IMPROVING COMPLIANCE WITH BEST PRACTICE STANDARDS FOR PATIENTS AT RISK FOR OPIOID USE DISORDER

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Abstract

Background: Available literature suggests that provider adherence to best practice guidelines regarding the prescribing and management of opioid therapies is low. Documentation of patient screening for present or future opioid use disorder is inconsistent. Provider incorporation of evidence-based guidelines into routine patient care is essential to optimizing outcomes related to opioid use disorders.

Purpose/Specific Aims: The purpose of this scholarly project was to facilitate recognition of patients at high risk for opioid use disorders and facilitate best evidence-based practices in the care of this population. Specific aims were to achieve provider compliance with: patient risk screening, PDMP review, completion of signed care plans, and reduction of inappropriate opioid prescriptions.

Methods: A quasi-experimental design was used for this quality improvement project. The sample included patients receiving treatment for acute or chronic pain, or who were identified as having a substance use disorder. The project was conducted at an internal medicine practice in the northeast region. The intervention included an educational program addressing the ASAM guidelines and ORT utilization with implementation of a SmartPhrase in Epic. Baseline data was collected for the two-month period preceding the intervention and post-intervention data was collected for the three-month period following the intervention. Differences in pre- and post- intervention results were analyzed using chi square.

Results: This project resulted in improved compliance with the implementation of urine toxicology screening, PDMP review, and completion of a controlled substance agreement. Compliance with ORT was not achieved.

Conclusion: This project led to an increase in compliance with best opioid prescribing practices. The ORT was not consistently implemented; however, the number of new opioid prescriptions remained negligible. Additional efforts will be necessary to maintain the progress achieved in this project including attention to continued provider education. Real-time auditing and feedback will also be incorporated, and opportunities to involve office staff will be explored.

Key Words: Opioid Use Disorder; Opioid Risk Tool; Evidence-Based Practice

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IMPROVING COMPLIANCE WITH BEST PRACTICE STANDARDS FOR PATIENTS AT RISK FOR OPIOID USE DISORDER

The prevalence of opioid use disorder (OUD) and subsequent related overdose rates have increased significantly over the last decade, resulting in considerable morbidity and mortality (Strain, 2018). Identification and implementation of strategies to mitigate the negative outcomes associated with OUD is essential. This scholarly project was designed to translate evidence-based guidelines on opioid prescribing into practice and to evaluate the effectiveness of the intervention on related processes and outcomes.

Background and Significance

Opioid use disorder is defined by the Center for Disease Control (CDC) as a problematic pattern of opioid use leading to clinically significant impairment (2018). Opioid use disorder has become a topic of national interest in the past decade, with aggressive reforms having been made to federal and state prescribing regulations. In the United States, there is an estimated incidence of opioid use disorder of two to sixteen million people (Barclay, Owens, & Blackhall, 2014; Reyes-Gibby, Anderson, & Todd, 2010; Shuckit, 2016; Wei, et al., 2019). Over four million people have reported non-medical use of prescription opioids in their lifetime (Rager & Schwartz, 2017; Schuckit, 2016). Nearly half of patients who report the recreational use of opioids meet the criteria for a diagnosis of opioid use disorder based on the criteria according to the Diagnostic and Statistical Manual – Fifth Edition (DSM-V) (Rager & Schwartz, 2017; Shuckit, 2016; Strain, 2018). According to the CDC (2018), opioid use disorder begins with a prescription medication in 62% of cases. These opioids are either prescribed for the individual or taken from a relative or friend (CDC, 2018; Rager & Schwartz, 2017).

Many patients who begin misusing prescription opioids later shift to illicit opioids, such as heroin, which is associated with a higher risk for overdose (Strain, 2018). Heroin is often mixed with the synthetic opioid, Fentanyl, which significantly increases the risk of overdose and mortality (NIDA, 2019).

To address the epidemic of opioid use disorder, the National Academies of Sciences, Engineering and Medicine released the seminal report *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Us*e (Bonnie, Ford, & Phillips, 2017). This report identified the need for broad intervention across various levels. Specifically, the report calls for the need to restrict supply, optimize prescribing practices, reduce demand, and reduce harm (Bonnie, et al., 2017). Optimization of prescribing practices is a primary responsibility of providers with authority to prescribe opioid medications.

Evidence-based guidelines supporting best practices in opioid prescribing include patient screening for risk of opioid use disorder using a valid screening tool and provider implementation of a controlled substance agreement, review of the prescription drug monitoring program (PDMP), and monitoring of urine toxicology results for non-prescribed substances for all patients receiving opioid medications (ASAM, 2015). Despite the development of national guidelines, provider compliance with these best practices is low, and data describing the effectiveness of interventions to achieve compliance with these best practices is limited (Naimer, Munro, Singh, & Permaul, 2019). Therefore, there is a need for new evidence to support best practices in the implementation of evidence-based best practices in opioid prescribing.

Literature Review

Opioid Use Disorder and Opioid Misuse

Opioid use disorder is a chronic relapsing condition that often occurs when an individual develops dependence on these medications. Opioids activate mu receptors, initiating intracellular communication by G protein stimulation (Strain, 2018). These receptors are present in the central and peripheral nervous system, with the stimulation of either causing different effects on the body. For example, central nervous system mu receptor stimulation results in physiologic responses such as respiratory depression, analgesia, euphoria, and miosis (Strain, 2018). Stimulation of the receptors within the peripheral nervous system results in physiologic responses such as cough suppression and opioid-induced constipation (Strain, 2018). Activation of both central and peripheral mu receptors may result in negative or positive effects, but adverse effects become more common with overuse.

The DSM-V defines opioid use disorder as a problematic pattern of opioid use that leads to clinically significant impairment or distress (American Psychiatric Association, 2016). To meet diagnostic criteria for opioid use disorder, a patient must have at least two of the following characteristics: opioids taken in larger amounts than intended, persistent desire or unsuccessful attempts to reduce use, increased time spent attempting to obtain the substance, the development of cravings when the substance is not obtained, use leading to failures in work or home life, continued use despite clear social and interpersonal problems, and signs of tolerance or withdrawal without constant use (APA, 2016). The severity of the disease is based on how many of the above conditions are met.

With continued use of the substance, tolerance may occur. As tolerance occurs, the patient becomes less responsive to the effects of the medication, eventually requiring a larger dose to achieve the same effect previously achieved with smaller doses (Strain, 2018). The addictive nature of these medications may also lead to withdrawal symptoms when the medication is stopped. These include tearing eyes, rhinorrhea, yawning, muscle twitching, and hyperactive bowel sounds, cravings, and dysphoria (Strain, 2018). Opioid withdrawal symptoms are measured by healthcare clinicians using the Clinical Opiate Withdrawal Scale (COWS), which classifies severity of symptoms based on clinical presentation and self-reported symptoms (ASAM, 2015). The desire to avoid a state of withdrawal often leads to continued escalating use, which puts patients at highest risk for overdose.

The overall rate of OUD is estimated to be between two to sixteen million Americans (Chen, Hom, Richman, Asch, Podchiyska, & Johansen, 2016; Florence, Luo, Xu, & Zhou, 2016; Bonnie, Ford, & Phillips, 2017). The estimated prevalence of OUD among patients who were prescribed an opioid is 8%, and the estimated incidence of combined misuse, OUD and aberrant behaviors ranges from 15-26% (Bonnie, et al., 2017). The incidence of OUD among patients prescribed opioids for chronic pain is even higher at 21-29% (Vowles, McEntee, Julnes, Frohe, Ney, & van der Goes, 2015). Not only is the problem of OUD far reaching, but the incidence has continued to increase. In fact, Florence, et al., (2016), report that the incidence of OUD has increased by 200,000 individuals since 2007.

Opioid use disorder carries a significant cost burden. The cost associated with the care of patients with OUD was found to be $13,000-$17,000 higher compared to patients

without an opioid use disorder (Florence, Luo, Xu, & Zhou, 2016). These authors further estimated the aggregate cost of OUD to be between $70-$80 billion (Florence, et al., 2016).

Screening Tools

As opioid use disorders are becoming more prevalent, screening tools are being developed to identify risk among populations of all ages, genders, and risk factors. These screening tools are imperative in better understanding aberrant drug-related behaviors to assist providers in recognizing early signs of addiction and referring to appropriate care centers (Moore, Jones, Browder, Daffron, and Passik, 2009). There is not currently one universal screening tool intended for use across all patient populations. There are, however, recommendations in place from the CDC and the American Society of Addiction Medicine (ASAM) that encourage clinicians to use at least one of the screening tools available to assess for opioid use and related risk in the general population. Most primary care offices for adult patient populations have incorporated screening tools into their initial assessment of the patient and continue to assess throughout their care length. If patients are identified as currently having, or as being at high risk for developing an opioid use disorder, clinicians are encouraged to implement evidence-based interventions as appropriate for each case. Examples of commonly utilized screening tools include the Screener and Opioid Assessment for Patients with Pain (SOAPP), the Opioid Risk Tool (ORT), and the Diagnosis, Intrac (NIDA, 2018). These screening tools vary in utilization based on patient population of each clinical site. One study performed by Moore, Jones, Browder, Daffron, and Passik, (2009), demonstrated that the SOAPP performed the best of the three screening tools with credit

given to its utility and specificity. The second best validated tool was the ORT score, with increased feasibility found in clinical settings (Moore, et al., 2009). Barclay, Owens and Blackhall (2014) utilized the ORT in their clinical practice due to its high sensitivity and specificity, especially with the combined assessment of results through clinical examination. They also noted that the ORT is the only screening tool to focus on family history and personal history of substance use (Barclay, et al., 2014). Overall, there is not one tool recommended over another and further research is required to standardize screening procedures.

The ORT has been recommended by the Rhode Island Department of Health as a best practice measure for screening patients for opioid use disorders. The ORT is well validated, and is more feasible for use in the proposed study settings due to ease of administration and minimal time requirements for implementation. For these reasons, the ORT has been selected as the screening tool for this study.

The ORT is a clinician or self-reported screening tool designed to assess adults, particularly in the primary care setting, for the potential abuse of prescribed opioid medications for acute or chronic pain. This tool should be administered before initiation of opioid therapy to determine future risk of opioid disordered behavior. The tool assigns point values differentiated by gender for family history of substance abuse, personal history of substance abuse, age group, history of preadolescent sexual abuse, and psychological disease presence. Higher scores are correlated with higher risk of disordered medication behavior and should alert the clinician that the abuse potential is high. The use of the ORT in clinical practice is intended to help clinicians weigh potential risks and benefits of initiation of opioids (NIDA, 2018).

The ORT score was validated using a c-statistic, in which sensitivity and specificity are measured simultaneously. The c-statistic measures predictive ability of a prognostic model and, specifically for the ORT score, it is defined as the likelihood that a patient who exhibits an aberrant behavior will have a higher predicted risk of such a behavior than does a patient who does not exhibit such an aberrant behavior (Webster & Webster, 2006). C-statistics are interpreted as $c = 0.5$ suggesting no discrimination, $0.7 < c < 0.8$ is considered acceptable discrimination, $0.8 < c < 0.9$ is considered excellent discrimination, and $c > 0.9$ is considered outstanding discrimination (Webster & Webster, 2006). The study found that the female prognostic model had a c statistic of 0.85 and the male model had a c statistic of 0.82 (Webster & Webster, 2006). These indicate the models had excellent discrimination and therefore, excellent validity when utilized in the clinical setting.

Addressing the Epidemic

In addition to utilizing a screening tool, other best practice requirements for providers include reviewing the Prescription Drug Monitoring Program (PDMP) in the state of residence prior to initiating an opioid prescription, performing random urine toxicology screening on patients receiving controlled substances to evaluate for compliance with prescribed therapy and abstinence from substances that are not prescribed, and ensuring that there is a provider-patient controlled substance agreement in place for those patients receiving opioid prescriptions that explicitly describes the expectations of both parties (provider and patient) with regards to compliance with the treatment plan (CDC, 2019; RIDOH, 2020).

Multiple authors describe success with PDMP utilization in clinical practice. Total opioid prescriptions decreased with consistent provider monitoring of the PDMP in cases where patients were using or being considered for an opioid prescription (Rasubala, Pernapati, Velasquez, Burk, & Ren, 2015; Ringwalt, Schiro, Shanahan, Proescholdbell, Meder, Austin, & Sachdeva, 2015). In addition, states using PDMP in their practices reported a smaller increase in opioid treatment admissions and lower mortality rates overall (Reisman, Shenoy, Atherly, & Flowers, 2009). Urine toxicology screens are also positively associated with compliance with prescribed substances and avoidance of non-prescribed substances (Blum, Han, Femino, Smith, Saunders, Simpatico, Schoenthaler, Oscar-Berman, Gold, 2014). In this study, patients were found to be 12% more compliant with prescribed substances than baseline data one year earlier with the addition of urine toxicology screens (Blum, et al., 2014).

Current guidelines set forth by the CDC and RIDOH may have limitations in predicting opioid use disorder or opioid overdose risk, and may have limited effectiveness in improving outcomes. Wei, Chen, Fillingim, Schmidt, and Winterstein (2019) posit that over 35% of commercially insured patients with OUD or opioid overdose had no opioid prescriptions filled within the last year per the PDMP, and those who did have opioid prescriptions filled were at a morphine milliequivalent lower than the CDC recommendation. In addition, not all states participate in the PDMP and information may not accurately cross state borders of those states who do (Griggs, Weiner, & Feldman, 2015). Griggs, Weiner, and Feldman (2015) also state that patients with fragmented care or undertreated care may have falsely assumed “suspicious” PDMPs, which may impact care received in a new office.

Colleen (2009) and Yarbrough (2018) challenged the effectiveness of a patient-provider controlled substance agreement, noting that it may imply distrust of the provider and undermine the therapeutic relationship. Rager and Schwartz (2017) also challenge that a CSA may not be ethical if the patient is asked to sign whether while in pain or in an attempt to gain controlled medications. These authors note that "their consent has questionable legal and moral status" (Rager & Schwartz, 2017, p. 24).

In addition, Collen (2009) noted that urine toxicology screening has low utility in the clinical setting. There is a large margin for error related to improper collection, transportation, and resulting of these tests, rendering them incorrect and ineffective for proper controlled therapy monitoring (Collen, 2009). Confirmatory testing, in which urines are sent out to a lab, takes almost one week to result, is more expensive to complete, and still often leads to false negative or positive results. Misinterpretations of these tests can lead to devastating outcomes for the patient, and patient-provider relationship.

Despite the above limitations, interventions such as the CSA, PDMP, and urine toxicology screening have shown modest to low improvements in outcomes (Bonnie, Ford, & Phillips, 2017; Yarbrough, C., 2018). Overall, evidence around these interventions is positive, and they are currently considered the best practice under current national and local guidelines. Further research is needed to better establish the effectiveness of these interventions, and to continue to identify new practices that may lead to improved outcomes.

Evaluating Effectiveness of Guidelines

Limited evidence describing the effectiveness of implementation strategies to translate evidence-based opioid prescribing and monitoring practices was found in the literature. Many providers lack confidence with opioid prescribing and report inadequate education related to the topic (Naimer, et al., 2019; Wei, et al., 2019). Specifically, academic family medicine teaching centers face challenges when it comes to opioid prescribing, including higher rates of opioid misuse in the resident patient population and lower levels of resident confidence and experience managing chronic non-cancer related pain (Naimer, et al., 2019).

Several published quality improvement studies have demonstrated the successful implementation of evidence-based opioid prescribing guidelines into practice. One prominent study performed in 2016 implemented guidelines into primary care clinics via in person and electronic education. Pre-intervention data was obtained through chart review for patients receiving more than three opioid prescriptions. After guidelines were introduced, patient charts were retrospectively reviewed during the post-intervention period. Researchers found that patients receiving acute or chronic opioid prescriptions decreased ($p = 0.02$, $p = 0.03$), while urine toxicology screenings increased ($p = 0.005$) (Chen, Hom, Richman, Richman, Asch, Podchiyska, & Johansen, 2016).

Naimer, Munro, Singh, and Permaul (2019) implemented and evaluated the HeLP, or “Healthy Living with Pain”, initiative aimed at improving family medicine resident opioid prescribing practices. Six core components were identified, to include a collaborative practice model, patient registry formation, resident education, clinical decision supports, faculty supervisors, and patient record reviews (Naimer, et al., 2019).

Implementation of these aspects into the clinical practice setting led to better resident adherence to national practice guidelines and safer opioid prescribing (Naimer, et al., 2019). This article was one of the first to demonstrate specific outcome measures related to resident prescribing practices. The authors call for further research demonstrating the ability to adapt and scale the model to other practice settings.

Organizational Assessment/Local Problem

Local Problem

Data collected by the National Institute on Drug Abuse reveals that there were 277 opioid-related overdose deaths in Rhode Island in 2017, with an adjusted rate of 26.9 deaths per 100,000 persons (NIDA, 2019). This is significantly higher than the national average in 2017, of 14.6 per 100,000 persons (NIDA, 2019). Deaths specifically involving fentanyl rose from 12 reported associated deaths in 2012 to 201 deaths in 2017 in Rhode Island alone (NIDA, 2019), with a reported 28,466 patient deaths related to fentanyl throughout the United States (NIDA, 2019). While Rhode Island providers were below the national average for opioid prescriptions, at 51.2 per 100 persons and 58.7 per 100 persons respectively, the ability to legally or illegally obtain opioids for Rhode Island residents increased tremendously (NIDA, 2019). This increase is connected to significant morbidity and mortality, demonstrated by rising overdose-related death rates. In addition, co-occurring disease rates are increasing as well. Specifically, 9% of the 40,000 new HIV diagnoses in the United States were attributed to intravenous (IV) synthetic opioid drug use (NIDA, 2019). In Rhode Island, 70 new cases of HIV occurred in 2017, with 11.8% male attribution to IV drug use, and 21.1% of female attribution to IV drug use (NIDA, 2019). Hepatitis C rates are also rising. In 2016, there was an estimated 41,200 new

national cases of acute Hepatitis C with 68.6% of these attributed to intravenous (IV) drug use (NIDA, 2019). In Rhode Island, there was an estimated 10,100 persons living with Hepatitis C in 2016, but specific data related to IV drug use was unavailable due to lack of reporting (NIDA, 2019).

In response to this upward trend in opioid-related deaths, the Rhode Island State Governor, Gina Raimondo, initiated a program in 2016 named the "Governor's Task Force." This taskforce is a committee established to reduce overdose deaths in Rhode Island by utilizing multiple techniques towards a goal of reducing opioid-related deaths by one third in three years (Prevent Overdose RI, 2019). The action plan associated with this committee involves four major components including prevention, rescue, treatment, and recovery.

To address the taskforce's action plan, the Rhode Island Department of Health (RIDOH) put forth guidelines for providers to follow when prescribing an opioid. These guidelines are in alignment with those set forth by the American Society of Addiction Medicine (ASAM), which aim to support evidence-based prescribing practices (RIDOH, 2019). The RIDOH recommends completing a full medical history and physical examination on each patient, including assessment of pain characteristics, physical and psychological functioning, personal and family history of substance abuse, coexisting conditions, and determination of the indication for the use of a controlled substance (RIDOH, 2019). According to these guidelines, patients should be screened annually to assess for the presence of substance abuse. Individuals demonstrating current substance abuse should be referred to treatment. Prior to prescribing opioid medications, the provider should discuss the risks of opioid medications and a create a treatment plan

balancing risks and expected benefits. This plan should be implemented in the form of a controlled substance agreement that is signed by both the provider and patient. Once an opioid prescription is determined to be necessary, the provider should have the patient sign an informed consent form, review the prescription drug monitoring program (PDMP), co-prescribe naloxone, and frequently reassess the patient for the continued need for opioids (RIDOH, 2019).

Prior to the implementation of this project, the practice setting did not routinely use screening methods for opioid use disorders, and implementation of PDMP checks, urine toxicology testing, and patient contracts was inconsistent. Improving compliance with these best practice measures is essential to optimizing outcomes related to OUD.

Organizational Assessment

An analysis was completed prior to the implementation of the project to identify potential strengths, weaknesses, opportunities and threats (SWOT). Strengths of the project relate to the internal factors that would benefit the project and contribute to its success. Strengths identified in this project included the availability of the intended patient population, with a majority of patients at the clinical site seeking care for pain management or substance use needs. Providers in the practice setting were easily engaged in the project, and there was strong support for the implementation of best practice for minimizing OUD among administrators at the organizational level. Given the limited compliance with best practice recommendations and the lack of current improvement initiatives related to this problem, there was a strong need for this project. Providers at the practice setting were already familiar with the use of evidence-based practice protocols and assessment tools used for other populations. Provider familiarity with the

use of such protocols facilitated the implementation of the RIDOH guidelines and ORT assessment. In addition, due to increasing national attention to the opioid epidemic, the public is increasingly aware of risks associated with opioid use, potentially increasing their willingness to follow prescriber recommendations.

Weaknesses refer to the internal factors that threaten the success of the project. Although engagement among administrators and providers was generally high, the potential for decreased administrative or provider engagement at any of the clinical sites was a risk. More specifically, there was a risk that providers may be resistant to changes in current practice or may view the time required for participating in the education sessions as either a distraction or loss of billable hours. Providers may have also felt that their discretion regarding the use of opioid prescriptions for patients with pain management needs was in question. In addition, staff turnover presented another challenge, with residents routinely rotating through the practice setting. To minimize the impact of turnover, the intervention was completed between resident rotation changes.

Opportunities are defined as external factors that increase social engagement in the project. Related to this project, a strong national public health initiative to reduce illicit opioid use and subsequent overdose risk was a major leverage point. At the state level, the RIDOH initiatives and creation of the Governor's Task Force has significantly increased the amount of public awareness given to the topic of opioid use and overdose-related deaths. It was thought that the presence of positive local and national attention would increase patient confidence in provider decision-making and the need for the proposed interventions.

Threats are described as external factors that may challenge the project goals. A major threat to this project included the presence of advocacy groups that have been forming to vocalize the need for increased pain management. These groups feel that restrictions on opioid prescribing are detrimental to the management of pain. Increasing resistance among groups opposed to the implementation of evidence-based opioid prescribing practices may contribute to provider fear of potential lawsuits or negative publicity regarding the provider or facility, thereby undermining project goals.

Problem Statement and Study Question

Currently available evidence suggests that provider adherence to best practices is low (ASAM, 2015; Naimer, et al., 2019). As the numbers of patients with opioid use disorder and subsequent overdoses rise, it is imperative that providers incorporate evidence-based prescribing and patient management practices into their practice. Optimizing outcomes related to opioid use disorders depends on the consistent implementation of best practices by providers in all care settings.

Purpose Statement and Specific Aims

The purpose of this project was to facilitate recognition of patients at high risk for opioid use disorders and facilitate best evidence-based practice in the care of this population. The specific aims were to achieve provider compliance with the implementation of best practice guidelines including

1. Opioid risk screening via ORT
2. Implementation of PDMP review, signed care plans, and urine toxicology screening and,
3. Reducing inappropriate opioid prescriptions.

Conceptual/Theoretical Framework

Kurt Lewin's Change Theory was developed in 1940 and identifies three distinct stages of behavior change (Petiprin, 2016). The Change Theory involves the concepts of driving forces, restraining forces, and equilibrium that relate to the change in behavior stages. Driving forces are those that push one in the direction of change, allowing acceptance of the change that will occur. Restraining forces, conversely, are those that hinder or oppose the change. Equilibrium is a state of being where driving forces are equal to restraining forces. When driving and restraining forces are in equilibrium driving forces are unable to overcome restraining forces, therefore, change will not occur. To lead change, the key forces related to the desired change are identified and manipulated so that driving forces are increased over restraining forces (Petiprin, 2016).

In regards to the proposed project, an initial assessment was employed to identify outdated or ineffective prescribing and assessment techniques with co-identification of driving and restraining forces for the adoption of new techniques. Change was facilitated by minimizing restraining forces and working to ensure that the reason for the intended change was perceived as beneficial to the participants. Work to establish refreezing is ongoing and will occur when the intervention becomes part of standardized practice and best practice adoption is identified in all appropriate clinical situations. Appendix C demonstrates the forcefield analysis for this project.

Another framework used to support this project was the middle range theory, the Theory of Pain: A Balance between Analgesia and Side Effects (Good, 2013). This theory describes the balance between efforts to increase patient satisfaction with relief from pain with ensuring minimal, or absence of, side effects (Good, 2013).

Pharmacologic measures to alleviate pain may include opioid or non-opioid pain medications, while non-pharmacologic pain measures may include any adjunct therapies known to alleviate pain or suffering, such as massage, imagery, music, or relaxation techniques (Good, 2013). The provider is required to perform adequate and regular assessments of pain and side effects at particular intervals with a mutually agreed-upon goal in mind. If the number and intensity of adverse effects are unacceptable to either party, the therapy is discontinued. The absence of reported adverse effects would be an ideal outcome for the patient and provider. Adverse effects from therapies may include a variety of unpleasant occurrences, ranging from acute gastrointestinal distress to the development of an addiction to a prescribed substance. Patient education is an important aspect of the theory and provides encouragement and instruction regarding expectations, actions, and mutually agreed upon, safe goals for relief (Good, 2013).

This theory may be applied to patients receiving chronic or acute opioid therapy in a primary care office setting for any number of conditions, as it addresses the complex balance of risks and benefits associated with high-risk medications. Patients experiencing pain seek relief, and practitioners treat pain with a variety of therapies with the intention of providing a reduction in pain and improvement in quality of life. If a provider feels an opioid prescription is a necessary component of the treatment plan, consistent evaluation of medication efficacy will be required to determine if the benefits of therapy are outweighing the risks associated with the controlled substance. If the patient is experiencing significant side effects or adverse reactions, including substance misuse, that outweigh analgesia, the provider should consider discontinuation of the therapy to ensure patient safety.

Methods

Setting

The project took place in a primary care practice within the Care New England Medical Group. The practice focuses on internal medicine and is located in an urban area with a large patient population. This practice consists of a resident clinic, with first, second, and third-year resident physicians who rotate through this setting. Each resident is supervised by an attending physician, and each attending physician is responsible for supervising five residents per shift. Each provider working in these settings usually performs visits on eighteen to twenty patients per day. These patients are seen in the office for a multitude of complex care needs, including managing chronic and acute pain needs. Patients are all age 18 and older.

Participants

This project involved the education of providers regarding implementation of the ORT and best practices in the management of patients at risk for opioid use disorder. Outcomes related to compliance at the patient and provider level, as previously described, was evaluated by retrospective chart review. Providers who were actively employed by the specified clinical site were included in the educational intervention. These providers consist of resident physicians (n = 15) and attending physicians (n = 8). Data related to patient compliance was collected by retrospective chart review of adult patients receiving treatment for acute or chronic pain, or who were identified as being at-risk for, or were receiving treatment for a substance use disorder. No patient identifiers were collected and data was evaluated at the aggregate level only.

Intervention

Baseline data was collected by retrospective chart review for a two-month period prior to the intervention (June to July 2019). The primary investigator (PI) independently screened all charts at the clinic for the above criteria. Specific data collected included compliance with ORT implementation, controlled substance agreements, PDMP review, and number of inappropriate opioid prescriptions. Following collection of baseline data, the PI delivered an educational program (October 2019) addressing the ORT, ASAM, and RIDOH guidelines for safe opioid prescribing practices and the potential benefits of compliance with these measures. The education was delivered in the form of a PowerPoint presentation and paper handouts were provided to reinforce teaching points. Education was delivered to providers in half-hour time slots dedicated to the project, as had been approved by the office manager. The educational sessions occurred during resident learning times or attending administrative times, thereby reducing the loss of clinical time. Provider participation was voluntary.

The intervention period continued for three months (October to December 2019), after which the PI collected post-intervention data for the immediate period following the intervention. Data was monitored for short-term sustainability of outcomes through May 2020. Appendix A demonstrates the complete timeline for project implementation and evaluation.

Measures and Analysis

Pre- and post-intervention data was collected by retrospective chart review. Demographic data was reported using descriptive statistics. Differences between pre- and post-intervention outcomes was analyzed using Chi-Square. As the project required only

aggregate level data, no patient identifiers were collected. Goals were to increase provider compliance with evidence based opioid prescribing practices.

Ethical Considerations

This project was reviewed and approved by both the organizational and educational setting's Institutional Review Boards (IRB). Waiver of informed consent was requested and was granted by the IRB, as this quality improvement project involved the implementation of established best practices and did not involve risk beyond that associated with routine practice. Participation in the education sessions was strictly voluntary and there were no penalties for lack of participation.

Results

Data collected in the post-implementation period demonstrated an increase in guideline implementation. Urine toxicology monitoring increased from 73.86% to 95.8% compliance ($p = 0.002$), PDMP review increased from 42.11% to 62.50% compliance ($p = 0.12$), and CSA in place increased from 42.11% to 58.33% compliance ($p = 0.13$). The number of cases in which two or more measures were simultaneously implemented rose from 36.84% to 54.17% ($p = 0.10$). New opioid prescriptions decreased from 5.26% to 4.17%, meaning less new opioid initiations took place. Because the ORT had not been implemented prior to the intervention, compliance with this measure was 0% at baseline. Implementation of the ORT was not achieved during this project with compliance remaining at 0% after the intervention. Urine toxicology monitoring had a statistically significant increase from pre- to post-intervention. See Table 1 and Figure 1 below.

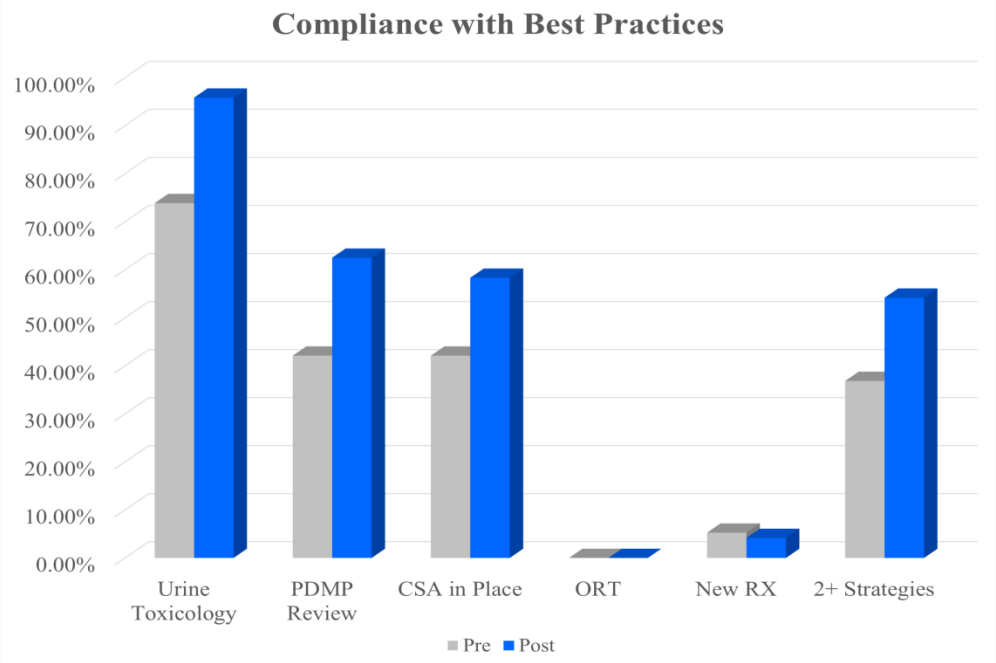
Table 1

Pre and Post-Intervention Data for Guideline Implementation

Pre-Intervention				Post-Intervention			
Urine Toxicology							
	Number Assessed	Number Compliant	%	Number Assessed	Number Accurate	%	p=
All Patients	19	14	73.68	24	23	95.83%	0.02
PDMP Review							
	Number Assessed	Number Accurate	%	Number Assessed	Number Accurate	%	p=
All Patients	19	8	42.11	24	15	62.50%	0.12
Controlled Substance Agreement in Place							
	Number Assessed	n=	%	Number Assessed	n=	%	p=
All Patients	19	8	42.11	24	14	58.33%	0.13
2 or more in place							
	Number Assessed	n=	%	Number Assessed	n=	%	p=
All Patients	19	9	47.37%	24	16	66.67%	0.10

Figure 1

Pre and Post Intervention Compliance with Best Practices



Discussion

This quality improvement study was performed to facilitate implementation of best practice guidelines. Although current guidelines are well established, limited quality improvement studies exist to inform the effectiveness of interventions to consistently implement these guidelines in practice. This project demonstrated strong improvements in all areas, except for the implementation of patient screening utilizing the ORT. Overall, improvements ranged from 20% to 48%. All improvements were clinically significant. Although a lack of patient screening using the ORT continued during the post-intervention period, this did not appear to impact implementation of other practices. It is unknown if patient screening would have further increased improvements in urine toxicology screening, PDMP review and implementation of CSAs. Further research is needed to better understand this relationship. Although clinically significant improvement

was noted in all areas, the only statistically significant improvement was noted in urine toxicology screening. However, the sample size for this project was small. Statistical significance in other areas may have been reached with a larger sample.

Strengths associated with this project included strong support of leadership and participating providers for project initiation and implementation. There was a measurable positive provider response to education seen in improvements in guideline implementation. There was an increased awareness among providers of evidence-based guidelines and the rationale for consistent implementation. Overall, a clear improvement in practice was noted in the clinical setting.

Limitations associated with the project included a short implementation time. In addition, this project was limited to a single setting and had a small sample size. The education took place in a resident clinic, in which residents were already inundated with weekly education seminars related to their program. Real-time auditing and feedback was planned, but was unable to be performed due to time constraints. There was also a lack of inclusion of ancillary staff in the intervention, which may have further improved urine toxicology monitoring as medical assistants were primarily responsible for ensuring this was performed.

Sustainability and Scalability

Sustainability is defined as locking in the progress made by an improvement initiative and adapting and spreading the initiative to other areas so that the greatest number of patients will benefit (Moran, Burson, & Conrad, 2020). This is often accomplished by first disseminating information about successful interventions and providing evidence that the intervention is worthwhile, beneficial, and cost-effective

(Moran, Burson, & Conrad, 2020). Sustainability requires obtaining input and buy-in for continued project support of the initiative from all key stakeholders and decision-makers. Short- and long-term objectives must be explicitly defined and determined so that a common goal is shared among all stakeholders (Moran, Burson, & Conrad, 2020). Resources required for this project included administrative support for provider participation and time of the investigator devoted to the continuation of the project.

The NHS Sustainability Model and Guide provides a practical resource for assessing and planning for optimal project sustainability (Maher, Gustafson, & Evans, 2017). The sustainability model consists of ten factors relating to staff, processes, and organizational issues (Maher, Gustafson, & Evans, 2017). This model was used to identify strengths and weaknesses during the planning phases of this project so that appropriate strategies could be implemented to optimize the chances of sustainability of the project. Sustainability was reassessed upon completion of the project (see Appendix D).

Conclusion

This project introduced evidence-based practice guidelines into a clinical setting where compliance was poor and measures were under-utilized. The intervention led to improved outcomes related to compliance with best practices in opioid prescribing. There is a need for ongoing work to adapt and scale this quality improvement project across multiple practices within this and other healthcare settings. There is a need for continued education for providers and members of the multi-disciplinary team to ensure sustainability of this intervention. There is also a need to educate patients and the

community about the rationale for these guidelines and benefits associated with implementation.

Future research should be performed to determine the relationship between risk assessment and screenings with regards to guideline implementation. The impact of including office staff in the education sessions, as well as the impact of implementing real-time auditing and feedback throughout the project, should be further explored in future studies. Future practice scholarship should also be targeted at improving long-term outcomes, including reductions in mortality and morbidity related to opioid use disorders.

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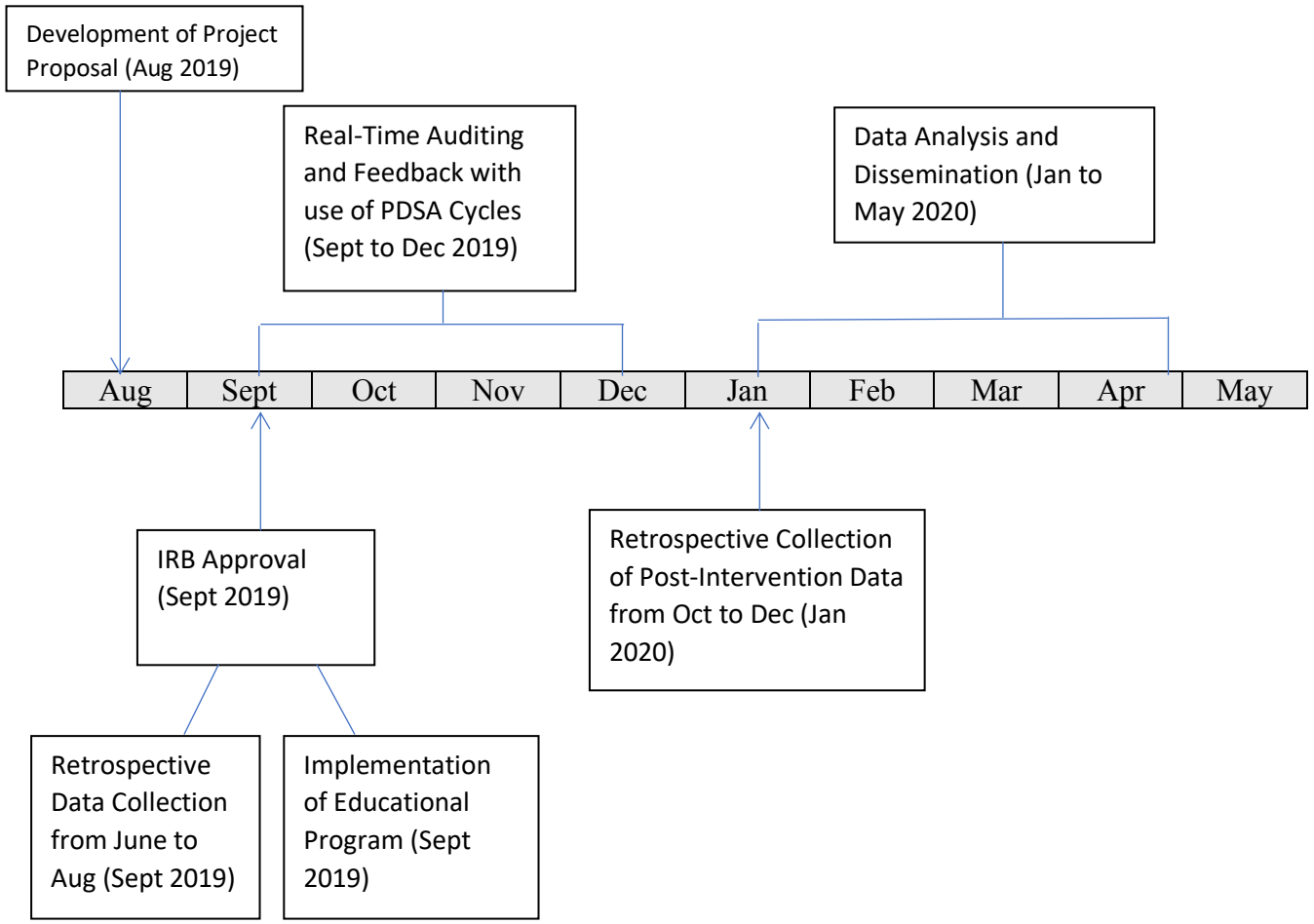
Appendices

Appendix A

Figure 1: Timeline/PERT Chart



Appendix B

Table 1: Cost-Benefit Analysis

Costs Associated with Project		
Category	**Details**	**Cost in 1 year**
Paper Materials - Paper handouts - Printing expenses - Copying expenses	Paper supplies, printing costs, and copying expenses will need to be considered in order to provide providers with handouts related to the subject material	$20-$30
Travel Expenses	Gas utilized for the travel time of the primary investigator between clinical site locations	$20-40
Time	Time will be required by the primary investigator to create the educational materials, as well as clinical site providers will need to utilize administrative time to attend sessions	Sessions will be held during pre-scheduled administrative times so clinical time will not be utilized. Productivity is not expected to decrease during educational sessions.

Benefits Associated with Project	
Benefit	**Benefits within 12 Months**
Increased provider knowledge of nationally recognized guidelines to manage controlled substances	Utilization of tools will increase provider cognizance of individual patient risk and positively impact treatment decisions
Increased integration and compliance with guidelines	Compliance with mandatory guidelines improves quality of care
Decreased inappropriate opioid initiations and generalized reduction in publicly circulating opioids	Improves patient and public safety with decreased access to controlled substances
Decrease incidence of OUD and overdose	Increases patient safety, decreases potentially life-threatening emergencies related to opioid use

Appendix C

Table 2: Force-Field Analysis

Driving Forces (For)	Actions to be Taken to Strengthen	Force Strength (1-4)
Availability and access to patient population	Coordinating project with a practice location well known to the PI	2
Provider engagement and established patient safety initiatives	Encourage providers to participate with the overall goal of patient safety as the focus of education and project objective	4
Familiarity of providers with utilizing protocols	Relate new proposed protocol to established protocols already in place that providers are already utilizing frequently (ie. Coumadin protocols, glucose monitoring)	2
National and patient interest in the subject matter	Most patients know someone with an OUD, which can personalize the objective of the study increasing compliance and engagement	4
Low overall cost for materials and education	Will utilize low cost materials to create handouts and offer electronic versions for future reference. Will also only utilize administrative time for education purposes so no clinical time with patients is lost	2
	Total =	14

Restraining Forces (Against)	Actions to be Taken to Weaken	Force Strength (1-4)
Lack of familiarity with subject matter, especially new ORT assessments	Spend as much time as needed providing education and feedback regarding topics unfamiliar to providers	2
Increased staff turnover at one clinical site, primarily residents moving on to new sites	Will plan the intervention for a period of stagnancy in the turnover rate with availability to repeat when a new cohort arrives	3
Provider perception that the intervention is questioning clinical judgment or punitive for opioid prescribing	Explain in detail the objective of the study and that the tools are used as adjunct assessments to strong clinical judgment skills. Define inappropriate opioid prescriptions more fully	2
Advocacy groups fighting for increased opioid prescriptions as they feel their pain has been unmanaged since RIDOH guidelines have been established	Explain in detail the objective of the study and that the tools are used as adjunct assessments to strong clinical judgment skills. Assessments are not meant to dictate provider decision making or restrict appropriate pain management	3
	Total =	10

Appendix D

Table 3: Sustainability Assessment

Modified from the NHS Sustainability Model and Guide (Maher, Gustafson, & Evans, 2017)

Process			
Factor	**Score**	**Description**	**Evaluation**
Benefits beyond helping patients	8.5	We can demonstrate that the change has a wide range of benefits beyond helping patients, for example, by reducing waste, creating efficiency, or making people's jobs easier	Development of an ORT score for easy clinical utilization
Credibility of the benefits	9.1	Benefits of the change are widely communicated, immediately obvious, supported by evidence, and believed by stakeholders. Staff is fully able to describe a wide range of intended benefits for this initiative.	Notable increase in clinical guideline use with increased staff support for implementation
Adaptability of improved process	3.4	The improved process can be adapted to support wider organizational change but it would be disrupted if specific individuals or groups left the project. Elements of this work will continue to meet our organization's improvement needs.	Will need sustained efforts to continue utilization in clinical practice. Will benefit from spread to other clinical sites within the practice setting.
Effectiveness of the system to monitor progress	3.3	There is a system in place to provide evidence of impact, including benefits analysis, monitor progress, and communicate the results. This is not set up to continue beyond the formal life of the project.	Will require a monitor moving forward to continue chart assessment for utilization
Staff			
Staff involvement and training to sustain the process	4.9	Staff have not been involved from the beginning of the change,	Education provided helped staff understand utility

		but they have received training in the new way of working	and importance of guideline implementation
Staff behaviors towards sustaining the change	11.0	Staff is able to share their ideas regularly and some of them have been taken on board during the project. They believe that the change is a better way of doing things and have been empowered to run small scale test cycles (PDSA)	Staff will engage in future research to support consistent utilization
Senior leadership engagement and support	15.0	Organizational leaders are highly involved and visible in their support of the change process. They use their influence to communicate the impact of the work and to break down any barriers. Staff regularly shares information with and actively seek advice from leaders.	Senior leadership will continue to support staff efforts to continue research in this area
Clinical leadership engagement and support	15.0	Clinical leaders are highly involved and visible in their support of the change process. They use their influence to communicate the impact of the work and to break down any barriers. Staff regularly shares information with and actively seek advice from clinical leaders.	Clinical leaders will collaborate with staff for further implementation strategies and education incorporation
Organization			
Fit with the organization's strategic aims and culture	7.0	The goals of the change are clear and have been widely spread. They are consistent with and support the organization's strategic aims for improvement. The organization has demonstrated successful sustainability of improvements before and has a "can do" culture.	There is a measurable change in patient and provider outcomes that will support the overall goals of the organization

Infrastructure	4.4	Staff is confident and trained in the new way of working. However, job descriptions, policies, and procedures do not yet reflect the new process. Some communication systems are in place. Facilities and equipment are all appropriate to sustain the new process.	This author will continue to help staff navigate clinical guidelines
Process Total (24.3) + Staff Total (45.9) + Organization Total (11.4) = Sustainability Score (81.6)			

Appendix E

Table 4: Opioid Risk Tool (ORT) Sample

Mark each box that applies	**Female**	**Male**
Family history of substance abuse		
Alcohol	1	3
Illegal Drugs	2	3
Rx Drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16-45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring Totals		

Key:

Score of 3 or lower → **low** risk for future opioid abuse

Score of 4 to 7 → **moderate** risk for future opioid abuse

Score of 8 or higher → **high** risk for future opioid abuse

(Webster & Webster, 2006)