Evaluation of Processes and Procedures for Care of the Opioid Recipient Patient in the Primary Care Setting

Anne Sproat

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Evaluation of Processes and Procedures for Care of the Opioid Recipient Patient in the Primary Care Setting

Anne Sproat

Kirkhof College of Nursing

Grand Valley State University

Advisor: Amy Manderscheid, DNP, RN, CMSRN

Advisory Team: Rebecca Davis, PhD, RN

Site Mentor: Kimberly Lanning, DNP, MSN, FNP-BC, APRN

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Abstract

Introduction: Chronic non-cancer pain is far reaching, affecting over 100 million Americans (Zgierska et al., 2018). Opioids are commonly prescribed for chronic pain, with approximately 20% of patients presenting to primary care offices with symptoms of pain or pain-related diagnoses (Dowell, Haegerich, & Chou, 2016). As a result, opioid prescribing rates are increasing at a faster rate for primary care practice compared with other specialties (Dowell et al., 2016). Within the United States population, it is estimated that three percent to four percent of the adult population are prescribed long-term opioids for the treatment of chronic non-cancer pain (Dowell et al., 2016). The use of opioid pain medication presents serious risks for patients receiving them, including overdose and opioid use disorder (Dowell et al., 2016). Long-term use of opioids for chronic pain is controversial and has been linked to dose-dependent harm, addiction, overdose, and death (Zgierska et al., 2018). Approximately 85% of those who misuse opioids obtain their main drug supply from opioid prescriptions (Zgierska et al., 2018). On the basis of Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) criteria, it is estimated that 1.9 million Americans abuse or are dependent on prescription opioids (Dowell et al., 2016). Opioid-related deaths in the United States have increased dramatically, making this a national public health crisis (Zgierska et al., 2018).

Objectives: The primary study objective is to assess whether evidence-based practice guidelines are being followed regarding the care being delivered to opioid recipient patients.

Methods: This is a quality improvement project that will include a retrospective evaluation of quality measures for evidence-based care being delivered to opioid recipients. This project will occur at a primary care office that is part of a large mid-western healthcare system. Resources needed for this project include access to patient charts located at the primary care clinic, use of a laptop, space within the primary care clinic in which to work, and materials needed to produce a toolkit. Additional resources include collaboration with the site mentor and office manager, utilization of information technology (IT) personnel, and consultations with a statistician. To be included in the analysis, patients must meet the following inclusive criteria: age greater than or equal to 18 years old; active patient status (seen in the past three years); have a primary care provider within this office; do not have a diagnosis of malignant neoplasm or hospice status; and have at least one opioid prescription in the past 45 days that was not prescribed for acute pain. Medical records will be reviewed for adult patients at the primary care clinic who are currently prescribed opioids. Furthermore, medical records will be assessed for quality measures of evidence-based care. Evidence-based action plans and a toolkit will be presented and provided to the primary care office’s leaders, providers, and staff to continue to improve measures reflecting organizational goals and measurement targets.

Results: Expected results include potential gaps of continual improvement in evidence-based care that is being provided to patients in the primary care setting.

Conclusions: Expected conclusions include identified areas of quality measures for evidence-based care.
**Implications:** Areas for practice change will be identified and strategies to improve quality measures of care will be implemented. Patients receiving an opioid prescription will receive evidence-based care leading to improvement in patient safety.
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Evaluation of Processes and Procedures for Care of the Opioid Recipient Patient in the Primary Care Setting

Assessment and treatment of chronic pain has been a challenge for healthcare providers and systems, as they have struggled to find a balance between effective treatment for chronic pain and its potential for harm (Dowell et al., 2016). Primary care clinicians report having concerns about prescribing opioids, feel they have had insufficient training in prescribing opioids, and find managing patients with chronic pain stressful (Dowell et al., 2016). Clinicians also report concerns about opioid medication misuse, addiction, and overdose (Dowell et al., 2016). With increasing regulatory scrutiny at the federal and state levels surrounding opioid misuse, primary care clinicians are less willing to manage chronic non-cancer pain with long-term opioid use (Jamison, Scanlan, Matthews, Jurcik, & Ross, 2016). Primary care clinicians also report difficulty in following opioid prescription guidelines, citing lack of time for opioid management practices (Becker, Merlin, Manhapra, & Edens, 2016).

In 2016, the Centers for Disease Control and Prevention (CDC) released guidelines for prescribing opioids for chronic pain. The CDC conducted a clinical systematic review of the scientific evidence to identify effectiveness, benefits, and harms of long-term opioid therapy for chronic pain (Dowell et al., 2016). On the basis of this systematic review, the CDC developed the guideline for prescribing opioids to treat chronic pain. Clinicians should use urine drug testing before starting opioid therapy and at least annually to assess for prescribed medications, other controlled substances, and illicit drugs (Dowell et al., 2016). Whenever possible, clinicians should avoid prescribing opioids and benzodiazepines concurrently (Dowell et al., 2016). For patients who are found to have opioid use disorder, clinicians should offer or arrange evidence-based treatment, usually with buprenorphine or methadone in combination with behavioral
therapies (Dowell et al., 2016). Additionally, patients with chronic pain should be assessed for depression, as this population is at a higher risk for developing depressive symptoms (Dowell et al., 2016).

In Michigan, new laws have recently gone into effect and have been the catalyst for change within the healthcare organization where this quality improvement project will take place. Starting June 1st, 2018, all providers prescribing or dispensing a controlled substance were required to be registered with Michigan Automated Prescription System (MAPS) in order to remain compliant. In addition, starting June 1st, 2018, the prescriber must provide the following information to the patient before prescribing an opioid:

- The danger of opioid addiction
- How to properly dispose of an expired, unused, or unwanted controlled substance
- That the delivery of a controlled substance is a felony under Michigan Law
- If the patient is pregnant or is a female of reproductive age, the short and long-term effects of exposing a fetus to an opioid, including but not limited to neonatal abstinence syndrome

After providing the information detailed above, the prescriber must obtain the signature of the patient or the patient’s representative on a start talking consent form. The signed form must be kept in the patient’s medical record. On July 1st, 2018, prescribers treating a patient for acute pain could not prescribe more than a seven day supply of an opioid within a seven day period. This information was disseminated to the primary care office via email communication with the office manager. The office manager passed these materials to providers and office staff during staff meetings.
Thus far, aside from the materials created by members of the organization’s opioid taskforce, no initiatives have been made to review or evaluate quality of care processes provided to opioid recipient patients. As evidence suggests, there are quality measures that should be part of how care is provided to patients being treated for chronic pain. In many health care settings, part of evaluating whether quality measures are being met involves implementation of quality improvement projects. The purpose of this written discussion is to describe a proposed evidence-based quality improvement project that addresses standards of care for opioid recipient patients, in partial fulfillment of the Doctor of Nursing Practice degree. The assessment of the organization will be discussed, along with evidence that was gathered during a literature review. In addition, the project plan will be described in depth.

**Assessment of the Organization**

This Midwestern health system is a non-profit healthcare organization that is part of a larger over-arching multi-institutional Catholic health system, which is sponsored by Catholic Health Ministries (XXX, 2018). Becoming part of a larger entity occurred recently and has made this healthcare system part of the second largest Catholic healthcare system in the nation (XXX, 2018). Within the West Michigan area, there are a total of 33 primary care offices that are part of the health system (XXX, 2018). To assess the organization, the Burke and Litwin Model of Organizational Performance and Change was utilized to explore the current needs within the organization and opportunities for change. Additionally, an assessment of the strengths, weaknesses, opportunities, and threats (SWOT) was completed to further analyze the identified problem. In combination, these two tools will serve as a platform for the completion of a doctoral nursing scholarly project.
Framework for Assessment

The Burke and Litwin Model of Organizational Performance and Change was created to provide a guide for organizational diagnosis and manage organizational change (Burke & Litwin, 1992). The model is used to help assess organizational and environmental factors, and how these dimensions should be linked to achieve change in performance or practice (Burke & Litwin, 1992). The model revolves around 12 organizational factors that interact together and affect one another (Appendix A). Burke and Litwin (1992) state that the two distinct variables within an organization are climate and culture. Climate can be defined in terms of organizational members’ perceptions, whereas culture can be defined in terms of values and beliefs (Burke & Litwin, 1992). Within the model, there are variables that influence and are influenced by climate, and variables that are influenced by culture (Burke & Litwin, 1992). The variables that define organizational climate are transactional factors, and the variables that define culture are transformational factors (Burke & Litwin, 1992).

Transformational factors are considered the most influential forces of change and include the external environment, mission and strategy, leadership, organizational culture, and individual and organizational performance (Burke & Litwin, 1992). Burke and Litwin (1992) state that of those factors, external environment is arguably the most persuasive factor to drive change. Transformational factors require analysis at the organization’s macro level in order to identify which organizational dimensions need to be highlighted during the change process (Burke & Litwin, 1992).

Transactional factors are the structural pieces of the work climate and consist of exchanges among members of the organization (Burke & Litwin, 1992). The transactional factors explain reciprocity among people and groups for mutual gain (Burke & Litwin, 1992).
Transactional factors include management practices, structure, systems, work climate, tasks and individual skills, motivations, individual needs and values, and individual and organizational performance (Burke & Litwin, 1992).

**Ethics and Protection of Human Subjects**

An application for review and approval or exemption of this project will be submitted to the health care system’s Institutional Review Board and to Grand Valley State University. Aside from project planning, no project activities will commence until the review is completed and Board approval or exemption is granted. The purpose and scope of this project are limited to evidence-based practice improvement or quality improvement. No patient identifiable information will be collected. There are no physical, social, psychological, legal, or economic threats to patients in association with this project. The impact of the project will pose no risk to participants. All members of the project team have completed human subject protection training via the Collaborative Institute Training Initiative and their actions will be guided accordingly.

**Stakeholders**

Key stakeholders in standards of care for opioid recipient patients include the leaders of the healthcare organization, healthcare providers (physicians, nurse practitioner, physician assistants), nursing staff (registered nurse and licensed practical nurses), medical assistants, office leaders (office manager, office practice leader for physicians, office practice leader for nursing), pharmacists, and patients. Leaders of the healthcare organization are committed to providing the highest level of care to opioid recipient patients, as evidenced by the creation of the opioid taskforce. The healthcare providers who care for and prescribe to opioid recipient patients are committed to patient safety and providing evidence-based care, as evidenced by enacting new initiatives put for by the physicians from the opioid taskforce. This includes
providing treatment forms, consent forms, and documenting that MAPS has been checked. Nurses and medical assistants work in tandem with the providers to care for the patient, assist with documentation, and assist with prescription re-fills. Pharmacists ultimately fill medications and deliver them to patients. Office leaders guide change management practices and are therefore key stakeholders. At the center of the stakeholder ring lies the patient, who represents the most important stakeholder. Patients who experience chronic pain and receive opioid prescriptions as treatment have the greatest vested interest in the care they receive from the healthcare organization.

**Strength, Weakness, Opportunity, Threat Analysis**

The Strength, Weakness, Opportunity, Threat (SWOT) analysis is a tool used to look at the settings internal strengths and weaknesses, and external opportunities and threats that ultimately help or hinder an organization’s project for change (Moran et al., 2017). For this SWOT analysis, the focus is on the primary care office, yet the organization as a whole will be considered in the context of external opportunities and threats (Appendix B). The SWOT analysis was completed in tandem with the organizational assessment and provided structure for evaluating the primary care clinic and the organization as a whole.

**Strengths.** Identified organizational strengths include affiliation with a larger health system. Being part of a larger health system allows access to many resources, both financially and in regard to professional talent and knowledge. The opioid taskforce is representative of pooling talent within a large organization. The opioid taskforce is a group of physicians that are passionate about the opioid epidemic and feel changes within the organization are needed. Having this taskforce in place represents a significant strength for the organization as a whole, and for projects that address opioids.
Staff members are committed to the organization’s mission and strategy and are therefore willing to change in order to improve care for patients. The environment is team-based and everyone strives to work cohesively. The majority of staff members at the primary care clinic are also flexible and open to new ideas.

Other strengths include management and practice lead physician buy in for changes regarding the care of opioid recipient patients. The office manager and practice lead physician of this primary care clinic agree that in order to provide safe and effective care to opioid recipient patients, changes are needed to support each individual and team to achieve success, in which the care team has been given the resources in order to care for patients safely and effectively. Evidence-based practice initiatives represent changes in practice that increase patient safety and allow for providers to effectively care for their patients. The primary care office manager and practice lead physician concur that it is important for the providers within the office to increase evidence-based practice initiatives regarding care being delivered to opioid recipient patients, especially in the midst of a state-wide crisis.

**Weaknesses.** Identified weaknesses related to providing safe and effective care to opioid recipient patients include practice inconsistencies. There is one staff member in the office that has already begun creating a new work flow process regarding practice changes required by law, instead of waiting for official instruction from the opioid taskforce. It may be difficult for some staff to accept new changes and to become consistent in both work flow and documentation. Some providers and nursing staff may feel negatively towards change because its seen as increasing their workload or making it more difficult to care for their patients. Some staff members have reported that they believe these changes will make their work more stressful, because patients who receive opioids are in distress over changes occurring with their care and
express these concerns to staff. While the majority of the staff are receptive to change, even a few staff members with negative attitudes represent a weakness within the primary care office. Additionally, there are no systems in place to assess whether providers and staff are practicing based on recommendations from the opioid taskforce, or whether they are practicing evidence-based care.

**Opportunities.** Opportunities identified for the primary care office include the attention the opioid epidemic is receiving at the national and state levels. Nationally, President Trump has declared the opioid crisis a national public health emergency under federal law and directed all executive agencies to use all available resources to fight the opioid crisis (The White House, United States Government, 2017). At the state level, politicians are equally concerned and have passed new laws to help reduce prescription opioid abuse and decrease the number of deaths related to opioid overdose (Michigan State Medical Society, 2018). At the organizational health systems level, there is a group of physicians whom are part of the opioid taskforce that have been appointed with guiding the outpatient settings through this practice change. The members of the taskforce intend to provide the primary care offices with tools, resources, and policies related to opioid prescription and the care of opioid recipient patients.

**Threats.** Threats to proposed practice change include negative attitudes held by opioid recipient patients regarding satisfaction with their care. Many patients have voiced concern that they are fearful they will no longer be given opioids for the treatment of chronic pain. Some patients have called the office in anger and frustration in regard to recent changes in Michigan law. This in turn causes staff to experience increased stress levels and feelings of resistance to change in practice.

In addition, patients will be required to complete additional forms and consents and will
be subject to random urine drug screens. Prescriptions may change or decrease depending on how they are currently prescribed. All of these changes may result in dissatisfaction among this patient population.

**Clinical Practice Question**

The identified clinical problem is related to opioid prescription and the standards of care for opioid recipient patients. In order to solve this problem, a quality improvement intervention must address the following clinical question: Are providers at the XXX primary care setting utilizing evidence-based practice when caring for opioid recipient patients?

**Review of the Literature**

**Method**

A comprehensive electronic search was conducted in PubMed, CINAHL, and Web of Science Core Collection and was limited to reviews in the English language during the period of 2014 to 2018. Keywords were drug monitoring, guideline, opioid, and primary care. Similar search terms were used by utilizing Boolean operators (OR, AND) which effectively broadened the search to include all relevant articles. The search yielded 332 articles. A total of nine duplicates were found. Each review was screened using inclusion and exclusion criteria (Appendix C). Review of titles and abstracts resulted in removal of 257 articles that did not meet the inclusion criteria. Additionally, a total of 69 articles were excluded after further examination of content, as they did not meet inclusion criteria. Many of the articles were reporting on the same guidelines that were released through the United States Centers for Disease Control and Prevention and were therefore excluded. The remaining six articles were included in this review. The types of articles and study designs include case studies, pre and post intervention patient cohorts, and a multi-pronged quality improvement project. Higher level evidence articles include
critically appraised topics with evidence synthesis and guidelines, systematic review, and prospective longitudinal controlled trial. While randomized controlled trials and evidence reflecting the highest levels of research were desired, it was acknowledged that proper opioid management may be a relatively new topic. Considering the 2017 announcement of the opioid epidemic, applicable research may be currently occurring, and has not been published for review and translation into practice.

**PRISMA**

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) is an evidence-based set of items for reporting in systematic reviews and meta-analyses (Moher, Liberati, Tetzlaff, & Altman, 2009). PRISMA focuses on the reporting of reviews evaluating randomized control trials and is particularly useful when evaluating interventions (Moher et al., 2009). The process utilizes a flow diagram that depicts the flow of information through the different phases of the systematic review (Moher et al., 2009). The flow diagram maps out the number of articles identified, which were included and excluded, and the reasons why certain articles were excluded (Moher et al., 2009). The PRISMA flow diagram was utilized during the literature review process for this project and provides meaningful understanding regarding how the literature review was completed (Appendix C).

**Summary of Results**

Upon review of the six articles selected to be a part of the literature review, a table was created to organize the information (Appendix D). Findings of this literature review highlight the guidelines for opioid prescription, as reported by the CDC (Dowell et al., 2016). To gain better understanding of how the guidelines operate and are utilized in the primary care setting, evidence was reviewed, and it was determined that interventions exist that make guideline implementation
more successful. Quality improvement projects have the propensity to enhance uptake of opioid policies in primary care (Zgierska et al., 2018). In addition to guideline implementation, the primary care provider must also become proficient in the management of patients with issues related to opioid safety, efficacy, and misuse (Becker et al., 2016). Primary care practitioners must also be equipped with strategies for preventing and managing aberrant opioid-related behaviors (Argoff et al., 2014). Evidence supports that there are interventions that assist providers with identifying patients at risk for misuse, increase provider confidence with opioid prescription, and increase positive communication with pain specialists (Jamison et al., 2016).

Evidence to be used for Project

The results of the literature review suggest that current standards of care regarding opioid prescription involve numerous activities that must be carried out by the prescriber. These activities are aimed at patient safety. The following paragraphs will discuss these actions in detail.

First and foremost, the patient should have a documented diagnosis of chronic pain, including the source of the pain and any details pertaining to the diagnosis (Dowell et al., 2016). This activity represents best practice and allows for improved intra-professional communication (Dowell et al., 2016). According to the CDC, it is also important that the prescriber documents morphine milligram equivalents per day in order to gain understanding of how much opioid the patient is ingesting per day (Dowell et al., 2016). Higher amounts of morphine milligram equivalents places the patient at a higher risk for overdose and death, and it is something the provider needs to take into consideration (Dowell et al., 2016). Calculating the morphine milligram equivalent essentially acts as a forewarning to the provider, allowing them to mitigate risk by prescribing naloxone and providing education to the patient and their family (Dowell et
al., 2016). Acknowledging concurrent benzodiazepine use is also evidence-based practice, because it places the patient at risk for respiratory depression and accidental overdose (Dowell et al., 2016). In addition, in alignment with evidence-based care, providers should be screening patients with chronic pain for depression since this population is at a high risk for developing concurrent depression (Zgierska et al., 2018). This can be achieved by using either the patient health questionnaire-2 (PHQ-2) or patient health questionnaire-9 (PHQ-9).

In order to identify and remedy aberrant behaviors related to opioid abuse, there are several evidence-based practice activities that prescribers should utilize. Providers should use urine drug testing before starting opioid therapy and at least annually to assess for prescribed medications, other controlled substances, and illicit drugs (Dowell et al., 2016).

Limitations of the literature review include the lack of high-level evidence, such as systematic reviews or meta-analyses. Because the opioid epidemic has only recently been declared a national crisis, high-level evidence in this arena simply has not been published. Therefore, recommendations implemented in practice are derived from a report published by the CDC (Dowell et al., 2016). It is clear that more research is needed to ensure safe practices regarding opioid prescribing and management practices.

**Phenomenon Conceptual Model**

Conceptual models serve as guides in understanding a phenomenon and also guide change initiatives within an organization. The Donabedian Model is a conceptual model that evaluates main dimensions of health care quality (Donabedian, 1988). These three main components include structure, process, and outcomes, and each component has a direct influence on the next (Appendix E). Structure has an effect on process measures, which in turn affect outcomes (Donabedian, 1988).
Structure

According to the Donabedian Model, structure refers to the characteristics of personnel who provide care to patients and the setting where care is being delivered (Donabedian, 1988). Structure measures reflect the attributes of the provider and organizational characteristics (Donabedian, 1988). In regard to this project, structure measures include use of electronic medical records and the strong support from physicians and staff within the healthcare organization. The physicians working within the opioid taskforce have initiated practice changes that reflect new Michigan state laws for opioid prescription. These initiatives have led to changes in the attitudes of the personnel providing care to patients, and all staff members are now aware of the seriousness of the opioid epidemic. Organizational leaders are currently putting other structures into place that embed certain aspects of care into the electronic health record, including the signed consent form, treatment agreement form, and verification of checking MAPS. However, the process for these structures being placed in the electronic health record have been put on hold because the organization will be changing its electronic record system within the next year.

Process

Process refers to all of the activities taking place while care is being delivered to the patients (Donabedian, 1988). Process measures reflect the way a healthcare system processes work to deliver desired outcomes (Donabedian, 1988). Examples include the length of time a patient waits for their appointment, if patients are receiving certain standards of care, and if staff are recording incidents that occur during a patient visit (Haj, Lamrini, & Rais, 2013). For this project, process measures include whether patients are receiving evidence-based standards of care, and whether these actions are integrated within care processes in tandem with proper
documentation. This includes a documented urine drug screen, documented diagnosis of chronic pain and the source of pain, documented concurrent benzodiazepine prescription, documented depression screening, and documented morphine milligram equivalent.

**Outcomes**

Quality of care can be assessed in terms of outcome measures which include health status indicators, as well as cost of care and patient satisfaction (Donabedian, 1988). Classic examples of outcome measures include reduced mortality, reduced length of stay, reduced infection rates, and improved patient experience (Haj et al., 2013). For this quality improvement project, outcome measures include percentages of eligible adult patients with completed urine drug screening, documented depression screening, documented concurrent benzodiazepine prescription, documented diagnosis of chronic pain with source, and documented morphine milligram equivalent.

**Project Plan**

This Doctor of Nursing Practice (DNP) project will be focused on assessing evidence-based care that is currently being delivered to adult opioid recipient patients. The quality measures that have previously been discussed will be audited through the access of patient charts. The results of the audit will be presented as percentages, depicting what percentage of patients are receiving evidence-based care for each of the quality measures. The results of the audit will be used to meet project goals, including development of a toolkit for continued improvement and sustainability of quality measures, and may be used to guide future initiatives.
Purpose of Project and Objectives

The purpose of this Doctor of Nursing Practice project is to implement a quality improvement program for standards of care regarding adult opioid recipient patients in tandem with designing an evidence-based toolkit for improvement and sustainment. This quality improvement project will be implemented using the Plan-Do-Study-Act model and an applicable toolkit.

Assessing the current state of evidence-based practice and improving upon the care being delivered to opioid recipient patients will be attempted by the DNP student through the following objectives:

- Complete a gap analysis for opioid prescription evidence-based practice in the primary care setting for adult patients receiving opioids by November 30th, 2018
- Communicate findings with leaders, providers, and office staff by March 31st, 2019
- Collaborate with leaders, providers, and office staff to design improvement and/or sustainment strategies by January 2019
- Design a toolkit with evidence-based improvement and sustainment recommendations by January 2019

Design for the Evidence-based Initiative

This is a quality improvement project that will include a retrospective evaluation of quality measures for evidence-based care being delivered to opioid recipient patients. After determination and approval from both the health care organization and Grand Valley State University institutional review boards, the Doctor of Nursing Practice student will perform chart audits of adult patients receiving opioid prescriptions from the primary care clinic. This
collection of data will begin November 2018 and will continue until April 2019. The data will be analyzed using descriptive statistics, and results will be presented to office leaders, providers, and staff for a collaborative discussion. Strategies for improvement and sustainment will be developed. In addition, a toolkit will be designed that addresses the gaps previously identified in the care being delivered to opioid recipient patients. The toolkit will also contain a checklist for prescribing opioids for chronic pain, treatment alternatives for chronic pain, strategies for minimizing opioid prescription abuse, and responding to aberrant drug-related behaviors.

**Setting**

The project will be conducted in a primary care office that is affiliated with a larger health system. The health system is a non-profit healthcare organization that is part of a larger multi-institutional Catholic health system (XXX, 2018). Within the West Michigan area, there are a total of 33 primary care offices that are part of the healthcare system (XXX, 2018). Services are provided to patients of all ages, with a strong focus on wellness and disease prevention. The providers assess and treat patients for acute illness and chronic disease management as well. The population they serve is not only diverse in age, but also in ethnicity and culture. The Doctor of Nursing Practice student has secured administrative approvals to conduct this quality improvement project from the health care organization (Appendix G) and Grand Valley State University (Appendix H).

**Participants**

To be included in the analysis, patients must meet the following criteria: age greater than or equal to 18 years old; active patient status (seen in the past three years); have a primary care provider within this office; do not have a diagnosis of malignant neoplasm or hospice status; and have at least one opioid prescription in
the past 45 days that was not given for acute pain. Patients will be excluded if they are younger than 18 years of age, have not been seen in the past three years, have a diagnosis of malignant neoplasm or are currently hospice status, or have not been given an opioid prescription in the last 45 days.

Model Guiding Implementation

The Plan-Do-Study-Act (PDSA) model is a four-stage problem-solving model that is used to improve a process and carry out changes within an organization (Appendix F). The PDSA model is typically used for small to medium scaled quality improvement projects (Institute for Healthcare Improvement, 2018). Improving quality means making healthcare safer, more efficient, patient centered, effective, and equitable (Donnelly & Kirk, 2015).

**Plan.** The first step of the planning stage is to assemble a team that has knowledge of the problem (Institute for Healthcare Improvement, 2018). Roles and responsibilities need to be identified, timelines must be set, and a meeting schedule must be established (Institute for Healthcare Improvement, 2018). Next, an aim statement should be made, which states what is trying to be accomplished and what changes can be made to improve the situation (Institute for Healthcare Improvement, 2018). Current process needs to be examined by completing a strengths, weakness, opportunities, and threats (SWOT) analysis (Institute for Healthcare Improvement, 2018). After the SWOT analysis is completed, a problem statement must be written to clearly summarize the problem (Institute for Healthcare Improvement, 2018). Lastly, an action plan needs to be developed that includes necessary resources and a timeline (Institute for Healthcare Improvement, 2018).

**Do.** The second step is to implement the action plan that was developed in step one. Data collection occurs during this step from a particular point in time and is measured over a period of
time in order to record patterns in the data (Donnelly & Kirk, 2015). The investigator should also document problems, unexpected findings, and general observations (Institute for Healthcare Improvement, 2018).

**Study.** The third step of the process is to use the aim statement from step one and the data gathered in step two in order to determine results and trends in the data (Institute for Healthcare Improvement, 2018). This involves studying and analyzing the data and the process itself (Donnelly & Kirk, 2015). To facilitate seeing trends in data, descriptive statistics can be used to present the data in a meaningful way. Information can be displayed in graphs and charts for ease of use.

**Act.** The fourth step of the process is to determine whether the plan resulted in success, or whether the process needs to be re-examined (Institute for Healthcare Improvement, 2018). Accomplishments from the project should be communicated to appropriate personnel and steps to preserve gains and sustain accomplishments should be taken (Institute for Healthcare Improvement, 2018). Lastly, the project should be documented and what was learned from the process must be clearly expressed (Donnelly & Kirk, 2015).

According to current evidence, standards of care for opioid recipient patients were identified and recommendations were published for primary care providers as a guide (Dowell et al., 2016). Current literature also provides evidence that providing health care providers with educational interventions, such as toolkits, can positively impact the care they provide to their patients (Zgierska et al., 2018). In order to complete this quality improvement project, the Doctor of Nursing Practice student will use the PDSA model as a guide for implementation, which will be discussed in the following sections.
Implementation Steps and Strategies

This quality improvement project will be implemented at a primary care clinic. Project procedures will occur tentatively between November 5, 2018-April 1, 2019. The project steps are as follows:

1. The Doctor of Nursing Practice student will perform chart audits at the primary care clinic on a monthly basis between November 2018 until April 2019, and data will be collected for evidence-based quality measures including the following:
   a. Documented urine drug screening (at least annually)
   b. Documented diagnosis of chronic pain and source of pain
   c. Documented concurrent benzodiazepine prescription
   d. Documented depression screening (PHQ 2 or PHQ 9)
   e. Documented morphine milligram equivalent (MME)

2. The Doctor of Nursing Practice student will collaborate with information technology personnel in order to obtain reports that address the evidence-based quality measures outlined in step one. This will be completed by January 31, 2019.

3. The Doctor of Nursing Practice student will assess the use of evidence-based practice guidelines by analyzing the gathered data using descriptive statistics. This will include a consultation with a statistician. Graphs and pie charts will be utilized in order to present the information in a meaningful way. This will be completed by March 31, 2019.

4. The Doctor of Nursing Practice student will communicate findings with leaders, providers, and office staff by April 30, 2019. Results of chart reviews, including statistics and outcomes reflecting quality improvement initiatives will be presented to
providers at the primary care office that shows collective results of the following quality measures:

a. Percent of eligible adult patients with urine drug screening completed

b. Percent of eligible adult patients with documented screening using PHQ 2 or PHQ9 depression screening tool

c. Percent of eligible adult patients with documented concurrent benzodiazepine prescription

d. Percent of eligible adult patients with documented diagnosis of chronic pain and source of pain

e. Percent of eligible adult patients with documented morphine milligram equivalent (MME)

5. The Doctor of Nursing Practice student will collaborate with leaders, providers and office staff to design improvement strategies that reflect organizational goals and sustainment strategies. This will be completed by February 28, 2019.

6. The Doctor of Nursing Practice student will develop a toolkit with evidence-based improvement and sustainment recommendations. The content of the toolkit will be based upon results obtained during data collection and data analysis. This will be completed by March 31, 2019.

7. The Doctor of Nursing Practice student will share recommendations for improvement of quality measures with leaders, providers and office staff by April 30, 2019.

8. The Doctor of Nursing Practice student will deliver an evidence-based toolkit to organizational leaders, providers and office staff by April 30, 2019. The toolkit content will entail the following at minimum:
a. Checklist for prescribing opioids for chronic pain
b. Treatment alternatives for chronic pain
c. Strategies for minimizing opioid prescription abuse and responding to aberrant drug-related behaviors

9. The Doctor of Nursing Practice student will ensure a sustainment plan is in place that includes the following:
   a. The identification of a staff member within the organization to monitor quality indicators after the student has finished the project by April 30, 2019.
   b. The organization will be presented with a toolkit for future use in practice, which will act as guide for everyday practice by April 30, 2019.

Measures

The first indicator to be assessed is whether the clinical question was able to be answered through the completion of a gap analysis for opioid prescription in the primary care setting. Data obtained from chart review and reports obtained through the assistance of information technology personnel will be analyzed by the Doctor of Nursing Practice student with the assistance of a statistician. The data will be presented through descriptive statistics and will be utilized in determining the answer to the previously stated clinical question.

The next indicator to be assessed includes whether findings were able to be communicated with leaders, providers and office staff. This will be achieved during a monthly staff meeting in March 2019. This will require collaboration with, along with approval from the office manager.

Lastly, indicators include whether an evidence-based toolkit was designed through collaboration with leaders, providers and office staff that includes improvement and sustainment
recommendations. The Doctor of Nursing Practice student will develop the toolkit based on needs identified during data analysis. The toolkit will be tailored to address measures that were found to be less than satisfactory.

**Data Collection Procedures**

The data collection will be conducted by the Doctor of Nursing Practice student. The data will be collected from two separate timeframes, which will be June 1st, 2018, to September 30th, 2018, and October 1st, 2018, to January 31st, 2019. All data collection will take place onsite at the primary care office and will occur between November 5th, 2018 and April 1st, 2019. The data will be collected from electronic health records of patients that fit the specified criteria. Again, this will include documentation of a urine drug screen, documentation of depression screening, documentation of morphine milligram equivalents, documentation of chronic pain diagnosis with source of pain, and documented concurrent benzodiazepine use. At this time, the sample size is not known. For this quality improvement project, an instrument will not be used for data collection, such as a questionnaire. Instead, the data will be collected during chart audits. The data collected from the patient charts by the Doctor of Nursing Practice student will be entered into a spreadsheet that can later be used for analysis by a consulting statistician.

**Data Management**

The Doctor of Nursing Practice student will be responsible for data management. The data will be generated through chart audits conducted by the Doctor of Nursing Practice student and entered into a spread sheet. The student will also consult with information technology personnel to obtain aggregate data. At this point, it has not been determined which measurements are capable of being pulled through reports generated by information technology personnel within the organization. There will be no identifiable data. Only project
team members and the consulting statistician will have access to the data and use it for completion of this project. All study records and data will be kept and accessible for a minimum of seven years, as required by the healthcare organization.

**Analysis**

Summary/descriptive statistics will be used to summarize the data in a meaningful way, allowing for simpler interpretation of the data. Frequency and percentage statistics will be utilized to present the data. The analysis will be completed by the Doctor of Nursing Practice student and a Grand Valley State University statistician. The data will be displayed using graphs, tables, and pie charts. Using the graphs, tables, and pie charts will allow the Doctor of Nursing Practice student to identify which measures will require the greatest amount of educational material to be presented in the toolkit. For example, if the majority of patients do not have a documented urine drug screen, there will be an educational element within the toolkit that addresses strategies to improve that quality measure.

**Resources & Budget**

The financial operating plan for this quality improvement project includes an evaluation of revenue and expenses (Appendix I). Expenses for this project include time and resources required of the Doctor of Nursing Practice student to gather data from patient charts, develop educational and toolkit materials, and implement education to the providers, leaders, and staff within the primary care office. The largest cost for this project is the time that the Doctor of Nursing Practice student is providing to the organization. This donation of time by the Doctor of Nursing Practice student will be made in an in-kind donation. The project site mentor and primary care office manager will also be providing an in-kind donation of time to the
organization by assisting the student with the project. Other costs of the project include consultations with a statistician and information technology staff. Additional costs also include laptop, the cost of occupying office space, and the cost of printed education and toolkit material.

The budget table displays data in both the expenses and revenue columns that are similar. This was done intentionally to show that the time and resources needed to support this quality improvement project were donated and can be considered revenue. However, if the staff were removed from their regular practices to participate in a meeting specific to the project, there is an expense for their time. The presentation of project findings and subsequent educational session will be completed during a staff meeting, therefore no additional costs for reimbursing staff will be incurred. However, it is important to consider the cost for their time, as there are six physicians, two nurse practitioners, and one physician assistant that will be present at the provider meeting. The average hourly wage for a primary care physician is $100 (Salary.com, 2018a). The average hourly wage for primary care nurse practitioners is $48 (Salary.com, 2018b). The site mentor for the project is a nurse practitioner, and it is estimated that she will spend an additional 30 hours working on the project in collaboration with the Doctor of Nursing Practice student. The average hourly wage for a primary care physician assistant is also $48 (Salary.com, 2018c). The office manager, and two staff lead registered nurses will also be present at the meeting. The average hourly wage for the office manager is $30 (Payscale.com) and her estimated time spent contributing to the project is 15 hours. The average hourly wage for registered nurses is $26 (Payscale.com, 2018b).
Consultations for the project will include a statistician and information technology personnel. It is estimated that the statistician will spend 6 hours analyzing data and producing meaningful descriptive statistics, with an average hourly wage of $50 (Salary.com, 2018d). It is estimated that information technology personnel will spend 5 hours complying reports for the project, with an average hourly wage of $32 (Salary.com, 2018e).

To mitigate costs incurred, it is important to consider the costs associated with risks of not implementing this project. This includes the value placed on human life and patient safety. Standards of care regarding opioid prescription as described in the literature strive to save lives by helping providers practice in a way that decreases risk of opioid overdose, whether it be intentional or accidental.

**Timeline**

Project planning began spring of 2018 with the completion of a project prospectus. During summer of 2018, an organizational assessment and literature review were completed. During fall of 2018, project planning continued, and documents were submitted to the healthcare organization’s institutional review board and Grand Valley State University’s institutional review board. The student will make a formal project presentation November 5th, 2018 that outlines the project for project members and advisors. The project work will take place between November 5th, 2018 and April 1, 2019. Data collection will take place between November 5th, 2018 and January 31st, 2018. After data collection is completed in January 2018, the student will compile the results and present them to the healthcare organization and Grand Valley State University team members in a final project.
Sustainability Plan

Sustainability is a vital piece to include when planning and implementing a quality improvement project. If a sustainability plan is not part of the project, the staff of the organization may find themselves repeatedly solving the same problems. In an effort to promote sustainability, the sustainability plan will address two categories which include staff and process. The sustainability plan for this project includes the identification of a staff member within the organization to monitor quality indicators. It is important that this individual is someone that is invested in the organization and is passionate about improving quality of care and patient safety. This could potentially be the practice lead physician or the office manager. In order to promote sustainability at a process level, the organization will be presented with a toolkit for future use in practice. By providing a toolkit, the providers and staff members will have access to resources that positively impact the care they provide.
References


https://www.payscale.com/research/US/Job=Primary_Care_Registered_Nurse_(RN)/Hourly_Rate

https://www1.salary.com/MI/family-physician-salary.html

https://www1.salary.com/MI/Nurse-Practitioner-salary.html

https://www1.salary.com/MI/Physician-Assistant-Medical-salary.html

https://www1.salary.com/Statistician-V-hourly-wages.html

https://www.whitehouse.gov/opioids/

http://www.who.int/dietphysicalactivity/griffiths-stakeholder-involvement.pdf

XXX. (2018). *XXX Health system, a member of XXX health*. Retrieved from
https://www.mercyhealth.org/about/trinity-health/

Appendix A

The Burke-Litwin Model

Appendix B

SWOT Analysis

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Support of larger health care system</td>
<td>• Negative attitudes within the primary care office among some individuals</td>
</tr>
<tr>
<td>• Positive culture within setting, motivated to keep patients safe</td>
<td>• Practices vary within the organization’s primary care offices</td>
</tr>
<tr>
<td>• Management and practice lead buy in</td>
<td>• Currently no system in place to evaluate current practices regarding care of opioid recipient patients</td>
</tr>
<tr>
<td>• Strong working relationships</td>
<td></td>
</tr>
<tr>
<td>• Strong leadership</td>
<td></td>
</tr>
<tr>
<td>• Strong emphasis on evidence-based practices</td>
<td></td>
</tr>
<tr>
<td>• Current initiatives that address care processes regarding opioid prescription</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>• US government has declared the opioid crisis a national public emergency</td>
<td>• Negative attitudes and beliefs held by some opioid recipient patients</td>
</tr>
<tr>
<td>• New state laws regarding opioids to combat the opioid epidemic</td>
<td>• Negative attitudes and beliefs held by some staff members</td>
</tr>
<tr>
<td>• Organizational opioid taskforce</td>
<td>• Electronic health system changes occurring in the near future prohibit growth within current electronic system</td>
</tr>
</tbody>
</table>
Appendix C

Flow Diagram

- **Identification**: Articles identified through 3 databases (n=332)
  - Articles after duplicates removed (n=323)
    - Articles screened (n=323)
      - Articles excluded after Title/Abstract screen (n=257)
      - Full-text articles assessed for eligibility (n=69)
        - Articles excluded because of population, setting, and intervention (n=63)
        - Articles included (n=6)
## Appendix D

### Table of Evidence

<table>
<thead>
<tr>
<th>Author (Year), Title, Purpose</th>
<th>Design (N)</th>
<th>Intervention/Methods</th>
<th>Results</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argoft, C. E., Kahan, M., &amp; Sellers, E. M. (2014). Preventing and managing aberrant drug-related behavior in primary care: systematic review of outcomes evidence. Purpose: To review evaluated data supporting basic strategies for addressing aberrant opioid-related behaviors.</td>
<td>Systematic Review</td>
<td>PubMed was searched using 9 general headings related to minimizing opioid abuse risk and addressing aberrant drug-related behavior.</td>
<td>Nine distinct strategies for minimizing abuse and responding to aberrant drug-related behaviors were identified and discussed.</td>
<td>Weak to moderate evidence supports the value of thorough patient assessment, risk-screening tools, controlled-substance agreements, careful dose titration, opioid dose ceilings, compliance monitoring, and adherence to practice guidelines. Moderate to strong evidence suggests that prescribing tamper-resistant opioids may help prevent misuse but may also have the unintended consequence of prompting a migration of users to other marketed opioids, heroin, or other substances.</td>
</tr>
<tr>
<td>Becker, W. C., Merlin, J. S., Manhapra, A., &amp; Edens, E. L. (2016). Management of patients with issues related to opioid safety, efficacy and/or misuse: a</td>
<td>Case studies (Series of 3)</td>
<td>The authors present three cases referred to their primary care clinic that highlight</td>
<td>With respect to assessment, the cases represent making the diagnosis of opioid use disorder, allowing the patient space, identification of co-occurring hazardous alcohol use, and</td>
<td>The three cases represent common challenges at the intersection between chronic pain and opioid safety, efficacy and misuse.</td>
</tr>
</tbody>
</table>
case series from an integrated, interdisciplinary clinic. Purpose: To improve the quality of care of patients with co-occurring chronic pain and issues related to opioid safety, efficacy and/or misuse.

| Purpose | complex clinical scenarios. | recognizing barriers to multimodal pain care. With respect to treatment, the cases represent changes in treatment with which the patient may not agree, effectiveness of buprenorphine/naloxone for treatments of chronic pain and making continued opioid therapy contingent on engagement with substance abuse treatment. |


| Pre and post intervention patient cohorts (N=119) | Guidelines were disseminated through presentation at mandatory meetings and e-mail distribution. Pre and post intervention evaluation periods to identify changes in patient and provider behaviors. | After disseminating guidelines, the percentage of noncancer clinic patients receiving any opioid Rxs dropped from 3.9% to 3.4% (P=0.02). The percentage of noncancer patients receiving chronic opioid Rxs decreased from 2.0% to 1.6% (P=0.03). The rate of urine drug screening increased from 9.2% to 17.3% (P=0.005) amongst noncancer chronic opioid patients. | An educational intervention for opioid prescribing in a general primary care setting is feasible and may be expected to modestly reduce overall opioid Rx rates and increase provider use of systematic monitoring methods. |

Dowell, D., Haegerich, T. M, & Chou, R. (2016). CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. Purpose: To report guidelines from CDC that addresses 1) when to critically appraised topic-Evidence synthesis and guidelines. CDC developed the guideline using the Grading of Recommendations Assessment, Development, Guidelines for prescribing opioids for chronic pain were created, as well as a checklist that providers can use when prescribing opioids for chronic pain. Checklist: http://stacks.cdc.gov/view/cdc/38025 This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve
<table>
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<tr>
<th>Initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use.</th>
<th>and Evaluation (GRADE) framework, and recommendations were made on the basis of a systematic review of the scientific evidence.</th>
<th>the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jamison, R. N., Scanlan, E., Matthews, M. L., Jurcik, D. C., &amp; Ross E. L. (2016). Attitudes of primary care practitioners in managing chronic pain patients prescribed opioids for pain: A prospective longitudinal controlled trial. Purpose: To help determine whether patient risk assessment and incorporation of a structured opioid therapy protocol of monthly monitoring and compliance checklists would improve practitioner confidence in managing challenging chronic pain patients within a busy primary care center.</td>
<td>Prospective longitudinal controlled trial (N=56 PCPS, N=253 patients)</td>
<td>The following measures were administered to each of the primary care participants: background and prescribing practices questionnaire, general health questionnaire, opioid therapy survey, concerns about analgesic prescriptions, and test of opioid knowledge. The following measures were administered to each of the patients that</td>
</tr>
<tr>
<td>The following measures were administered to each of the patients that</td>
<td>After 1 year all the PCPs reported improvement in identifying patients at risk for misuse (P&lt;0.05), perceived confidence in prescribing opioids for pain (P&lt;0.05), and increased satisfaction with communication with pain specialists (P&lt;0.05). The patients reported greater compliance with their opioid medication and felt that the monthly monitoring was beneficial.</td>
<td>The results of this study demonstrated improvement in the number of practitioners who could identify patients at risk for misuse, were satisfied with communication are the center, and felt sufficiently trained in opioid prescribing.</td>
</tr>
</tbody>
</table>
Zgierska, A. E., Vidaver, R. M., Smith, P., Ales, M. W., & Nisbet, K. (2018). Enhancing system-wide implementation of opioid prescribing guidelines in primary care: protocol for a stepped-wedge quality improvement project. Purpose: The goal of this quality improvement (QI) project is to assess whether a clinic-tailored QI intervention improves the implementation of guideline-driven recommendations in primary care. The authors hypothesize that the addition of this intervention will enhance implementation of guideline-driven recommendations in primary care. Developing methods for a health system-tailored QI intervention required a multi-step process to incorporate end-user feedback and account for the needs of targeted clinic team members. Delivery of such tailored QI interventions can enhance uptake of opioid policies in primary care.
of a health system-wide, guideline-driven policy on opioid prescribing in primary care.

treated chronic pain. The QI intervention included clinic-wide and individual clinician-level educational interventions. To evaluate the impact of the QI intervention, the team collected two main types of data before, during, and after intervention: a) EHR-based clinic-level data on elements of the health system’s opioid policy; and b) process measures from the clinical staff, and project team experiences, and perceptions related to the QI intervention implementation.
Appendix E

Donabedian Model

Appendix F

Plan Do Study Act Model

Appendix G

Health Care Organization Internal Review Board Determination Letter

NOTICE OF CLINICAL QUALITY IMPROVEMENT MEASUREMENT DESIGNATION

To: Anne Sproat, RN, BSN
8420 Corvette Ct.
Jenison, MI 49428

Re: IRB# 18-1019-3
Quality Improvement Project: Evaluation of Processes and Procedures for Care of the Opioid Recipient Patient in the Primary Care Setting

Date: 10/25/2018

This is to inform you that the Mercy Health Regional Institutional Review Board (IRB) has reviewed your proposed research project entitled "Quality Improvement Project: Evaluation of Processes and Procedures for Care of the Opioid Recipient Patient in the Primary Care Setting". The IRB has determined that your proposed project is not considered human subjects research. The purpose and objective of the proposed project meets the definition of a clinical quality improvement measurement. All publications referring to the proposed project should include the following statement:

"This project was undertaken as a Clinical Quality Improvement Initiative at Mercy Health and, as such, was not formally supervised by the Mercy Health Regional Institutional Review Board per their policies."

The IRB requests careful consideration of all future activities using the data that has been proposed to be collected and used "in order to assess the use of evidence-based practice guidelines regarding the care delivered to opioid recipient patients."

The IRB requests resubmission of the proposed project if there is a change in the current clinical quality improvement measurement design that includes testing hypothesis, asking a research question, following a research design or involves overriding standard clinical decision making and care.

Please feel free to contact me if you have any questions regarding this matter.

Tiffany VanTilburg, CIC
Office of the IRB

Copy: File

Appendix H

Grand Valley State University Internal Review Board Determination Letter

DATE:          October 31, 2018

TO:            Amy Mauerscheid
FROM:          HRRC
STUDY TITLE:   Quality Improvement Project: Evaluation of Processes and Procedures for Care of the Opioid Recipient Patient in the Primary Care Setting
REFERENCE #:   19.127.H
SUBMISSION TYPE: HRRC Initial Submission
ACTION:        Not Human Subjects Research
EFFECTIVE DATE: October 31, 2018
REVIEW TYPE:   Administrative Review

Thank you for your submission of materials for your planned scholarly activity. It has been determined that this project does not meet the definition of research* according to current federal regulations. The project, therefore, does not require further review and approval by the Human Research Review Committee (HRRC).

A summary of the reviewed project and determination is as follows:

This quality improvement project will assess use of evidence-based practice guidelines regarding the care being delivered to opioid recipient patients in tandem with recommendations for further improvement and/or sustainment. While this is a systematic investigation, it is not designed to contribute to generalizable knowledge as the project seeks to improve the care at a single local institution. Therefore, it does not meet the federal definition of research and IRB oversight is not needed.

An archived record of this determination form can be found in IRBManager from the Dashboard by clicking the "_xForms" link under the "My Documents & Forms" menu.

If you have any questions, please contact the Office of Research Compliance and Integrity at (616) 331-3167 or mrc@gsu.edu. Please include your study title and study number in all correspondence with our office.

Sincerely,
Office of Research Compliance and Integrity

*Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(f)).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (45 CFR 46.102(f)).

Scholarly activities that are not covered under the Code of Federal Regulations should not be described or referred to as research in materials to participants, sponsors or in dissemination of findings.
## Appendix I

### Budget for Project

<table>
<thead>
<tr>
<th>Project Financial Operating Plan</th>
<th>Standards of Care for Opioid Recipient Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td></td>
</tr>
<tr>
<td>Project Manager Time (in-kind donation)</td>
<td>9,000.00</td>
</tr>
<tr>
<td>Team Member Time:</td>
<td></td>
</tr>
<tr>
<td>Site Mentor Time (in-kind donation)</td>
<td>1,440.00</td>
</tr>
<tr>
<td>Primary Care Office Manager</td>
<td>450.00</td>
</tr>
<tr>
<td>6 Physicians (1 hour staff meeting)</td>
<td>600.00</td>
</tr>
<tr>
<td>1 Physician Assistant (1 hour staff meeting)</td>
<td>48.00</td>
</tr>
<tr>
<td>2 Registered Nurses (1 hour staff meeting)</td>
<td>52.00</td>
</tr>
<tr>
<td>2 Nurse Practitioners (1 hour staff meeting)</td>
<td>90.00</td>
</tr>
<tr>
<td>Consultations:</td>
<td></td>
</tr>
<tr>
<td>Statistician</td>
<td>300.00</td>
</tr>
<tr>
<td>IT staff</td>
<td>160.00</td>
</tr>
<tr>
<td>Cost of space</td>
<td>800.00</td>
</tr>
<tr>
<td><strong>TOTAL INCOME</strong></td>
<td>12,940.00</td>
</tr>
</tbody>
</table>

| Expenses                          |                                               |
| Project Manager Time (in-kind donation) | 9,000.00                                    |
| Team Member Time:                 |                                               |
| Site Mentor Time (in-kind donation) | 1,440.00                                     |
| Primary Care Office Manager       | 450.00                                        |
| 6 Physicians (1 hour staff meeting) | 600.00                                       |
| 1 Physician Assistant (1 hour staff meeting) | 48.00                                         |
| 2 Registered Nurses (1 hour staff meeting) | 52.00                                        |
| 2 Nurse Practitioners (1 hour staff meeting) | 90.00                                         |
| Consultations:                    |                                               |
| Statistician                      | 300.00                                        |
| IT staff                          | 160.00                                        |
| Laptop                            | 800.00                                        |
| Cost of space                     | 800.00                                        |
| Cost of printed education and toolkit material | 40.00                                      |
| **TOTAL EXPENSES**                | 13,780.00                                     |

| **OPERATING INCOME** | -840.00 |
Appendix J

Approval of Use for Burke-Litwin Model
Appendix K

Approval of Use for Donabedian Model

*Awaiting
Appendix L

Approval for Use of Plan Do Study Act Model