the Department Chief has been obtained, and any other outstanding items are completed (i.e. CMS device coverage approval letters, material shipment arrangements, etc.).

From: rci@gvsu.edu
Subject: HRRC Research Determination Form - Not Human Subjects Research [19-159-H]
Date: December 3, 2018 at 1:39:58 PM EST
To: <ARISK@MAIL.GVSU.EDU>, <THOMATR@GVSU.EDU>, <DAVIREBE@GVSU.EDU>

Dear Patricia Thomas,

An HRRC Research Determination Form has been reviewed for the following project.

Study Title: Implementation of an Evidence Based Toolkit to Reduce Risk of Overdose in High Risk Primary Care Patients
PI: Patricia Thomas
Study Number: 19-159-H

This study has been determined to NOT meet the federal regulations for Human Subjects Research. An official determination letter is attached to this email.

To view a copy of the submission in IRBManager, click here: HRRC Research Determination Form [Human Subjects Research]

If you have any questions, please contact the Office of Research Compliance and Integrity at rci@gvsu.edu or 616-331-3197.

Thank you,
Office of Research Compliance and Integrity

Stakeholders

- Prescribers
- Medical Assistants
- Registered Nurses
- Leadership teams at the sites
- Opioid Steering Committee
- Pain Management physician leads
- Additional mentors (CNS)
- Patients

SWOT

Strengths	Weaknesses
• Engaged Leadership including supervisor, manager, director • Low provider and staff turnover • Consistent Medical assistant/prescriber relationship • Consistent providers in the practice • Process improvement in place • DNP prepared NP	• High panel load for each provider • Patients on long term opioid regimens • No current EHR notification for high mmEQ • Many screening tools already in place • Recent EHR change with large focus on recent big changes.
Opportunities	Threats
• Consumer demographics • Recent state policy changes • Organizational policy changes coming • Increase quality of care with evidence based care solutions • Part of a larger health care organization • Reduce risk of overdose	• Patient satisfaction regarding pain management regimens and their satisfaction with pain control. • Patients unaccepting of changes in long term regimens. • Limitations in health literacy in the community • Limited transportation • High no show rate at the office • Staff and provider buy in to practice change.

Clinical Practice Question

- Does implementation of an opioid prescribing evidence-based toolkit increase provider confidence in prescribing best practice and increase adherence to organizational policy?

Literature Review

Aim of Literature Review

Goal: Synthesize opioid prescribing best practice literature to generate a toolkit with targeted guidelines for implementation in primary care.

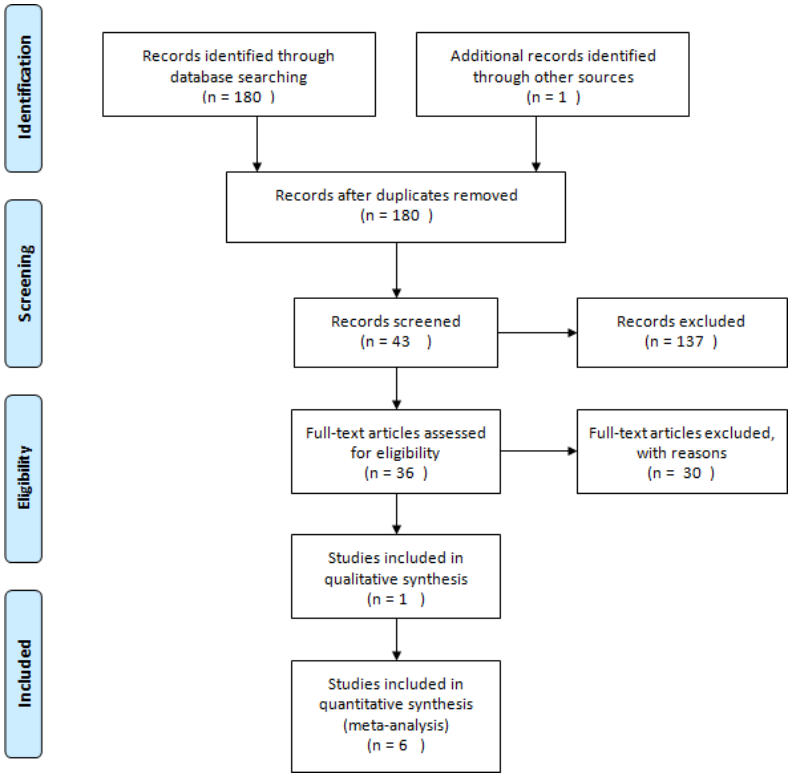
Questions to address:

- Does implementation of evidence-based opioid guidelines impact patient outcomes, including reduction of total morphine mil-equivalents, reduction in risk for overdose, and co-prescription of naloxone?
- Does implementation of opioid guidelines increase provider awareness to best practice with regard to opioid prescribing?
- Do evidence-based opioid guidelines for chronic pain reduce risk of abuse/addiction for patients treated by primary care providers, including adherence to office policies and protocols?
- What are the most effective methods for implementation of evidence based tools and guidelines in primary care?

Review Method

- Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) method.
- CINAHL and PubMed Databases.
- 2008-2018.
- Studies examined pertaining to physicians in primary care and was centered around opioid prescribing and excluded other pain management strategies.
- Palliative care, cancer and pediatrics/neonatal excluded.
- Keywords: opioid, opioid guidelines, risk reduction and primary care.

PRISMA Figure



Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Summary of Table and Results

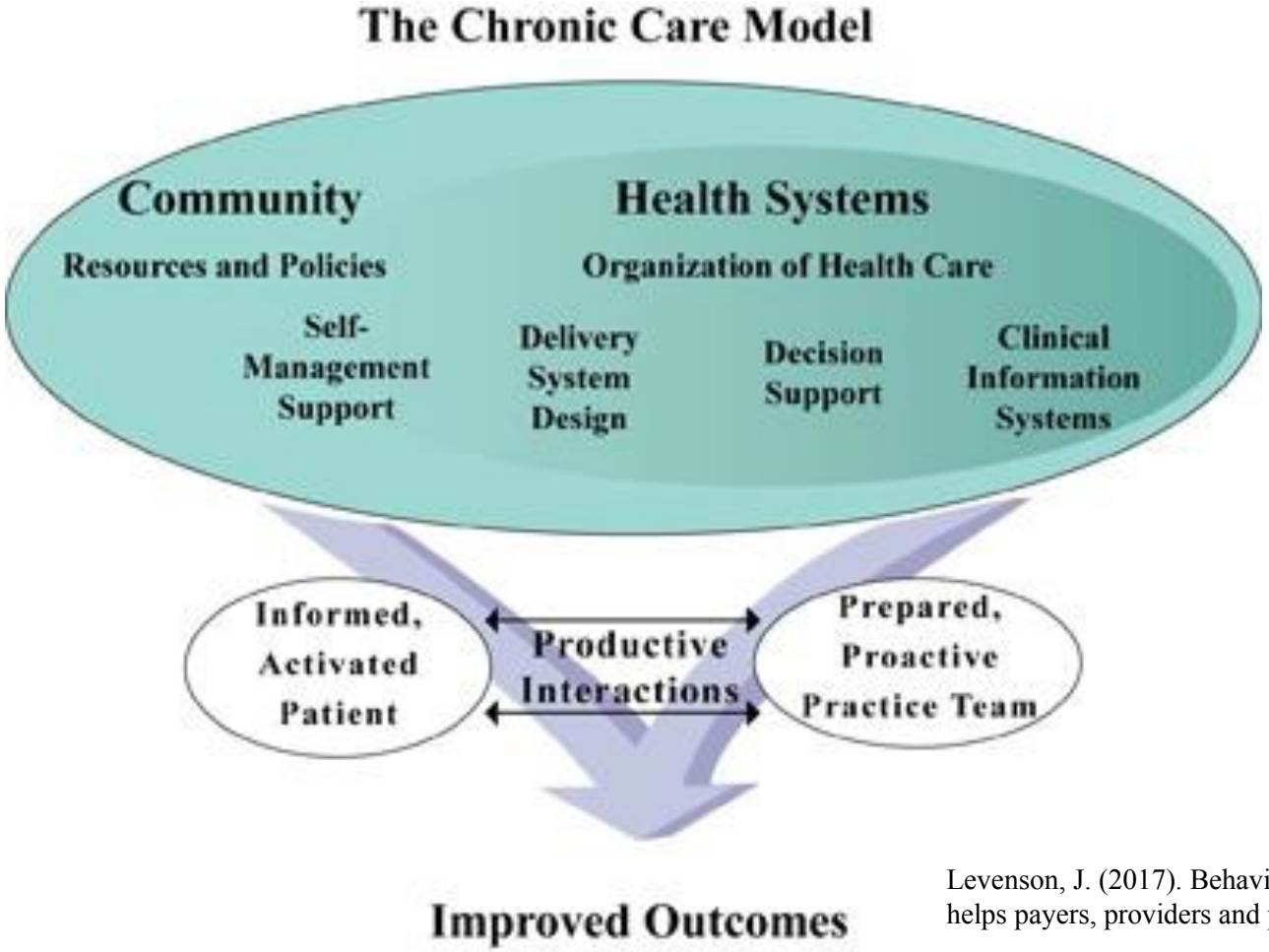
- Gaiennie and Dols (2018)
  - Quality Intervention
- Liebschutz et al. (2017).
  - RCT
- McCracken et al. (2012)
  - RCT
- Quanbeck et al. (2018)
  - RCT
- Tournebize et al. (2016)
  - Systematic Review
- Von Korff et al. (2016).
  - Quasi-experimental design

Evidence for Project

- 3 RCT, 1 systematic review, 1 quasi-experimental, 1 quality improvement intervention.
- Sources reported the outcome measures as improvement in provider knowledge and adherence to guidelines.
  - Increased adherence to urine drug testing, use of treatment agreements, and opioid-benzodiazepine co-prescribing rates.
  - Increase in provider intention to use tools and well-being.
  - Reductions in total opioid prescriptions and reduction in total morphine mill-equivalents.
  - Increase in pain management referrals.
  - Overall increases in quality of care and safety.

Conceptual Models and Frameworks

Model to Examine Phenomenon



Levenson, J. (2017). Behavioral health: moving to a chronic care model helps payers, providers and patients. *MAP Health Management.*

Implementation Model

Kotter's 8 Step Model for Change

Kotter, J. (1996). *8 Step Process for changemanagement.*

Project Plan and Implementation

Project Purpose & Objectives

- Goal: Assist primary care providers in their care of patients who are on opioid therapies.
- Objectives are to address:
  - Provider comfort level with opioid prescribing, policy and guidelines.
  - Adherence to MI opioid laws and organizational policy, including use of medication contract, opioid start talking document and urine drug screen.
  - Identification of and reduction in total morphine mmEQ.
  - Rates of co-prescribing for benzodiazepines and opioids.
  - Co-prescription of naloxone

Design, Setting and Participants

- Design: The design for this evidence-based initiative was a quality improvement project and translation of evidence into practice.
- Setting: 2 northern Michigan primary care offices.
  - 8 total prescribers (3 Physicians, 3 PA, 2 NP).
  - 28,000 annual patient visits
- Primary staff included: Prescribers, RNs, Medical Assistants.

Implementation Strategy & Element

Steps for Implementation using Theory

1). Create urgency
- -Literature review and organizational assessment
- -Present this topic across various forums

2). Build a coalition:
- -Meeting with medical director
- -Attend clinical practice steering meetings
- -Cultivate relationships with staff

3). Create a vision for change with creation of the toolkit, using the following as a guide:
- -Evidence based guidelines
- -Site Leadership
- -Organizational policy

Implementation Strategy & Element

Steps for Implementation using Theory

4) Communication of the vision through education and information around toolkit to all involved:
   - -Presentations
   - -Emails
   - -1:1 Face to face discussion

5) Empower action: go live with the evidence-based toolkit.
   - -Provide at the elbow support, as needed.
   - -Identify and target toolkit changes/updates as needed.

Implementation Strategy & Element

Steps for Implementation

6) Create quick wins:
   -Create and embed a best practice advisory into the electronic health record to aid the providers in their daily work (i.e. naloxone co-prescription suggestion and ease of ordering).
7) Build on the change:
   -Weekly feedback to providers and staff.
   -Weekly discussion of key points and reinforcement of concepts.
8) Make it stick:
   -Deliver final report to leadership and present sustainability plan.

Implementation Strategy & Element

Toolkit contents:

- Organizational guideline.
- CDC guidelines for opioid prescribing in primary care.
- Patient education materials through the CDC
- Harm Reduction Coalition and the Lazarus Project information.
- UptoDate
- Screening tools and methods.

Primary delivery methods:

- Handbook format.
- Checklists.
- Updates

Evaluation & Measures

- Evaluation through retrospective data review occurred following IRB approval at the site and through GVSU

- Additional primary measures:
  - Observation through site shadowing during clinical rotations
  - Discussion with clinicians
  - Pre and post survey for prescribers

Sample Survey for Primary Care Prescribers

Please rate the following on a scale of 1 to 5.

1 = strongly disagree 2 = disagree 3 = neutral 4 = agree 5 = strongly agree

Comfort Level

- I feel confident in understanding the legislative changes in the state of Michigan with regard to opioid prescribing.
- I feel confident in understanding the organization's policies for opioid prescribing.
- I find it easy to know how many morphine mill equivalents for my patients who are prescribed opioids.
- I think patients could use more education with regard to opioid prescribing changes.

Awareness/Practice

- Most of my patients on opioids have signed opioid prescribing contracts.
- Most of my patients on opioids have at least one UDS per year.
- Most of my patients on opioids are under a daily limit of 50 mmEQ.

Data Review

Data Variables for Pre- and Post Implementation Evaluation

- Age
- Gender
- Previous diagnoses of opioid overdose
- Current diagnosis of opioid overdose
- Short acting opioid name, dose, and strength
- Long acting opioid name, dose and strength
- Benzodiazepine presence or absence
- Screening tool presence or absence (PEG, SOAPP, ORT)
- Morphine mill equivalents (calculated by me)
- Urine drug screen presence or absence
- Medication contract presence or absence
- Start talking document presence or absence
- Provider pre- and post comfort level with guidelines.

Analysis Plan

- Report out of the EHR from the site data analyst
- Placed on a password driven, secure m: drive
- The DNP student was the primary source of data collection; all data points were then collected from the EHR following guidelines put forward by the site for data security.
- De-identified prior to transfer to Statistician
- The GVSU Statistician assisted in review and analysis of data and appropriate statistical method for evaluation.

Analysis Plan

- Analysis of data pre-implementation:
  - Data is exploratory data and helped for foundation for implementation of the toolkit.
  - Calendar year 2018 selected
  - Site A: Small n, reviewed all possible patients without duplicates (n=22).
  - Site B: Large n, reviewed every 10th chart, removing cancer pain (n=39).
- Analysis of data post-implementation:
  - Obtained at one month post implementation
  - Both sites small n = need to review every chart without duplicates (Site A = 6, Site B = 14)
  - Data determined effectiveness of interventions.
  - Data determined next steps for dissemination, adjustment of toolkit contents, further education needs and sustainability.

Timeline

April-May 2018:
- Advisory team formation and DNP project identification

June 2018
- Prospectus Written

July-August 2018
- Organizational Assessment and Literature review

September-October 2018
- IRB Application and Determination

November 2018
- Proposal Defense

December 2018
- Creation of toolkit
- Prescriber level setting focus group

January/February 2019
- Staff education through emails and face to face communications
- Implementation of toolkit and support
- BPA change request in EHR

March 2019
- Auditing and feedback, Analysis of data post-implementation, recommend changes

April 2019
- Final presentation to leadership, sustainability, project defense, and submission to Scholar Works.

Results and Sustainability

Prior State Practices

- Combined Site Data
  - Total Prescriptions: 427
  - Total N reviewed: 61
  - 27 Male Patients
  - 34 Female Patients

Prior State Practices

Site A

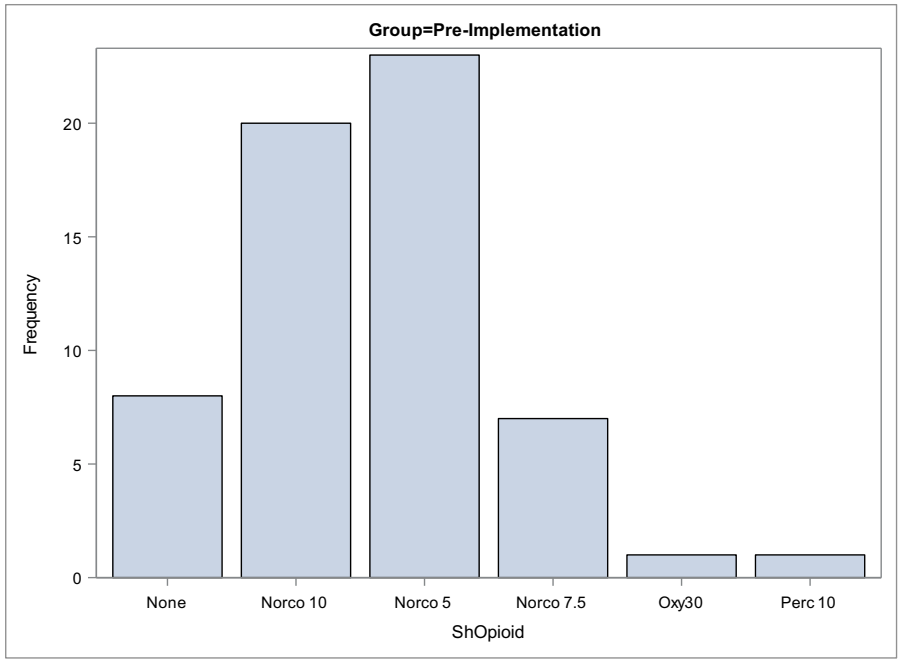
- Total prescriptions written: 48
- Total N reviewed: 22
- 12 Male Patients
- 10 Female Patients
- No patients with short and long acting prescribed.

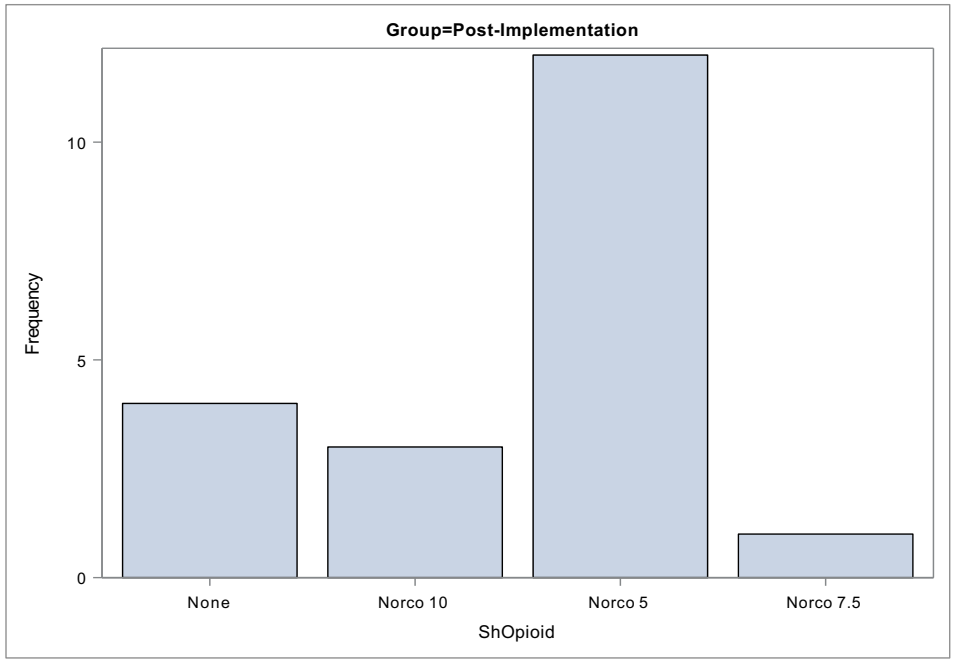
Prior State Practices

Site B

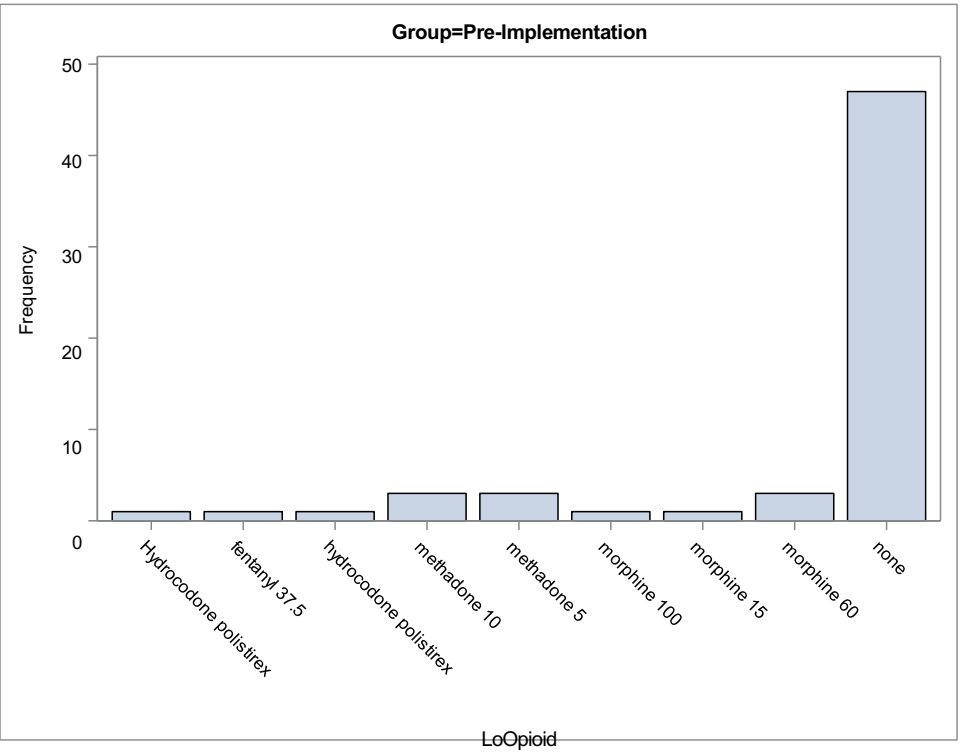
- Total prescriptions written: 379
- Total N reviewed: 39
- 15 Male patients
- 24 Female Patients
- 6 patients on both long and short acting opioids

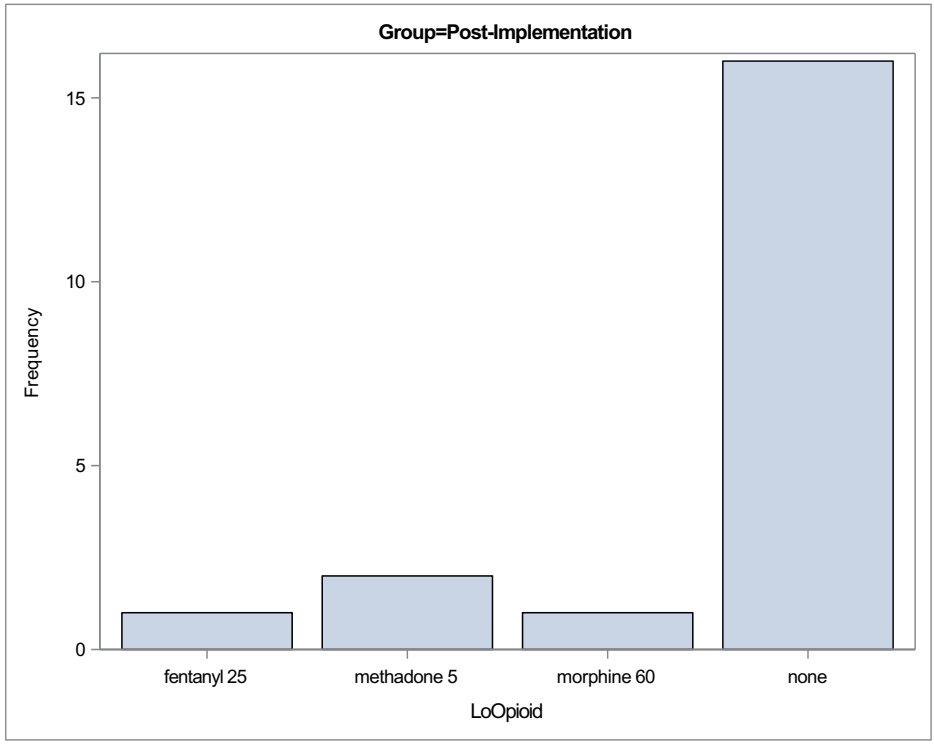
Short Acting Medications Combined Data





Long Acting Medications Combined Data





Measures

- Morphine mmEQ
  - Both sites:
    - Pre: Total Daily mmEQ: 61.4
    - Post: Total Daily mmEQ: 35
  - Site A Pre/Post Implementation
    - Pre: Total Daily mmEQ: 17
      - One patient >50mmEQ
    - Post: Total Daily mmEQ: 25
      - One patient >50mmeQ
  - Site B Pre/Post Implementation
    - Pre: Total Daily mmEQ: 85
      - 14 patients >50 mmEQ
    - Post: Total Daily mmEQ: 39
      - 2 patients >50mmEQ

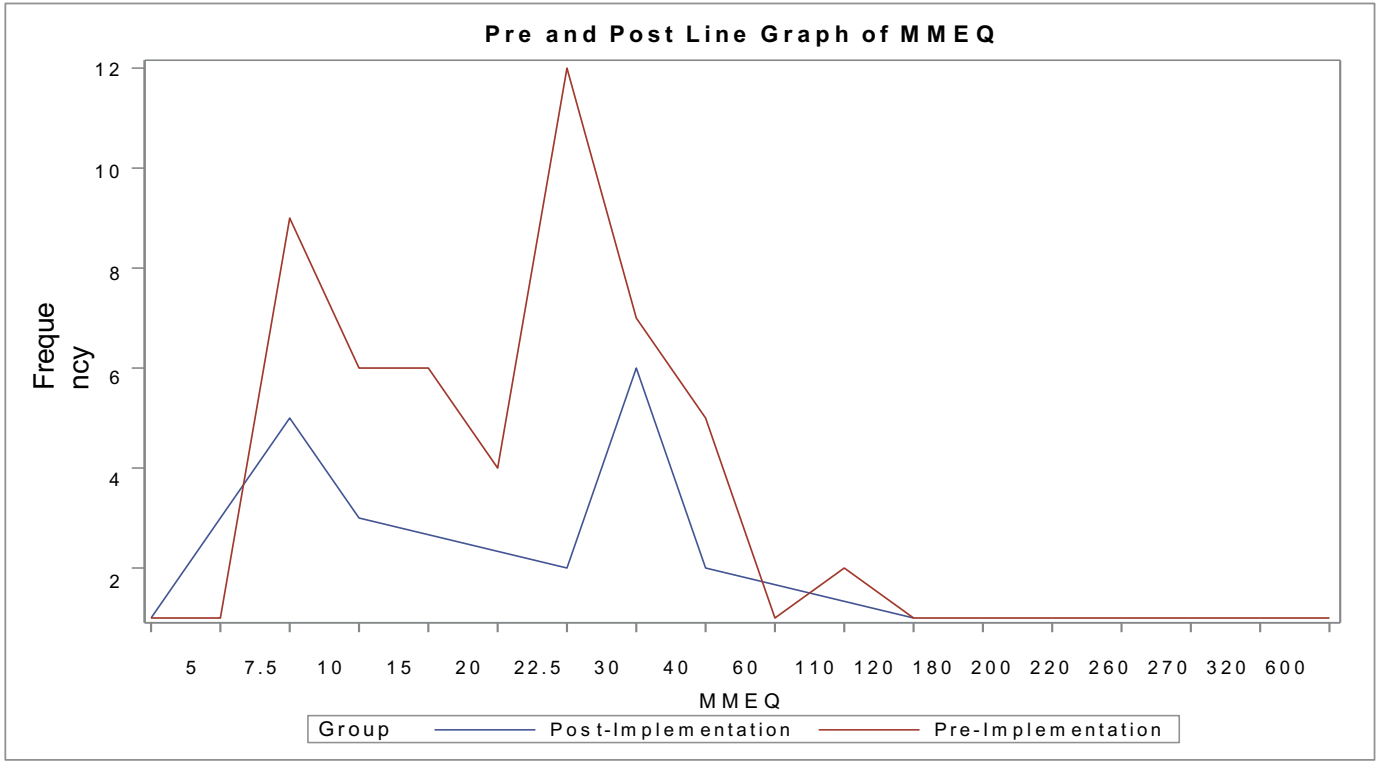
Goal: Reduction of mmEQ overall

Reduction of 26.4 mmEQ/day

Increase of 8 mmEQ/day

Reduction of 46 mmEQ/day

Morphine Milliequivalents



Measures

Morphine mmEQ

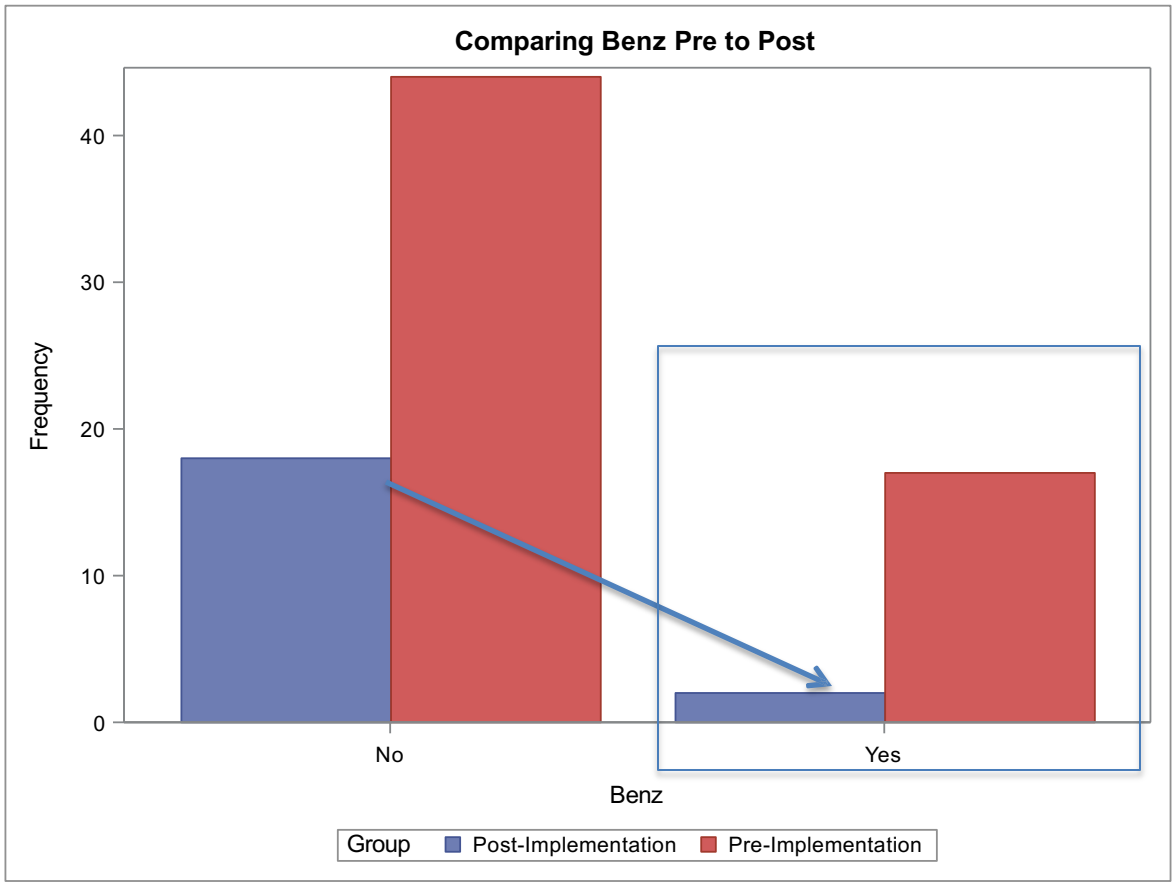
- There is not sufficient evidence to say that the distribution of morphine milliequivalents differs pre and post implementation.
- Wilcoxon Rank Sum test (S = 7.575, p=0.495)

Measures

- Co-prescribed benzodiazepine
  - Both sites:
    - Pre: 17/61 present (28%)
    - Post: 2/20 present (1%) → Reduction of 18%
  - Site A Pre/Post Implementation
    - Pre: 3/22 present (14%)
    - Post: 1/6 present (17%) → Increase of 3%
  - Site B Pre/Post Implementation
    - Pre: 14/39 present (36%)
    - Post: 1/14 present (7%) → Reduction of 29%

Goal: Reduction of co-prescribed benzodiazepines

Benzodiazepine Comparisons



Goal: Reduction of co-prescribed benzodiazepines

Measures

Co-prescribed benzodiazepine

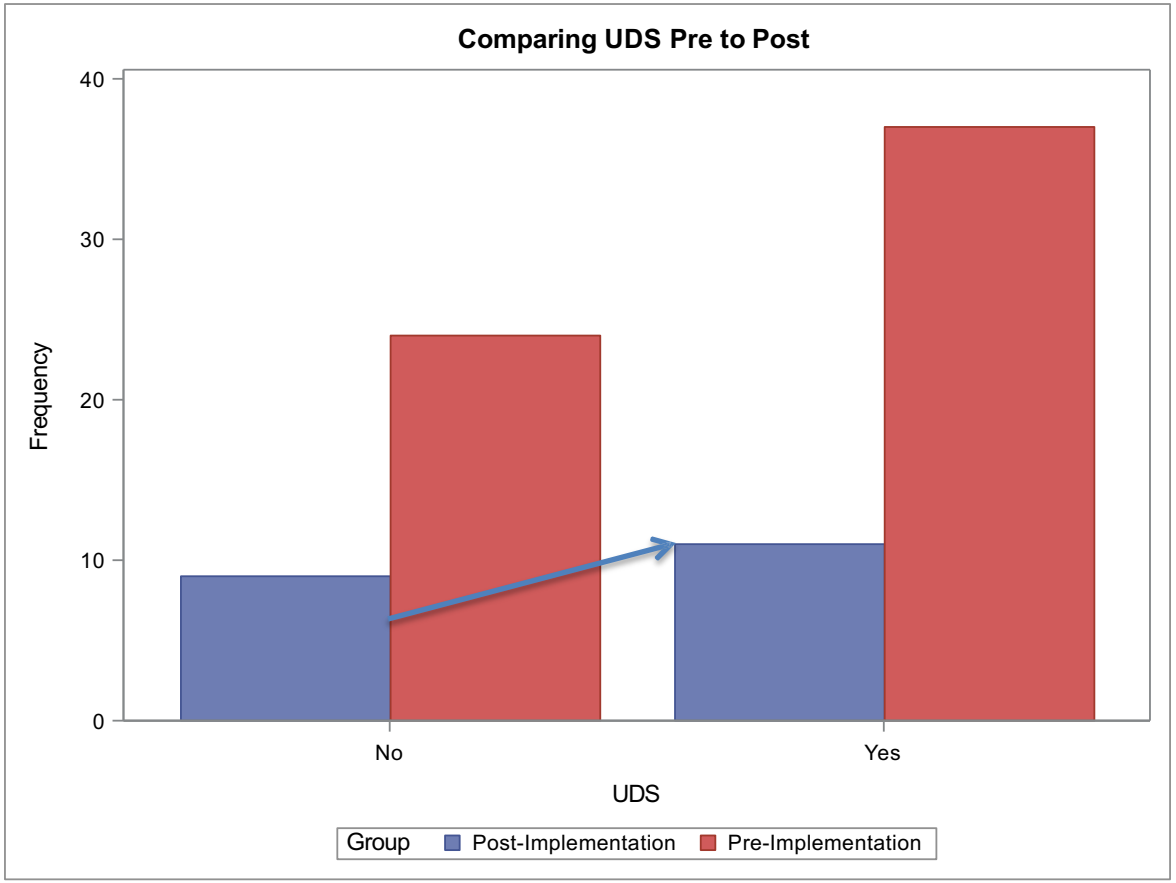
- There is not sufficient evidence to say that proportion of patients that had benzos differs pre and post implementation
- Fisher's Exact Test ($p = 0.1339$)

Measures

- Urine Drug Screen
  - Both sites:
    - Pre: 37/61 present (61%)
    - Post: 10/20 present (50%) → Reduction of 11%
  - Site A Pre/Post Implementation
    - Pre: 12/22 present (55%)
    - Post: 5/6 present (83%) → Increase of 28%
  - Site B Pre/Post Implementation
    - Pre: 25/39 present (64%)
    - Post: 5/14 present (36%) → Reduction of 28%

Goal: Increase % of patients with a UDS

Urine Drug Screen Comparisons



Goal: Increase % of patients with a UDS

Measures

Urine Drug Screen

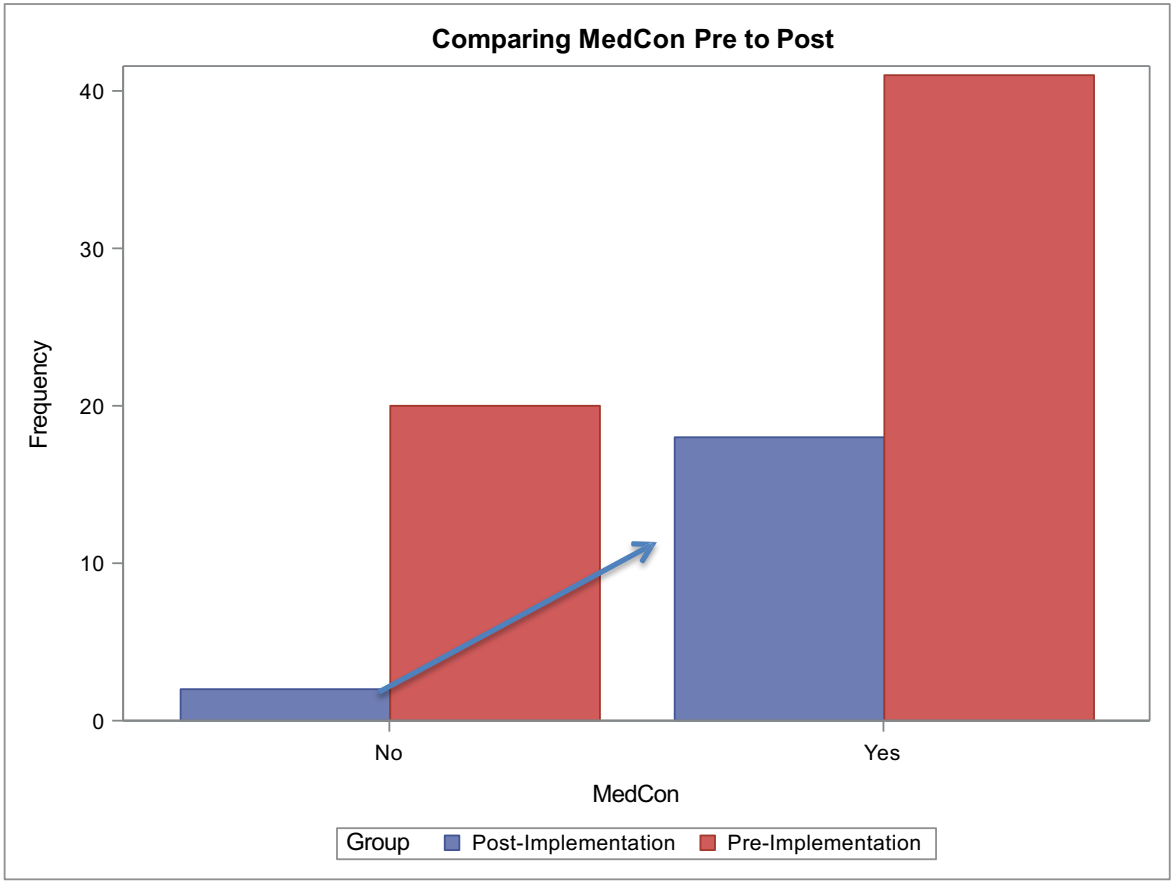
- There is not sufficient evidence to say that proportion of patients that got a drug screen differs pre and post implementation
- Chi Square test, x^2=0.2, p = 0.6551)

Measures

- Medication Contract
  - Both sites:
    - Pre: 41/61 present (67%)
    - Post: 18/20 present (90%) → Increase of 23%
  - Site A Pre/Post Implementation
    - Pre: 20/22 present (91%)
    - Post: 6/6 present (100%) → Increase of 9%
  - Site B Pre/Post Implementation
    - Pre: 21/39 present (54%)
    - Post: 12/14 present (86%) → Increase of 32%

Goal: Increase % of patients with a Med Contract

Medication Contract



Goal: Increase % of patients with a Med Contract

Measures

Medication Contract

- There is sufficient evidence to say that proportion of patients that had a medical contract differs pre- and post implementation.
- Chi-square test, x^2=3.95, p=0.0468.
- 90% post versus 67% pre implementation

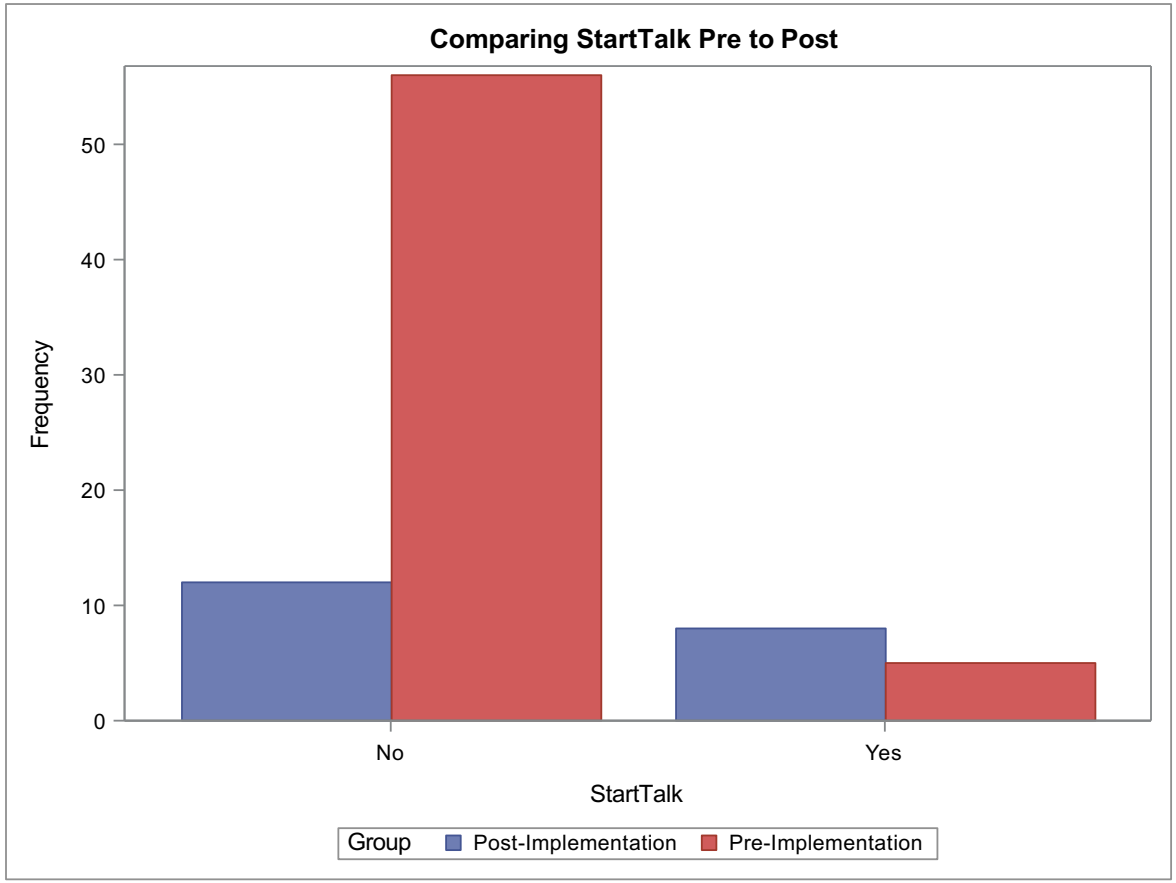
Measures

Goal: Increase % of patients with a Start Talking Document

Michigan Start Talking Document

- Both sites:
  - Pre: 5/61 present (8.2%)
  - Post: 8/20 present (40%) → Increase of 31.8%
- Site A Pre/Post Implementation
  - Pre: 3/22 present (14%)
  - Post: 2/6 present (33%) → Increase of 19%
- Site B Pre/Post Implementation
  - Pre: 2/39 present (5%)
  - Post: 6/14 present (43%) → Increase of 38%

Michigan Start Talking Frequencies



Goal: Increase % of patients with a Start Talking Document

Measures

Michigan Opioid Start Talking Document

- There is sufficient evidence to say that proportion of patients that had a document differs pre and post implementation
- Fisher's exact test, $p = 0.0022$.
- 40% post versus 8.2% pre implementation

Measures

Naloxone Co-prescription and Screening Tools

- Both sites had no instances pre- or post implementation of naloxone co-prescription or use of screening tools.

Provider Characteristics

- N= 4
- Completion: 75% (3/4 responses)
- Pre-implementation:
  - Highest ranking: Awareness questions
  - Lowest ranking: Confidence questions
- Post-implementation:
  - Highest ranking: Confidence questions
  - Lowest ranking: Awareness questions

Discussion

- mmEQ:
  - Higher mmEQ associated with higher overdose risk
  - 50mmEQ is CDC gold standard for prescribing
  - Site A: generally safe profile for prescribing in association with mmEQ
    - Increase in post-implementation phase due to small N
  - Site B: room for improvement which was gained with toolkit.
    - 46% reduction in mmEQ
    - Not statistically significant but is clinically significant
  - Formulation of opioids (LA/ER vs. SA)
    - Site B: Complete reduction in dual formulation

Discussion

- Co-prescribed benzodiazepine
  - Concurrent use is associated with higher overdose risk
  - Site A: generally safe profile for prescribing in association co-prescribed benzos
    - Increase in post-implementation phase due to small N
  - Site B: room for improvement which was gained with toolkit.
    - 29% reduction in patients on co-prescribed benzos
    - Not statistically significant but clinically significant

Discussion

- Urine Drug Screen
  - Helps assess overdose risk due to additional substances on board
  - Site B: reduction in adherence; may be due to decreased mmEQ and co-prescribed benzos
- Start Talking Document and Medication Contracts
  - Increases patient's understanding of risks of opioids
  - Came into practice June 2018
  - Both statistically significant change from adherence pre and post intervention

Discussion

- Screening Tools
  - Screening tools for assistance in opioid prescribing of mixed results in literature.
  - Organizational policy guides providers to assess overall pain management goals and function, thus use of screening tools are necessary.
- Naloxone
  - Risk mitigation with naloxone has not been studied in primary care but is successful in community based interventions.
  - Post implementation, fewer patients met this need as described by the CDC.

Additional interventions and education needed to promote adherence.

Discussion

- Provider Comfort Level
  - Lack of confidence in prescribing opioids known in the literature
  - Per CDC, most providers not consistent with practices to decrease risk for mis-use/overdose
  - Post: Increase in provider comfort characteristics and decrease in provider awareness (EHR is a factor)
  - Again, not statistically significant but clinically relevant
    - Guides efforts needed to address practice gaps.

Limitations

- Electronic Health Record
- mmEQ/day tabulation
- Michigan Start Talking Legislation
- Missing Data
  - Prescriber and patient characteristics
  - Lack of qualitative approach
  - No consideration of indication, duration, co-morbidities, mental health, age, etc.
- Sample weaning plans not included, alternative pain management modalities and referrals not included.
- Data review timeframe
- Survey
- Short implementation period and small sample sizes
- Pain management physician

Implications for Practice

- Evidence-based approach to changing practice
- Patient centered approach to care
- Ensuring understanding of risk
- Ease of use of electronic health record for viewing.
  - BPA request
- Consider the "person" behind the numbers.

Next Steps

- Completion of Naloxone BPA and patient education materials.
- Continued emphasis on prescriber/patient relationship and MA conversations/scripting.
- Implementation of additional Opioid tools in EHR (dashboard).
- Initiation of work on electronic care-set for withdrawal.
- Support of prescriber algorithms
  - Weaning
  - Opioid Use Disorder Treatment
  - Alternative Pain Strategies with medication and non-pharmacological solutions
  - Referral to pain management or alternative professionals

Resources & Budget

Evidence Based Toolkit: Initial Budget	
Expenses	
Project Manager (RN) Donation for education and support	$1,230.00
Data Analyst (Donation)	$216.00
Statistician (Donation)	$122.00
Color Printed Educational Fliers	$25.00
Binder and paper	$25.00
RN education Time	$33.00
Medication Assistant Education Time	$130.00
Physician, NP and PA Education Time (including focus groups)	$1,076.00
Clinical Nurse Specialist Time	$49.00
Project Mentor Time	$99.00
Total:	$3,005.00
Revenue	
Project Manager Donation for education and support	$1,230.00
Data Analyst (Donation)	$216.00
Statistician (Donation)	$216.00
Overdose death prevention	10 overdose patients in surrounding counties (Mecosta, Osceola and Lake) per year $1917.00 x 33 (ED) = $63,261=$632.610. $10,000 (inpatient)x10 =$110,000 per person x 10 1,100,000.00 Source: Mack (2018)
Total	$1,101,662.00

Sustainability Plan

- Feedback provided during implementation phase of project.
- Provide final presentation of overall work completed and outcomes with leadership team.
- Share barriers and successes.
- Give best practice recommendations and lessons learned following implementation.
- Provide feedback and recommendations for continuation and/or alteration of best practice advisory within the organization based on implementation.
- Prepare for implementation of this project system wide.
- Provide recommendations for updating of organizational policy, checklists and implementation tools with legislative changes upcoming in 2019.

Dissemination

- Local newspaper and 9&10 News
- The Crisis Next Door Presentation
- 1:1 Feedback to Prescribers
- Local Leadership and provider meetings
- Opioid Steering Committee and leadership committees as requested
- Poster Presentation

DNP Essentials Reflection

- The Grand Rapids Red Project
- Naloxone education to Emergency Department staff
- Overdose Prevention Training: inpatient and outpatient based rehabilitation units and 1:1 counseling.
- Needle and Medication Takeback Days
- Ethics Shadow and various ethics education offerings
- Opioid Education and Buprenorphine Certificate
- Policy and Advocacy
- AANP Conference

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Questions?