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Prior Authorizations and Continued Treatment in Addiction Medicine

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Abstract

Introduction: Patients that require medication assisted treatment for opioid addiction can have their treatment delayed through the prior authorization process. A prior authorization is required by many insurance companies and can cause lengthy delays before the drug is approved. The two drugs that were considered for this project were Suboxone® (buprenorphine/naloxone) and Sublocade® (buprenorphine). These drugs are used for the treatment of opiate addiction. The proposed solution to the problem was to use quality improvement methods to implement a tracking and tickler system to improve the approval time from the insurance company.

Objectives: The project goal was to decrease the amount of time from the time the prescription was written until the medication assisted treatment was initiated.

Methods: This project used quality improvement methods to review pre and post intervention data. The setting is a single physician addiction medicine clinic.

Results: There were no changes in the amount of time between prescribing and start of treatment with the tickler and tracking system. When drugs are added to the insurance company's formulary, prior authorizations are not required. Any improvement in the time from prescribing to medication start was related to changes in the insurance company's formulary.

Conclusions: Tracking the prior authorizations did not change the time frame of which they were completed.

Implications: With the opioid epidemic, patients are dying daily across the U.S. due to drug overdose. Patients that experience a gap in their treatment are at a higher risk for relapse and possible overdose. The insurance industry needs to improve their process for approving medications for patients being treated for opioid addiction.

Keywords: Suboxone® (buprenorphine/naloxone), Sublocade® (buprenorphine), prior authorization, treatment delays**,** addiction medicine, opiate addiction.

Prior Authorizations and Continued Treatment in Addiction Medicine

In 2017, the United States Department of Health and Human Services declared a public health emergency related to the opioid crisis (HHS.gov, 2019). As of January 2019, it has been estimated that 2.1 million people abuse opioids in America and 130 people die every day related to overdoses of opioids (HHS.gov, 2019). These numbers are staggering. To help treat the disease of opioid addiction, medication assisted treatment has been shown to be safe and effective (SAMHSA, 2019).

Buprenorphine is one of the many drugs available to treat opioid addiction. Buprenorphine is an opioid partial agonist which means that it can produce many of the same effects as opioids. However, the effects are weaker. Buprenorphine can be taken transmucosal in a film form and mixed with naloxone (brand name for the combination medication is Suboxone®). Adding naloxone helps to decrease the likelihood of diversion and misuse of the drug (SAMHSA, 2019). If the film is altered or broken down to be used in the injectable form, the naloxone effect dominates and can bring on opioid withdrawals (SAMHSA, 2019). Once a patient is stable on buprenorphine/naloxone, they can be switched to a long acting injection of buprenorphine (brand name Sublocade®). The medication is injected once every 28 days by a certified provider.

In order to treat the patient with buprenorphine or buprenorphine/naloxone, the provider must have a special DEA number which can only be obtained after taking a 24-hour training course (SAMHSA, 2019). Once completed, the provider is limited in the number of patients that they can treat with buprenorphine (SAMHSA, 2019). The law limits providers to 30 patients in the first year after waiver certification is completed. When the law was initially put into place back in 2005, the limit of 30 patients was a fixed limit. In 2006, the Food and Drug Association

(FDA) increased the number of patients a provider could see to 100 after one year of certification. In addition to the limited number of prescriptions available to provide treatment for patients with opioid addiction, the insurance industry has a significant amount of control over how quickly treatment will be authorized and paid for. One concerning delay is the requirement for a prior authorization for medication assisted treatment. The purpose of this project is to develop and implement an evidence-based practice improvement project to improve the process of prior authorization completion.

Assessment of the Organization

An organizational assessment was conducted in a single-physician clinic specializing in the treatment of patients struggling with addiction. In addition to the physician, business is conducted with an office manager. The organizational assessment included both the clinical and the non-clinical settings. In this assessment, the Burke and Litwin model was utilized as the framework for the organizational assessment (Burke & Litwin, 1992). All elements of the model are reviewed with an explanation of the corresponding information gathered from the clinical practice. After that, a Strengths, Weakness, Opportunities, and Threat (SWOT) analysis was used to organize the findings within the organization (William and Anna Newman Library, 2018). Lastly, an analysis of the organization assessment, the clinical problem and conclusions are provided.

Organizational Assessment Tool: Burke and Litwin Model

The Burke and Litwin organizational performance and change model illustrates the foundation of 12 factors which are: external environment, mission and strategy, leadership, organizational culture, structure, management practices, systems, work unit climate, task and individual skills, individual needs and values, motivation, individual and organizational

performance (Reflect & Learn, n.d., Stone, Brown, Smith, & Jacobs, 2018, and Burke & Litwin, 1992). The 12 factors are further divided into two groups: transformational and transactional dimensions. Figure one illustrates the Burke and Litwin model. The transformational factors are more consistent with leadership and are located at the top of the figure. In contrast, the transactional factors which are located on the bottom of the model (see figure 1) include: management practices, structure, systems, climate, motivation, task and skills abilities, and needs and values which are more consistent with management (Stone, et al. 2018, Burke & Litwin, 1992).

The reliability and validity of the Burke-Litwin organizational assessment is well documented by Stone in 2015 (Stone, et al., 2018) and the validity of the tool was noted to be the "strongest" as supported by Burke (2018) and Burke and Litwin (1992). Stone also notes that "structural validity through factor analysis by Anderson-Rudolf (1996), Fox (1990), and Stone (2010) (Stone, et al. 2018). Figure one best demonstrates the complexity as the arrows go in both directions which reflects that a change in one area will influence another. This is also called a casual model (Burke & Litwin, 1992).

Components of the Burke and Litwin Model: Transformational

Transformational factors include external environment, mission and strategy, leadership, and culture (Burke & Litwin, 1992). Changes in these areas are likely to be caused by external environmental forces. When an organization undergoes transformational change, new behaviors must be accepted for an organization to be successful (Burke, 2017).

External Environment

Burke and Litwin defined the external environment as "any outside condition or situation that influences the performance of the organization" (Burke and Litwin, 1992, p. 531). The

physician's patient population is mostly self-referred. If a patient is referred by another physician or counselor, the office manager awaits a call from the patient to schedule as it shows motivation towards treatment (personal communication, XXX, 2018). Some of the referrals come from the drug court. Drug court is a one to two-year program that is provided through the county judicial system. This program focuses on individuals who have been arrested for misdemeanor and felony drug and drug-related offenses who have an abuse history. Individuals that participate in the drug court program have additional responsibilities as required by the court (61st District Court Drug Court, N.D.). Another referral base is from an organization that works with medical providers that have become addicted. This organization allows employees that have addiction to keep their job with the understanding that they follow the treatment plan as set forth by the physician.

A significant outside influence that the addiction clinic deals with is the insurance industry. Currently, the clinic uses a private billing service biller, but it is up to the organization to get authorization to treat the patient. If the patient has insurance other than Medicaid, the office manager collects a co-pay. Currently, the clinic has no process to determine the actual co-pay amount due from a patient based on the patient's reimbursement source; this causes the office manager to be unsure of the amount of money to collect (personal communication, XXX, 2018). For follow up visits, the non-Medicaid insured patients are informed by text, prior to their visit of the amount of money they owe for payment at the time of the appointment. Some insurers, such as Priority Health, also require prior authorization for the medications that are typically prescribed by the physician to treat addiction.

Buprenorphine/naloxone, otherwise known as Suboxone® is a medication that the physician primarily prescribes for patients being treated for opioid addiction. To prescribe

buprenorphine, the provider must complete the waiver process set forth by the American Society of Addiction Medicine (ASAM). Currently, the requirement is 24 hours of education that reviews the national guidelines for treatment of these patients which includes the requirements for prescribing of buprenorphine to be granted the waiver. With these requirements, many insurance companies will require a prior authorization, just to verify that the physician has obtained the appropriate waiver. Once the waiver is verified, they will issue the authorization and cover the medication. This multi-step process can result in delays in starting treatment. The prior authorization delay is problematic for patients as the goal of therapy is to start buprenorphine when they are in the early phases of withdrawal. The time frame between the abused medication stopping and withdrawal symptoms vary. Heroin withdrawal can start within 6 hours of the last use whereas methadone withdrawal symptoms may not present for upwards of 96 hours (Prunty, 2016). Withdrawal symptoms that may be present include: agitation, anxiety, dysphoria, insomnia, and temperature inability (Prunty, 2016).

Prior authorizations are granted for a specific period depending on the dose prescribed. Each insurance company has their own guidelines for the length of approval. When the approval is close to expiration, the office manager must then complete another prior authorization where, at times, the insurance company may request additional information to continue to pay for the medication. This can again, result in a delay or gaps in treatment.

Mission and Strategy

A mission statement is a written statement of what the organization believes is the purpose of the organization. Per the physician, the mission statement of the practice is “I have made my life, my career, and my passion about caring for, and protecting the rights of individuals in our society who have been marginalized, shamed, blamed, and even punished for

their disease- alcoholism, drug dependence/addiction, and mental health disease" (XXX, 2018). From observation in the clinic and outside of the clinic, the physician and the office manger live this mission statement every day.

Leadership

Burke and Litwin defined leadership as "executives providing overall organizational direction and serving as behavioral role models for all employees" (Burke & Litwin, 1992). This organization has a physician and an office manager. The physician is the leader of the organization from a clinical standpoint and the office manager is the lead for business management. Overall, the office manager leads the practice and takes responsibility for all aspects of the day to day activities that make the practice successful. She ensures that the physician has everything that she requires to be successful. The purpose of this organization assessment is the one-physician clinic. The other activities as an employed physician are outside the scope of this assessment.

Organization Culture

Organizational culture reflects how things are done in the clinic (Burke & Litwin, 1992). This includes rules (norms) of the organization which can be further be broken down to explicit and implicit rules (Burke, 2017). This clinic has few written policies but one of their policies- related to patients being on time- is strictly enforced. Patients are required to be 10-15 minutes early for their scheduled appointment. This provides time for the required urine drug testing and vital signs to be completed as well as the collection of co-pays.

This milieu of this office is relaxed. The physician and the office manager support and encourage each other on a personal and professional level and both manage the clinic. The physician and office manager dress casually and their office interactions are casual. This relaxed

presence appears to make patients, new and established, feel more comfortable with coming in. The office also has two therapy dogs that are allowed to come and go during the office visits.

Components of the Burke and Litwin Model: Transactional

Transactional components include management practices, structure, systems, task requirements and individual skills, work unit climate, individual needs and values, motivation, and individual and organizational performance. The components concern the day-to-day operations or the organization and drive continuous improvement rather than reactionary improvement (Burke, 2017).

Management Practices

This category reviews what the managerial practices are from day to day (Burke, 2017). In 1992, Burke and Litwin defined it as "what managers do in the normal course of events to use the human and material resources at their disposal to carry out the organizations strategy" (Burke & Litwin, 1992). The office manager is available Monday through Friday from 9AM-5PM. The physician makes herself available to the patients 24 hours a day seven days a week.

The office manager's role requires independence in the day to day tasks regardless of the place of work. Patients are checked in by the office manager and she is responsible to ensure that each patient completes a drug screen at the beginning of their appointments. Urine drug screen results are reviewed with the patient at their next appointment. Additional tasks that the office manager completes in this setting include: prior authorizations, scheduling appointments, sending reminders for appointments, checking MAPS (Michigan Automated Prescription System), answering the phone and texts throughout the day, and keeping up with all of the paperwork and scanning of paperwork to the electronic health record. She also is responsible for keeping the financial records up to date and ensuring that the bills related to the clinic are paid.

Collaboration and communication are key between the physician and office manager, which has allowed for many of the recent clinic changes. Some of the recent changes include: 1) the change of office manager, 2) the addition of seeing telehealth patients in some rural areas and, 3) working with an organization that provides care to the underserved.

The physician has a strong desire to treat patients regardless of their insurance coverage. The reimbursement from Medicaid is very low and the physician must limit the number of patients to be financially sustained. The reimbursement from Medicaid is lower than what is reimbursed by private insurance companies. Accepting a patient with Medicaid dictates that the provider will accept the reimbursement from Medicaid. The provider cannot bill the patient for the difference. In the past year, the physician began to work with an organization two days a week that provides mental health services to the underserved. This enabled her to expand the number of patients that had Medicaid coverage. If a patient has Medicaid and lives in Kent County, they can be evaluated at an off-site clinic. Patients that have Medicaid from any other county are treated in the physician's office.

Structure

Burke defines structure as "arrangement of organization functions (for example accounting, manufacturing, human resource management) and operational units (for example the western region) that signify levels of responsibility, decision-making authority, and lines of communication and relationships that lead to implementation of the organization's missions, goals, and strategy" (Burke, 2017, p. 281). This is a small organization that is led by a physician and office manager. The billing staff is off site and works one day a week for the clinic patients. This physician has no back-up and has accepted responsibility for after-hours patient call every day.

Systems

Systems refer to policy and procedures (Burke, 2017). Policy and procedures support the organization members (and key stakeholders) and defines jobs and role responsibilities (Burke, 2017). The clinic has a policy for banking and payroll with a page of policies that are mixed together. This page reflects the policy related to appointment scheduling.

Systems can also encompass information technology (Burke, 2017). In the clinic, the physician uses Practice Fusion® software for the EMR. Practice Fusion® software has built a variety of templates for documentation purposes for use by providers but are cumbersome for the physician in the clinic. The physician can build her own templates for documentation. The process to build the templates takes an understanding of the software that requires additional time and training that the physician has not been able to accomplish at this time.

The physician uses Google docs for patient tracking. Google docs is also used for keeping track of patient accounts. The office manager is unsure if the Google software is HIPAA compliant (personal communication, XXX, 2018).

Task Requirements and Individual Skills

Task requirements and individual skills is ensuring that the right person is doing the right job (Burke, 2017). Burke goes on to further define it as a "job-person match: the degree to which there is congruence between the requirements of the job, role, and responsibilities and the knowledge, skills, and abilities of the individual holding the job" (Burke, 2017). The physician is licensed to practice and has the certification required to prescribe buprenorphine.

The office manager, admittedly, did not have management experience when she started working in the office. Upon completing a google search, the recommended education for a medical office manager ranges from high school diploma to a bachelor's degree depending on

the size of the practice. The office manager does have a degree in psychology and she is continuing her education in health. She is familiar with the clinic as she is a family member to the physician (personal communication, XXX, 2018).

Work Unit Climate

The work climate is the perception of the employees in a work unit. These perceptions can include: clarity of what is expected of the person/team, how the performance is recognized, and how supported the person feels (Burke, 2017). The two employees in the clinic support each other both personally and professionally. Together, they make all the decisions for the clinic and the climate of the clinic is relaxed and positive.

Individual Needs and Values

Individual needs and values are the employee's perception with job satisfaction (Burke & Litwin, 1992). The physician reported that in 2016 she made under $10,000 per her W2 but that she "wouldn't change a thing". She states that when patients overcome their addiction, she feels fulfillment that money cannot give her. The physician and office manager take pride in their work and want to be able to do more but find that there isn't enough time each day to do so.

Motivation

Motivation is the desire to move towards the goals of the organization and act on that desire (Burke, 2017). The physician is motivated by the success of the patient in overcoming their addiction. The patients present to the office going through withdrawal from substances such as opiates, heroin, and cocaine. She also treats patients that have an addiction to alcohol. The physician is motivated to get the word out to the community about the treatment of addiction. The physician is active in the local community and lectures multiple times each month on opioid addiction.

Individual and Organizational Performance

Burke (2017) reported that performance is "defined and measured by indices such as productivity, customer satisfaction, quality of product or service, and profit or earnings per share". This clinic is productive, and it is thought to be related to a strict policy for appointment scheduling. The physician will not see a patient that arrives late. A patient that does not arrive at least 10 minutes prior to their appointment with the physician will be rescheduled. This can be problematic for patients as their medication for their addiction is prescribed for the days until the next office visit. The physician is productive in her visits and ensure that they do not go over the time allotted. New patients are allowed an hour and return patients are allowed 20 minutes. This is an area that patients have difficulty with honoring.

Customer satisfaction is another area that could be eventually improved upon. The clinic does not provide patients the opportunity for patient satisfaction surveys. Some websites do allow for online reviews of providers and at this time, the reviews are not all good.

Ethics and Protection of Human Subjects

An application for review and approval or exemption of this project was submitted to the Grand Valley State University Institutional Review Board. Beyond further planning, no project activities commenced until the review was completed and Board approval or exemption is granted. The purpose and scope of this project were limited to implementation of a quality improvement project. No patient identifiable information was collected. No physical, social, psychological, legal, or economic threats to patients were associated with this project. As such, the impact of the project posed minimal or no risk to participants. All members of the team completed human subject's protection training via the Collaborative Institute Training Initiative and their interactions with patients were guided accordingly.

Stakeholders

The clinic has key stakeholders that are involved with and were affected by any practice change. The main stakeholder is the practice owner, the physician. In addition, the office manager, billing coordinator, and patients have the potential to be affected by practice change. If this quality improvement project works, we should be able to improve the lives of the patients served by decreasing the time between treatment being prescribed and started.

SWOT

A SWOT analysis is a tool that analyzes an organization in four categories: strengths, weaknesses, opportunities, and threats (William and Anna Newman Library, 2018). Gomer and Hille defined a SWOT analysis as "a methodological tool designed to help workers and companies optimize performance, maximize potential, manage competition, and minimize risk" (N.D., p.1). A SWOT analysis can be used on companies large and small (Gomer and Hille, N.D.). A benefit of a SWOT analysis is that it can help to understand the practice better while pointing out opportunities for deterring threats. A downside to a SWOT analysis is that it is not meant to provide solutions when problems are identified (William and Anna Newman Library, 2018).

Strengths

Some of the strengths of this organization include the physician's passion about working with this population. She makes herself available to her patients' day and night so that she is able to provide support at any time. Another strength is that the office manager and the physician live in the same home and are related. This could also be considered a weakness depending on the relationship between the two; at this time, the relationship is strong and nurturing. Nationally, the opioid crisis is a popular topic and a priority public health crisis with

limited provider availability to prescribe the medications used to treat opioid addiction. While the physician states that this is a weakness of the medical community, it does ensure a continued referral base.

Weaknesses

A significant weakness of the clinic is the limited written policy and procedures. Another weakness includes only having one provider with no back up in place. This limits the provider's ability to take time off from caring for her patients. An additional weakness is related to the time it takes to complete and keep up with the prior authorization process for patients' treatment. Finally, the EMR that is being used in the clinic may not be being used to its full capacity which can have direct impact on time management.

Opportunities

An opportunity for the clinic is to create and implement policies and procedures; this would ensure consistency in practice and adherence to regulations. Another opportunity would include hiring an advanced practice provider to assist the physician in providing care to patients and giving some time off by taking after hour calls. An opportunity would be to assess the patient's satisfaction in a formal fashion. An opportunity that may improve the patient's satisfaction would be to change the office policy for appointment scheduling.

Threats

Competition is a threat to this small clinic. To obtain the certification for prescribing buprenorphine is not difficult and can usually be completed in less than a weekend. The more providers being able to do this could limit the number of patients that are seen in the clinic. Another threat to patients is changes to the affordable care act. Patients with mental illness, including addiction, may have difficulty obtaining a job that has health insurance coverage. At

this time, the affordable care act provides protection to patients, but this could change due to changes in the political arena.

Clinical Practice Question

The practice that the organizational assessment was completed in is new and provides care that cannot be found in most primary care offices. This organizational assessment has identified multiple areas where the office could grow and improve. For the purpose of this project, the clinical question chosen is: Can a systematic and evidence-based method improve the timeliness of prior authorizations for patients' addiction treatment medications?

Review of the Literature

Method

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline served as the framework for this review (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009). A comprehensive electronic search was conducted in the Cochran, CINAHL, Google, Google Scholar, and PubMed and was limited to reviews in the English language during the period of 2008 to 2018. The criteria for inclusion was studies that reviewed policies and addiction medicine. Studies from prior to 2008 were included to review the length of time this problem has existed. Keywords were prior authorization, addiction, addiction medicine, mental health.

Summary of Results

The search yielded 23 PubMed reviews. No duplicates were found. Each review was screened using inclusion and exclusion criteria according to PRISMA criteria (Moher, et al., 2009). Review of titles and abstracts results in removal of six articles that did not meet the inclusion criteria. In addition, nine articles were excluded after in-depth examination of content,

as did not meet inclusion criteria. The remaining eight articles were included in this review.

Results

Access to care. The number of patients receiving treatment for substance use disorders have been consistently very low. The biggest reasons that are reported by patients include cost and access to treatment. Prior authorizations were listed as a barrier related to access to treatment (Reif, et. al., 2017).

Currently, the Food and Drug Administration (FDA) has approved methadone, buprenorphine, and naltrexone for the treatment of opioid use disorder (Huskamp, Riedel, Barry & Busch, 2018). In office-based opioid use disorder treatment, experts agree that the recommended drug is buprenorphine/naloxone preparations (Huskamp, Riedel, Barry & Busch, 2018). In a study that compared the Marketplace Insurance plans in 2017, it was found that 14 percent of the plans did not cover any formulation of buprenorphine/naloxone and only 10 percent will cover the extended release injectable buprenorphine (Huskamp, Riedel, Barry & Busch, 2018).

When comparing state Medicaid plans, every state had buprenorphine on their drug list but every single one of them imposed some type of utilization limit (Andrews, et. al., 2019). The limitations included requiring co-pays, annual limits, or prior authorizations for buprenorphine (Andrews, et. al., 2019). These limitations can have a negative effect on a provider being willing to prescribe any form of buprenorphine (Andrews, et. al., 2019).

The effects of a treatment delay for patients with opioid use disorder can result in relapse. The state of Massachusetts Medicaid program attempted to implement a stricter prior authorization criterion for patients that were on high doses are buprenorphine (defined as greater than 24mg daily) in order to save money. The study unfortunately noted a significant increase in

patient relapses after full implementation of prior authorization requirements (Clark, Baxter, Barton, Aweh, O'Connell & Fisher, 2014).

Provider burden. In 2010, the American Medical Association (AMA) completed a survey of over 2,400 physicians to review their experience with prior authorizations. Two-thirds of the physicians reported that they had to wait several days to receive a prior authorization for drugs and 10 percent reported waiting more than a week (AMA, 2015). It is estimated that interactions with the insurance company costs $82,975 annually per physician. The American Medical Association estimates that close to 20 hours a week can be taken up by the medical office staff to complete prior authorizations (AMA, 2015). These hours are not reimbursed by the insurance industry and disrupt the workflow in the office, thus reduce the time that a physician is able to spend with patients (AMA, 2015).

Recommendations to reduce prior authorization burden. The American Medical Association has made recommendations to reduce the burden of prior authorizations (PA) on practice.

1. "Check PA requirements before providing services or sending prescriptions to the pharmacy.
2. Establish a protocol to consistently document data required for PA in the medical record.
3. Select the PA method that will be most efficient, given the particular situation and health plan's PA options.
4. Regularly follow-up to ensure timely PA approval.
5. When a PA is in appropriately denied, submit an organized , concise and well-articulated appeal with supporting clinical information" (AMA, 2015, p. 2-5).

Another recommendation that was presented in the evidence was that the insurance company needs regulation regarding the amount of time that they take to respond to prior authorizations (Andrews et. al., 2019). The literature reviewed regarding buprenorphine and prior authorization consistently recommends that the limitations be lifted by the insurance industry (Andraka-Christou & Capone, 2018). The insurance industry's recommendation is for the provider to increase office support to complete the prior authorizations (Huhn & Dunn, 2017).

Discussion

In the past, treatment for mental health services, including addiction medicine, have been more limited than treatment for medical services (Horgan, et. al., 2015). In 2008, the Mental Health Parity and Addiction Equity Act was enacted to equalize coverage in mental health (Horgan, et. al., 2015). Researchers compared the coverage pre and post enactment and unfortunately, they did not find a significant change in access to care nor reimbursement. They found that insurance companies continued to delay payment for care, thus delaying treatment for patients through other techniques such as utilization management and "selective contracting with providers" (Horgan, et. al., 2015, p. 168). Another technique that insurance companies use is to place medications on different tiers that represent the amount of money that they will reimburse, leaving the patient to provide the remaining. Many times, the medication that is covered without a prior authorization is not the most evidenced based treatment (Reif, et. al., 2017). The prior authorization process in and of itself can delay treatment. Knowing that relapses are common in patients that struggle with addiction, delays can be catastrophic in the recovery process (Reif, et. al., 2017).

The literature that reviewed the state Medicaid systems found that each state had their own requirements for approval of medication assisted addiction treatment (Andrews, Abraham,

Grogan, Westlake, Pollack, Friedmann, 2019). In a study completed in 2015, it was noted that 48 of the 51 programs evaluated across the United States required prior authorizations (Mark, Lubran, McCance-Katz, Chalk & Richardson, 2015) even though it was noted in their recommendation that buprenorphine/naloxone is the medication of choice for opioid use disorder.

The literature presented evidence that providers avoid prescribing buprenorphine in the treatment of addiction related to the burdensome process to obtain prior authorizations (Andrews, et. al., 2019). The more generous the state is to cover buprenorphine without significant restrictions, the more likely a provider is to prescribe (Andrews, et., al. 2019). "Considering that approximately 60% of the nation's 14,500 addiction treatment programs are operating in states requiring prior authorization, the dampening effects of these policies on buprenorphine availability may be wide reaching" (Andrews, et., al. 2019).

In the review of the literature, a significant amount of information is found stating that the prior authorization process is a barrier to treatment for patients with opioid use disorder. The prior authorization process is also a burden to providers and their office staff. Unfortunately, there is not a significant amount of information to guide the prior authorization process to get these medications approved timely. For patients being treated for opioid addiction, barriers to treatment can be deadly. This needs to change.

Project Plan

Purpose of Project and Objectives

The purpose of this project was to improve the time and tracking related to the completion of prior authorizations. In general, prior authorizations are granted for a specific time frame and if not renewed prior to the expiration date, a patient's treatment could be denied

coverage resulting in treatment delays (personal communication, XXX, 2018). A secondary purpose of this project is to assist the mental health office with a starting point for their policies and procedures. The provider was practicing without a formal set of policies and procedures.

Design for the Evidence-based Initiative

Utilizing models to guide change can be helpful. "A framework can be used to connect all the important aspects of the project" (Moran, Burson & Conrad, 2017, p. 258). The theory that was chosen to guide this initiative was Lewin's change theory.

Lewin's change theory

Lewin's change theory uses the image of an ice cube as the current state. Once an organization desires to undergo a change, the ice cube is thawed (unfreezing). After the change is implemented, the fluid is then re-frozen into a different shape to represent the change. The MindTools team feels that this represents that change is common and something that occurs quickly (N.D.).

In the unfreezing step of Lewin's change theory, the organization needs to review the status quo and determine if change is necessary. It is during this step that the attitude of "this is how we have always done it" is broken (MindTools, N.D.). Allowing the team to re-examine how things have been done and being part of the team to create change is thought to be imperative to successful change (MindTools, N.D.). The unfreezing step was completed prior to the proposal defense. The office manager was ready to make a change as the prior authorization process was her responsibility. The office manager was instrumental in identifying the need for a new process and had the support of the physician in making changes as necessary.

Change is the second step in Lewin's change theory. This step happens slowly as "people need time to embrace new direction" (MindTools, N.D.). Change for some can be

difficult and to assist the team with getting on board, they need to understand how the change will benefit them. Communication is of great importance during this phase (MindTools, N.D.). Rumors can arise during change and being open and honest during communication will help to decrease the chaos from rumors. Empowering and involving those who will be directly affected by the change can also help to make the change successful (MindTools, N.D.).

The implementation of the project was messy. Many ideas were shared during the proposal defense that could help the office manager in being more efficient with the prior authorization process. One of those ideas was to provide the patients with the phone number from the drug manufacturer and specialty pharmacy as they could receive phone calls from each. This idea was added early in the hopes that the delay that the office was experiencing related to the patients being contacted could be diminished. The office manager stayed in close contact with the DNP student in addition to reaching out to the drug manufacturer for additional help once the preliminary data wasn't looking hopeful.

Finally, re-freezing is the third step in Lewin's change theory. In this step, the team has embraced the new way of practice and the period of change has stabilized (MindTools, N.D.). It has been questioned if stabilization should be obtained as change if ever present, but Lewin's theory feels that stabilization allows for the team to know how things are supposed to be prior to the next change (MindTools, N.D.). Re-freezing was not able to be completed related to changes that occurred in the office. The changes are explained later in this document.

Setting

The setting this project took place is a one-physician clinic that provides care for patients struggling with addiction. This office has a manager that assists the physician with clerical duties in addition to some clinical duties to prep the patients for their visit with the physician.

This project was also completed away from the office setting for the drafting of the policies. This office sees patients two days a week. The physician and owner expressed support for this initiative.

Participants

Participants that were involved in the project include the physician and the office manager.

Model Guiding Implementation

A conceptual framework is similar to a map for guiding a project (Moran, Burson, & Conrad, 2017). Kotter's model for change will guide this implementation. Kotters model for change was created based on John Kotter's experience. Kotter's change model includes the following eight steps for change:

1. Establish an urgency about the need for the change. Kotter states that "successful change efforts must begin with individuals and groups evaluating a company" (Applebaum, Habashy, Malo, Shafiq, 2012, p.767) and urges the use of outside influences to complete this step (Applebaum, Habashy, Malo, Shafiq, 2012).
2. Create a guiding coalition. According to Kotter, no one person can manage a change process in an organization (Applebaum, Habashy, Malo, Shafiq, 2012). The coalition team should include positional power, expertise, credibility, and leadership (Applebaum, Habashy, Malo, Shafiq, 2012).
3. Develop a vision and a strategy. The first step of the change process after the team is created is to formulate the vision. A clear vision can help to drive the objectives for the change and provide direction (Applebaum, Habashy, Malo, Shafiq, 2012).

4. Communicate the change vision. Communication of the change vision can "reduce uncertainty, decrease ambiguity and can even affect the type of positive or negative responses to the change" (Applebaum, Habashy, Malo, Shafiq, 2012, p. 770).
5. Empower broad-based action. Employees are more likely to embrace new ideas after communication across the organization, however, employees may need help to get rid of obstacles to the change vision (Applebaum, Habashy, Malo, Shafiq, 2012). Kotter reports that the most common obstacles organizations face during change are: structures, skills, systems, and supervisors. "Kotter stresses the pivotal role of training in the empowerment process" (Applebaum, Habashy, Malo, Shafiq, 2012, p.772).
6. Generate short term wins. Seeing the change happen and watching it work can help the organization obtain its longer-term goals (Applebaum, Habashy, Malo, Shafiq, 2012). Celebrating the change as it is occurring can help to keep the momentum going.
7. Consolidate gains and produce more change. Throughout the change process, the organization is encouraged to continually evaluate the change. During the process, changes can regress back if the team does not remain focused on the vision (Applebaum, Habashy, Malo, Shafiq, 2012)
8. Anchor new approaches in the corporate culture.

Implementation Steps and Strategies

1. Complete proposal and acceptance for the project by faculty at GVSU and stakeholders at the organization by January 11, 2019. The proposal defense was completed as scheduled. Multiple interventions were discussed during the proposal.

2. Begin observation and time tracking of prior authorizations the week of January 14, 2019. Data was collected with the office manager related to new patients/prescriptions and renewal of expiring prior authorizations as needed.
3. Chart review and data was collected with dates to include October 2018-January 11, 2019.
4. Creation of policy and decision was made to assist with how to best track prior authorizations with the current tools available to the practice.
5. Obtain formal commitment from the office manager for the continuation of the tracking tool for prior authorizations. This commitment may also pertain to the off-site clinic that the physician currently sees patients with local county Medicaid insurance coverage
6. Present the electronic and written policy and procedure to the organization in May 2019 regarding the completion of prior authorizations. As the project was being completed, patient need outweighed the need for the project and the office manager completed what needed to be done to get the patient's medications authorized. This may have resulted in additional calls to the insurance company and the specialty pharmacy as appropriate.

Measures

The office manager will observe and track the time that she requires for completion of prior authorizations. Data that will be collected includes:

- Date prescription is written by the physician
- What drug is being prescribed
    - Buprenorphine or buprenorphine/naloxone
- What type of insurance the patient had at the time of the medication prescription
- Date of initial contact with the insurance company (initiation of prior authorization)

- Dates of correspondence with the insurance company about pending prior authorization if requested (ie. Additional information required for completed of prior authorization)

- Date of approval or denial (if approved, prior authorization completed)
  - If denied, the reason for denial was collected
    - Date appeal initiated
  - Outcome
    - Approval (prior authorization completed)
    - Denial with scheduled Peer to peer consideration
      - Outcome

Data Collection Procedures

Data will be collected and stored electronically on an encrypted flash drive. Pre-implementation data was collected from a chart review (October 2018-December 2018) and the office manager collected post implementation data each onsite encounter (January 2019-April 2019). The DNP student did not have direct access to the electronic medical record.

Data Management

No patient sensitive information was shared nor, was sensitive office information shared during this project. Data from the interviews and observations was stored on an encrypted flash drive.

Analysis

The scope of this project included analysis of the implementation of a tracking tool and policy on the completion and tracking of prior authorizations. Time studies were analyzed to determine if the tracking tool can improve time management for the office manager.

Resources & Budget

This project was completed by a Doctor of Nursing Practice student who donated time for the completion of the project. Time with the office manager, physician, and insurance company representatives for assistance with policy creation and evaluation of implementation was required.

The average salary for an addiction medicine physician is $150 an hour (neuvoo.com, 2019). An office manager's average salary is $18.00 an hour (PayScale, N.D.). The American Medical Association (AMA) reported in 2015 that on average, a physician will work an hour a week on prior authorizations, nursing works 13.1 hours per week, and clerical staff works 6.3 hours per week. This clinic does not have nursing support so all of the requirements fall on the physician and the office manager (AMA, 2015).

A phone call to complete a prior authorization for buprenorphine with Medicaid can take an average of 15-30 minutes depending on hold time. The process for completion of a prior authorization for the extended release injectable buprenorphine starts with paperwork that goes to the drug manufacturer and takes an average of 15-30 minutes to complete. After the drug manufacturer completes the benefit investigation, the insurance company then respond with the request for the prior authorization. This process takes an average of 30 minutes to either complete the paperwork or initiate the prior authorization over the phone. If the insurance company requires additional information, the data collection can take 15-30 minutes to collect and to fax the information back. All of these steps of a prior authorization can be completed by the office manager. If an appeal with a peer to peer is required, the office manager is no longer able to assist and the physician must complete the process. One peer to peer was required during the implementation and took 30 minutes. In one day, the prior authorization process can take up

a significant amount of the office manager's time

Timeline

The proposal was defended on January 14, 2019. At the time of the proposal, the office manager and physician announced that they were transitioning the practice to a hospital system but the time frame was not known. This changed the proposed timeline to include de-identified information from the patients' medical record regarding prior authorizations and approvals rather than a 28-day pre intervention observation period. The tracking tool and policy were implemented, and a 28-day observation period took place for comparison. The projected completion date was moved up due to the "soft" closure of the office and the need to delay starting new patients on buprenorphine.

Methods

A process was created with the goal to decrease the amount of time between drug prescription to actual administration. The office currently uses an online documentation software for patient tracking and additional information was added to the patient's flowsheets for communication between the office manager and the physician. The office manager also kept a tickler system for patients starting new drugs that were undergoing the process of obtaining the prior authorization in the form of a paper chart. The paper chart became the tracking system as all of the interactions with the insurance company were kept in the paper chart. The office manager also was able to keep documentation that was sent to the insurance company for reference when she made phone calls.

Intervention

During the organizational assessment, the office manager stated that she did not have experience working with the insurance industry. When buprenorphine/naloxone in films were

first being prescribed by the physician, every insurance company required a prior authorization. The companies would allow her to complete the process over the phone and, for the most part, give an approval by the end of the phone call. When the physician began to prescribe the extended release injectable buprenorphine, the insurance company did not provide approvals over the phone. A new process for completion and tracking of prior authorizations was needed.

1. The process for prior authorization completion was observed and chart reviews were completed to evaluate current state.
2. Policy was drafted with the help of the office manager (See figure XXX). With the limited resources available to the office, the manager was instrumental in drafting the policy to ensure that the proposed intervention was doable. A tickler system was chosen to ensure ease for follow up. This tickler system was in the form of a paper chart. This allowed the office manager to keep all of the correspondence with the drug manufacturer, insurance company, and the patient in one place. The charts were reviewed regularly and kept in the filing system for pending prior authorizations until approval was obtained. A policy was created to reflect the process. The policy reflected the protocol to be followed and was updated as information was received by the insurance companies.
3. Policy was implemented to reflect this process: New patients to the practice that are in withdrawal from an opioid are started on Suboxone. At the completion of the first appointment, the patient leaves the office with a prescription. If the patient has Medicaid, the office manager calls, and the prior authorization is completed. The drug is authorized prior to the patient leaving the office. Some of the private insurance companies that the physician accepts have added buprenorphine/naloxone to their formularies and they no longer require prior authorization and the patient will be able to fill their prescription

after their visit. Of the private companies that still require a prior authorization, a call will be made to initiate and complete (if possible) the prior authorization.

After a patient is stable on buprenorphine/naloxone at the approved dose per the manufacturer's guidelines, the physician and patient may decide to transition to the extended release injectable buprenorphine. The physician communicates this change to the office manager who initiates the benefit investigation with Indivior, the drug manufacturer. The patient is provided with the drug information and the contact information for Indivior as the patient will be contacted to review their insurance and possible program assistance for drug coverage. After the benefit investigation is completed, Indivior contacts the office with their findings regarding co-pays and assistance programs. If a call is not received by Indivior in a timely manner, the office manager will call for an update. This benefit analysis also provides the office with the information regarding which specialty pharmacy is to be used for dispensing of the medication. The office manager can then initiate the prior authorization with the insurance company. A tickler system is in place to contact the private insurance companies once to twice weekly depending on the patients proposed date to start the long acting injectable buprenorphine. If the patient has Medicaid, the benefit investigation is not required, and the office manager initiates the prior authorization.

4. Data was collected with the help of the office manager. This data included pre-intervention data with dates into the fall of 2018.

Approach

The impact of the intervention was assessed using pre and post intervention data. Through observation and patient chart review with the office manager, de-identified information was gathered and reviewed.

Measures

Time frames from start of prescription to the actual start of treatment were measured. A tickler system was used by the office manager to track the prior authorization process. Other data collected included medication that was prescribed, insurance company, dates of correspondence with the insurance company, and approval/denial date. If denied, additional information was collected to include the reason for denial, appeal start/end dates and final outcome of appeal if appropriate.

Analysis

Time frames were compared pre project initiation and post intervention.

Ethical Considerations

The DNP project was submitted to the Grand Valley State University Human Research Review Committee for institutional board determination (IRB) and was determined to be non-research (see Figure 4). The organization did not require a formal presentation for the ethics review board. All data analyzed was de-identified of any patient sensitive information.

Results

This project took place in 3 phases. Evaluation of the current state, implementation of new processes and evaluation of the future state. All data was collected with the assistance of the office manager as the DNP student did not have access to the electronic medical record.

Current state

Chart reviews were completed with the office manager during the time frame of October 1, 2018 through December 31, 2018. This review was completed to enable comparison to the new process. During the described timeframe, the physician had six new patients present to the office. Of those patients, four were started on buprenorphine/naloxone films. Their insurance coverage consisted of: Two self-pay, one Blue Cross Blue Shield, one Medicaid and two Priority Health. The office manager reported that the only prior authorization that had to be completed during this time was for the patient with Medicaid. She reports that with the changes in the insurance formularies, buprenorphine/naloxone has been covered without the need for prior authorization (Personal communication, XXX, April, 2019).

Implementation

Implementation of the tracking/tickler system took place after the proposal was defended in January. Prior authorizations for the extended release injectable buprenorphine that were in process were included in the data collection if the approval was not received. The office manager implemented using the patients' paper charts as her tracking system for the prior authorizations. This allowed the office manager to keep all paperwork in one place separated out by patient.

Post Implementation

The physician had five patients that were successfully transitioned from buprenorphine/naloxone to an extended release injectable buprenorphine. Two of the patients had State of Michigan Medicaid, one patient had Blue Cross Blue Shield (BCBS) of Michigan, another had United Health Care and the last patient had Priority Health insurance. The patients with Medicaid were approved to start the extended release injectable buprenorphine within two

weeks of their prescription being written with a mean time of 15 days. The patient with BCBS, the approval time was nearly six weeks (38 days). The first prescription was written at the end of November. BCBS responded requesting additional information which was provided to them. The first injection was authorized in early January and administered soon after. The patient with Priority Health had a similar authorization time. The request started the third week of December 2018 with Priority Health requesting additional information in early January with a final approval at the end of January 2019 (42 days). The office manager, using a tickler system called these insurance companies twice weekly to get updates and to try to expedite the process with no success. United Health Care gave the office manager the most trouble with obtaining the prior authorization. The process started the third week of December 2018 and required multiple faxes, a peer to peer phone call, and finally, a call to the medical director. The patient was finally given the first injection in early February 2019 (49 days). The patient with United Health Care required an additional prior authorization when the dose changed from 300mg of the injectable buprenorphine to the 100mg maintenance dose. The prior authorization process was initiated in mid- March 2019 and as the completion of the data collect, the prior authorization was still pending.

Discussion

When discussing the situation with the office manager, it became apparent that changes in the time frame between the initial prescription and the start of treatment happen because of changes in formularies with the insurance company. In the spring of 2018, most insurance companies required a prior authorization for buprenorphine/naloxone. By January of 2019, few insurance companies required a prior authorization. For those that did, the office manager was able to complete the process over the phone with same day approval that was good for one year

from the date of request. The office manager found that her process truly did not change, but the change in formulary, shortened the time between prescribing and starting treatment (XXX, April 4, 2019). A significant issue, each insurance company has it own requirements for medication assisted treatment for opioid addiction.

Priority Health lists that they require a prior authorization for buprenorphine/naloxone or the extended release injectable buprenorphine. Buprenorphine/naloxone is a Tier 1 medication which means that the medication is available in generic form and cost less. Priority Health limits the amount of buprenorphine/naloxone they will prescribe each month and they will not cover any other opioids for a patient that is receiving buprenorphine/naloxone. In contrast, the extended release injectable buprenorphine is a Tier 7 medication which is a medical benefit specialty medication. This means that the prescription drug program does not cover this medication and the medical benefit makes the determination. Priority Health requires that the extended release injectable buprenorphine be filled at one of their approved specialty pharmacies (Priority Health Approved Drug List, 2019).

Blue Cross Blue Shield of Michigan does not require a prior authorization for buprenorphine/naloxone as of the latest clinical drug list update (April 2019). The extended release injectable buprenorphine is not listed as being covered or not covered. When a call was made to the insurance company, the representative stated that the drug may be covered with certain plans that they offer. The representative did not reflect which plans would cover the medication (XXX, personal communication, April 11, 2019).

United Health Care provides a policy online regarding the long acting injectable buprenorphine (Sublocade®) and combination buprenorphine/naloxone (Suboxone®) coverage. For buprenorphine/naloxone, an authorization is provided for 3 months for patients on 24mg

daily. After that time frame, if the patient requires the same dose, the physician must provide a rationale for exceeding the maximum dose set by United Health Care and the patient must fail a trial of the plans accepted dose. This policy could be dangerous to patients undergoing treatment for addiction. This could result in treatment delays and relapses. The prescribing information for buprenorphine/naloxone states that the recommended dose is 16mg, but the acceptable daily dose is up to 24mg (Suboxone® prescribing information, 2018). If the patient is on 16mg daily of buprenorphine/naloxone, the authorization from United Health Care will be extended to 12 months.

The policy from United Healthcare on the extended release injectable buprenorphine is consistent with the drug manufacturer's guidelines for treatment which states that after a patient is stable on buprenorphine/naloxone, the patient may be transitioned over to the extended release injectable buprenorphine. The policy reflects the recommendation for the patient to start on the 300mg dose and after two months, be reduced to the 100mg maintenance dose. The policy goes on to give guidance for patients that cannot tolerate the lower dose in approving the patient for the higher dose. The initial approval is to be for 6 months and continuation therapy is to be approved for 12 months. The difficulty with obtaining the prior authorization from this company is not understood with such a clear policy in place. United Health Care would only authorize the extended release injectable buprenorphine based on the dose. The extended release injectable buprenorphine is administered at 300mg for the first two injections and then the maintenance dose is 100mg. At the time of this writing, the office manager is still having difficulty getting the maintenance dose covered for a patient who will be delayed in treatment if not resolved soon.

State of Michigan Medicaid also provides the requirement for authorization online. For an approval the patient must be on buprenorphine/naloxone or equivalent. The patient is

provided approvals for six months at a time. Medicaid does further require that patients undergo urine drug screens every 30 days in addition to treatment counseling. There is no lifetime limit but extending requests for the extended release injectable buprenorphine are completed on a case by case basis.

Of interest, in the state of Michigan, the Medicaid program requires that the patient be dispensed the name brand Suboxone®. The provider cannot write the prescription for the brand name or request the brand name but when the pharmacy tries to run the claim online for the patient, a denial is granted since the generic medication is not covered. A special code for Medicaid patients must be added to the prescription but this information was not forwarded to dispensing pharmacies or to the provider (personal communication, XXX, March, 2019).

With each company having their own requirements for the approval of these important medications, it is understandable that the office manager is having difficulty with prior authorizations. At the American Society of Addiction Medicine conference in April of 2019, review of the process with other professionals found the same struggles in getting medication assisted treatment covered with the private insurance companies. Providers that worked exclusively with state funded Medicaid programs were having success with obtaining authorizations for some of the newer treatments in a timely manner.

To place all the blame on the insurance industry would not be fair. The current pricing of the medications as set by the drug manufacturer is a limitation to many insurance companies placing the drugs on their formularies (Wang, 2018). It has been noted the drug prices greatly exceed the clinical benefit for new treatments thus making it difficult to easily prescribe to patients (Wang, 2018).

Limitations

A limitation to this project was that the physician accepted a position to work with a hospital system which resulted in a soft closure of the practice. Patients were being seen off-site until the physician was able to start with the new organization which limited the physician in being able to continue prescribing the extended release injectable buprenorphine due to DEA requirements for delivery and administration of the drug. The physician continued her current patients on their medications, but no new patients were accepted during the period of transition to the new hospital system. Another limitation is the measures used have no reliability or validity. A significant limitation to this study is its dependence on a third party which was the insurance industry for the success or failure when the third party was not aware. An additional limitation to this study was that the physician was newly prescribing injectable buprenorphine and much of the pre intervention data is related to the prescribing of buprenorphine/naloxone which was noted to be added to some of the private insurance company's formulary, thus skewing the data.

Implications for Practice and Further Study in the Field

This DNP project has multiple practice implications. The insurance industry can have a significant effect on patients' success or failure with treatment for addiction. It shouldn't be easier to obtain opioids through the insurance industry than the treatment that helps patients get off opioids. With the current opioid crisis, something needs to change when it comes to authorization of these medications.

Conclusion

The United States is currently experiencing an emergency when it comes to the opioid crisis. People are dying every day due to overdose when treatment is available. This treatment

should not be difficult to obtain. The insurance industry requiring prior authorization is understandable. The medications have requirements for prescribing but long turn around times for the prior authorizations are not appropriate. Attempting to provide a resource to the clinic to improve the time frame from the time the prescription is written until the patient is able to start the medication did not help. Changes in formularies at the level of the insurance companies can, and have in the past, help. It is unfortunate that people are dying when medication assisted treatment is available.

Dissemination of Results

The results have been reviewed with the physician and the office manager but will be formally reviewed with the Grand Valley State University faculty that participated with this project at the Dissemination Defense in late July. These results were informally discussed with professionals in addiction medicine at the American Society of Addiction Medicine conference in early April 2019. These results will be uploaded to Scholar works.

Reflection on DNP Essentials

The American Association for Colleges of Nursing (AACN) requires that all DNP students meet the eight essential competencies in order to graduate (AACN, 2006). "The DNP essentials exemplify thoughtful contribution and roadmap of the competencies that nursing scholar must exemplify to have an impact on health care from a nursing perspective" (Moran, Burson & Conrad, 2017). These essentials were met through the clinical portion of the DNP program and through the scholarly project.

I. Scientific Underpinnings for Practice

The AACN adopted a definition of nursing science as "an entity in itself with a growing body of scientific knowledge, while acknowledging the value of incorporating knowledge from

other sciences" (Zaccagnini & White, 2017, p. 6). This is the foundation of knowledge for nursing practice. In the completion of the project, gaining an understanding of the effects of withdrawal made the project more important. While the project has an outward appearance of being related to getting treatment paid for timely, it truly has an even more important role in continuation of treatment for a vulnerable population.

II. Organizational and Systems Leadership for Quality Improvement and Systems Thinking

Zaccagnini & White stated that "the advanced practice nurse must be able to discern issues quickly and effectively and contribute to strategic energy and system redesign" (2017, p. 43). In the completion of this project, the goals remained the same while trying to adjust to the ever-changing world related to the insurance industry. This addiction medicine field is getting a lot of attention at this time related to the opioid crisis and the insurance industry is adjusting their formularies to reflect the urgency, some better than others. In medicine, change will be constant as research continues to show that we can improve in our treatment of patients. Improving processes to reflect the changes will be necessary to be successful in the field.

III. Clinical Scholarship and Analytical Methods for Evidence-Based Practice

"In advanced practice, scholarship should be integrated with practice a purposeful, systematic, and conscious endeavor. The emphasis is on inquiry, outcomes, and evidence to support practice" (Zaccagnini & White, 2017). Being able to review the literature for high level evidence was important in the completion of this project. In addiction medicine, a lot of expert opinion is printed in the literature and presented as being evidenced-based. As a DNP prepared nurse, this information is able to be reviewed and analyzed prior to implementing into practice. This is a critical step in quality improvement.

IV. Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care

For the DNP-prepared advanced practice nurse, the use of technology is essential. From the electronic medical record to the wireless communication devices, the DNP-prepared nurse needs to be up to date and be able to effectively use the devices for the best patient outcomes (Zaccagnini & White, 2017). In the clinic that this project took place, the physician provides care to patients in rural southern Michigan through tele-health. While tele-health was outside of the scope of this project, the DNP student was able to observe the process for seeing patients in this capacity. In addition, the DNP student was able to observe an informatics nurse at a large hospital system for a day to learn about their role.

V. Health Care Policy for Advocacy in Health Care

"There are three critical ingredients to democratic renewal and progressive change in America: good public policy, grassroots and organizing and electoral politics" (Paul Wellstone as quoted by Zaccagnini & White, 2017, p.189). This essential was met when at the Michigan Nurse Practitioner Advocacy Day. This day provided the opportunity for students and practicing providers to meet with their representatives and senators to discuss what nurse practitioners are trained to do, and where the limitations are regarding providing care to patients. In addition, a luncheon was attended with the office physicians and a selection of local state representatives and senators to discuss the issue of prior authorizations and medication assisted treatment.

VI. Interprofessional Collaboration for Improving Patient and Population Health Outcomes

The professions in nursing and in medicine agree that interprofessional collaboration is needed and have even went on to acknowledge that "the future of healthcare delivery requires

interprofessional teams that are prepared to meet the diverse, multifaceted health issues of the population" (Zaccagnini & White, 2017, p. 235). In addiction medicine, the physician is assisted with the treatment of the patients by psychiatry, social work, counselors, and primary care. One provider cannot bring all the necessary components together for the treatment of this population. Working together brings about the best patient outcomes.

VII. Clinical Prevention and Population Health for Improving the Nation's Health

In the completion of a preceptor led clinical experience, this essential was met. The physician provided care to a rural community that was evidenced-based. The DNP student was trained to view the current health maintenance due on every patient regardless of the reason of the visit to the practice. It was felt that many times, patients will only come into the practice when not well and it may be the only opportunity to approach health maintenance with them. It was noted that during many of these visits, patients were given their influenza vaccinations or screening studies were ordered for the patient. The scholarly project also provided a view into the prevention of the disease of addiction. The physician speaks in many different arenas to teach the community about prevention rather than the care that she provides.

VIII. Advanced Nursing Practice

"The DNP-prepared nurse practitioner will continue to provide health care through assessment, diagnosis, and treatment of the complex responses of individuals, families, or communities to actual or potential health problems, prevention of illness and injury, maintenance of wellness, and provision of comfort" (ANA, 2010 as cited by Zaccagnini & White, 2017, p. 339). This essential was met in the clinical portion of the DNP program in addition to during the scholarly project. The clinical opportunities taught me to assess, diagnose, and treat illness in addition to other opportunities in which wellness was promoted. While no patient contact took

place during the scholarly project, the DNP student was in the background working toward getting medications covered so that the patient would not be denied their treatment and treatment was continued and not segmented based on prior authorizations.

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Appendix

Figure 1. Burke-Litwin Model

The Burke-Litwin Model of Organizational Performance and Change

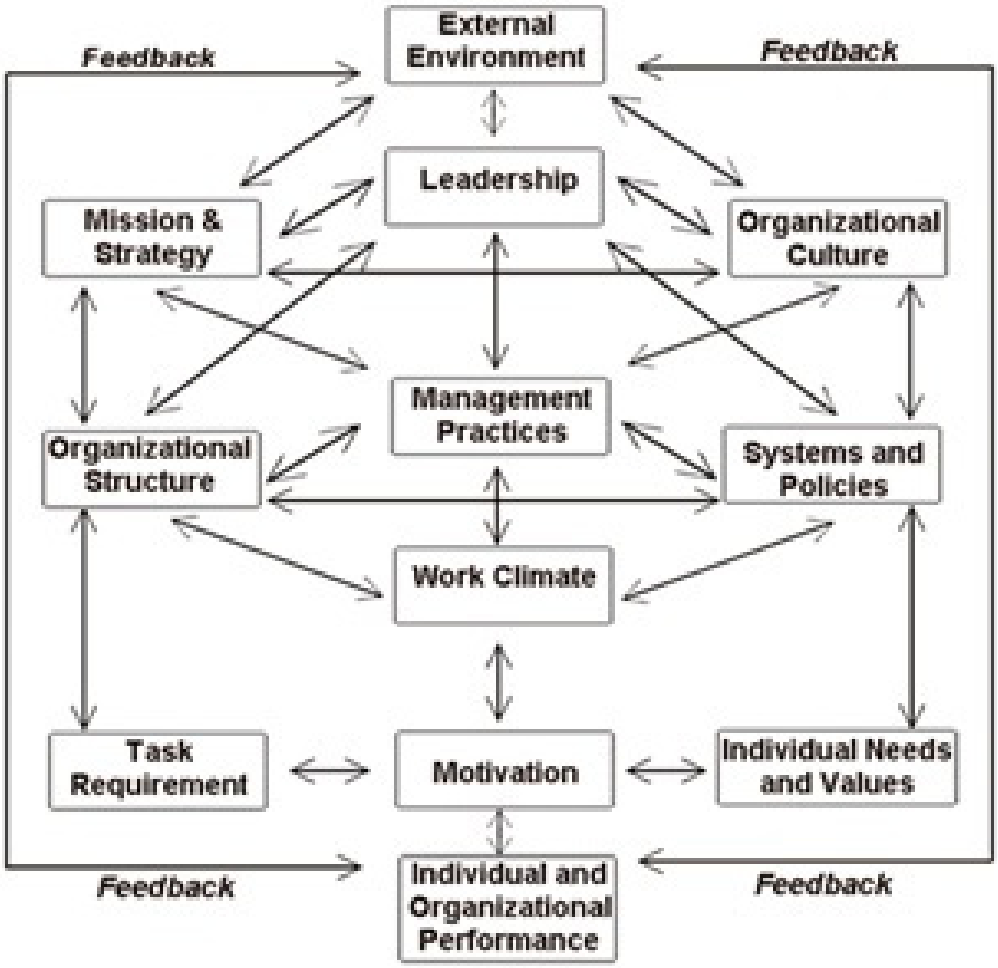

Figure 1. A model of organizational performance and change. Reprinted from "A Casual Model of Organizational Performance and Change," by Burke and Litwin, 1992, *Journal of Management, 18,* 528. Copyright 1992 by Southern Management Association

Figure2. Flow Diagram of search selection process (Prior Authorization)

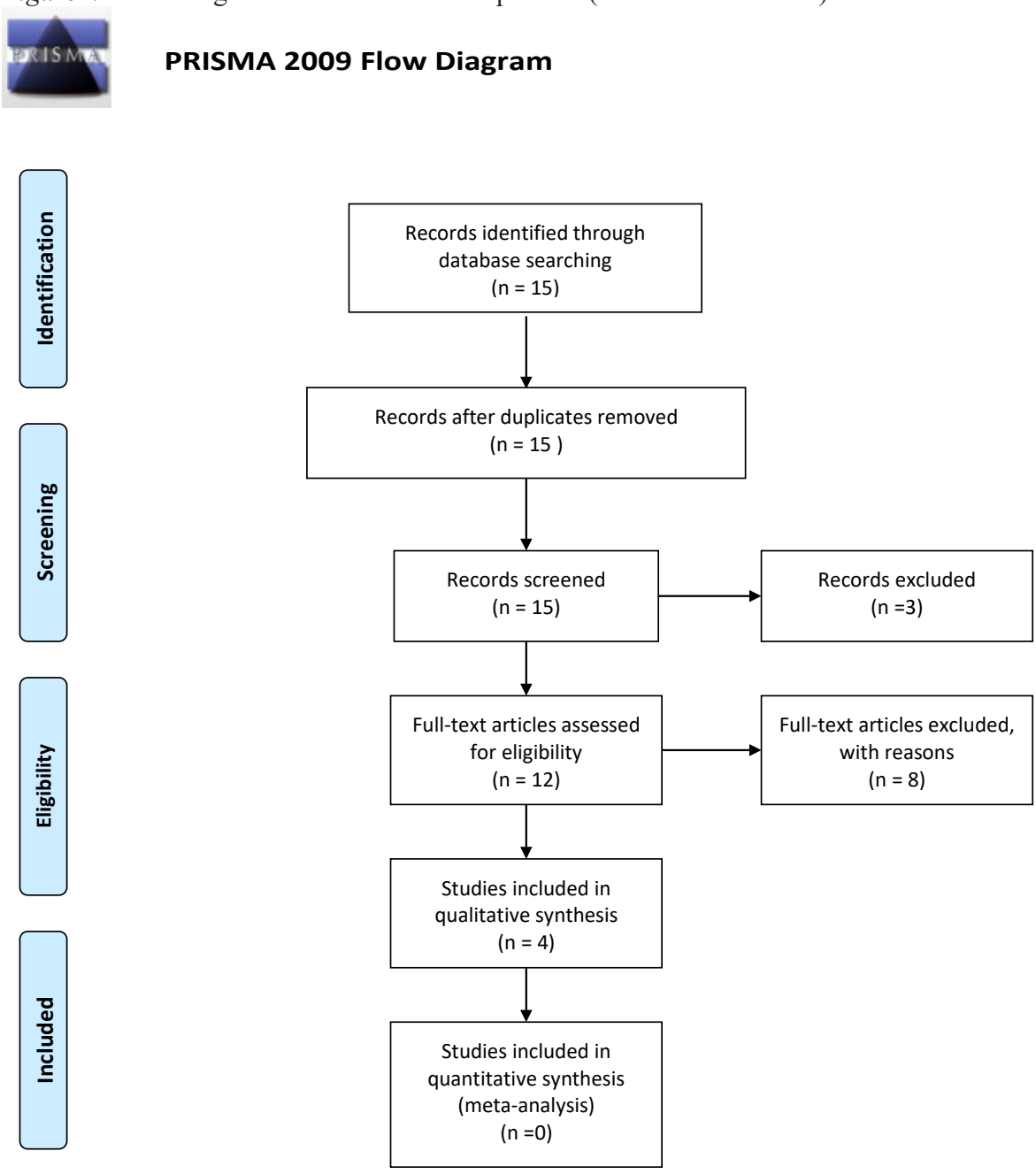

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Figure 3. SWOT Analysis of New Mental Health Organization in West Michigan

Strength	**Weaknesses**
• Physician is passionate about her calling • Opioid epidemic is a popular topic right now (political) • Office Manager and Physician are related and live in the same home. • Patient referral source is expanded related to off-site organization and tele-health • EMR for off-site organizations has access to templates to ensure that all categories are documented for reimbursement. • Off-site reimbursement for physician and office manager paid hourly, not by the patient. • Service is a significant need at this time.	• Office Manager and Physician are related and live in the same home. • No Policy and Procedures in plan • One Physician- no back up • Billing (for patients evaluated in the clinic) is not consistent • EMR in clinic is not possibly being used to it's full capacity related to templates for appropriate billing. • Many patients are on Medicaid and the reimbursement is limited for these clinic patients
Opportunities	**Threats**
• Create policy and procedures to protect both the patient and physician. • Hire an advanced practice provider to assist the physician in providing care and taking after hour call. • Change how appointments are scheduled (only give the patient the arrival time, not the actual time scheduled with the provider) • Use EMR in the clinic to the fullest capacity for improved time management, insurance/billing reimbursement, and consistency. • Use of G-Suite through Google for patient treatment records and account information. (Increased security that is HIPAA compliant)	• New Physicians in the area that provide similar care • Popular topic in this day and age with training available for providers to give this type of care without referral to the clinic. • Changes to the affordable care act may restrict access for patients with mental health concerns, including addiction. • Google Document not HIPAA compliant and at risk for compromise

Figure 4. IRB Determination

GRAND VALLEY STATE UNIVERSITY
www.gvsu.edu

DATE: March 29, 2019

TO: Karen Burritt
FROM: Office of Research Compliance & Integrity
PROJECT TITLE: Prior Authorizations and Continued Treatment in Addiction Medicine
REFERENCE #: 19-292-H
SUBMISSION TYPE: IRB Research Determination Submission

ACTION: Not Research
EFFECTIVE DATE: March 29, 2019
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 IRB. 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. While performing this project, you are expected to adhere to the institution's code of conduct and any discipline-specific code of ethics.

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

The purpose of this quality improvement project is to initiate a policy and procedure for the completion and tracking of prior authorizations at a local medical practice. This is a systematic investigation designed to improve the care being provided to patients. It is not designed to create new generalizable knowledge. Therefore, it does not meet the federal definition of research and IRB oversight is not needed.

This determination letter is limited to IRB review. It is your responsibility to ensure all necessary institutional permissions are obtained prior to beginning this project. This includes, but is not limited to, ensuring all contracts have been executed, any necessary Data Sharing Agreements and Material Transfer Agreements have been signed, and any other outstanding items are completed.

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) 331-3197 or rci@gvsu.edu. Please include your study title and study number in all correspondence with our office.

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

Office of Research Compliance and Integrity | 1 Campus Drive | 049 James H Zumberge Hall | Allendale, MI 49401
Ph 616.331.3197 | rci@gvsu.edu | www.gvsu.edu/rci

Figure. XXX

Insurance Coverage

Month	Drug Prescribed	Insurance Company	PA required?
October	Buprenorphine/naloxone	Self pay	N
	SQ Buprenorphine	Medicaid	Y
	Buprenorphine/naloxone	Medicaid	Y
	SQ Buprenorphine	Medicaid	Y
November	Buprenorphine/naloxone	Priority Health	N
	SQ Buprenorphine	BCBS	Y
	SQ Buprenorphine	Medicaid	Y
December	Buprenorphine/naloxone	Self pay	N
	SQ Buprenorphine	Priority Health	Y
January	Buprenorphine/naloxone	United Healthcare	N
February	Buprenorphine/naloxone	BCBS	N
March	Buprenorphine/naloxone	BCBS	N
	SQ Buprenorphine	United Healthcare	Y

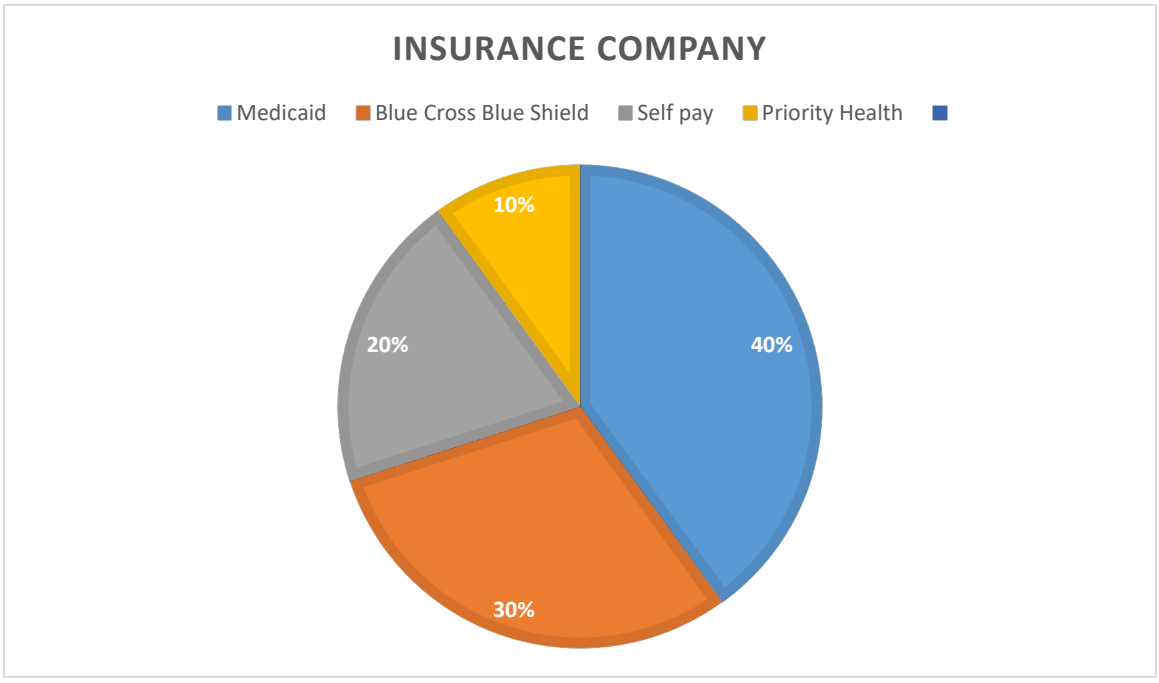

Figure XXX.

Date PA initiated	**Drug**	**Insurance Company**	**Date of Ins Decision**	**Decision**
10/17/18	Buprenorphine/naloxone	Medicaid	10/17/18	Approved for 6 months
10/29/18	SQ Buprenorphine	Medicaid	11/14/18	Approved for 6 months
10/29/18	SQ Buprenorphine	Medicaid	11/16/18	Approved for 6 months
11/28/18	SQ Buprenorphine	BCBS	1/4/19	Approved for 6 months
12/19/18	SQ Buprenorphine	United Healthcare	2/6/19	Approved for 300mg dose x2
12/20/18	SQ Buprenorphine	Priority Health	1/31/19	Approved for 6 months
3/15/19	SQ Buprenorphine	United Healthcare	N/A	No decision as of 4/1/19- patient due for 100mg dose

Figure XXX. Policy and Procedure

Policy Name:	**Completion of Prior Authorizations for Medication Assisted Treatment.**
Date last reviewed:	
Approval or last revision:	
Approved by:	

POLICY
Prior authorizations will be completed in a timely manner to ensure timely initiation and/or continuation of medication assisted treatment for patients.

SCOPE
This policy applies to staff of The XXX Center.

PROCEDURES
1. New patients to the practice that are in withdrawal from an opioid and found to be appropriate for treatment by the physician are started on Suboxone. At the completion of the first appointment, the patient leaves the office with a prescription. If the patient has Medicaid, the office manager calls, and the prior authorization is completed. The drug is authorized prior to the patient leaving the office.

2. After a patient is stable on buprenorphine/naloxone at the approved dose per the manufacturer's guidelines, the physician and patient may decide to transition to the extended release injectable buprenorphine.

- The physician communicates this change to the office manager who initiates the benefit investigation with Indivior, the drug manufacturer.
- The patient is provided with the drug information and the contact information for Indivior as the patient will be contacted to review their insurance and possible program assistance for drug coverage.
- After the benefit investigation is completed, Indivior contacts the office with their findings regarding co-pays and assistance programs. If a call is not received by Indivior in a timely manner, the office manager will call for an update. This benefit analysis also provides the office with the information regarding which specialty pharmacy is to be used for dispensing of the medication.
- The office manager can then initiate the prior authorization with the insurance company.
- A tickler system, in the form of a paper chart, is in place. The system is to remind the staff member to contact the private insurance companies once to twice weekly depending on the patients proposed date to start the long acting injectable buprenorphine.
- If the patient has Medicaid, the benefit investigation is not required, and the office manager initiates the prior authorization.

Table

Table Articles included in review with author, year, purpose, design, inclusion, results, conclusions

Author (Year) Purpose	Design (N)	Inclusion Criteria	Intervention vs Comparison	Results	Conclusion
Reif, Creedon, Horgan, Stewart & Garnick (2017).	Correlational study	Telephone survey to health plan executives and/or patients receiving care for opioid use disorder.	Comparison (before/during/after the implementation of the affordable care act)	With the "leveled" playing field-reduced disparities in coverage for mental health it was hopeful that significant changes would be noted in the coverage for opioid use disorder. This was not the case	Insufficient coverage for patients with opioid use disorder
Andraka-Christou & Capone (2018)	Qualitative	Physicians had to be licensed as a physician in the United States	Comparison	Physicians in the addiction medicine field were interviewed regarding barriers to treating patients with opioid use disorder. The findings were consistent across the sample.	Limited insurance reimbursement/ regulatory restrictions for treatment/restricted access for medication assisted treatment.
Andrews, Abraham, Grogan, Westlake, Pollack & Friedmann (2019)	Systematic Review	Treatment facilities that accept Medicaid for reimbursement.	Comparison (assessment of 2 utilization restrictions imposed on buprenorphine benefits)	Found that many providers will not prescribe buprenorphine related to the burdensome process related to prior authorizations. Another tactic that providers felt was being used by the insurance industry was annual limits which would deter the provider in providing buprenorphine as it was known that the provider would	Some providers are hesitant to prescribe buprenorphine related to the tactics used by the insurance industry (prior authorizations and annual limits)

				have to change the medication shortly	
Mark, Lubran, McCance-Katz, Chalk & Richardson (2015)	Systematic Review	Pharmacy (medication assisted treatment)	Comparison of utilization data for state Medicaid programs	Many state Medicaid programs require coverage of medication assisted treatment but yet require a variety of techniques that can make coverage/prescribing difficult	States need to re-examine their substance use disorder benefits.
Clark, Baxter, Barton, Aweh, O'Connell & Fisher (2014)		Patients with Medicaid insurance coverage and a diagnosis of opioid use disorder	Effects of the insurance companies requirement that buprenorphine/naloxone be dose reduced to 16mg for patients that were stable on 24mg.	The dose reduction requirement did not save a significant amount of money for the insurance industry- patients relapsed initially but were noted to be stable on their treatment within 3 months	Lower doses of the medication did not save the state money but it was thought that the decreased dose decreased diversion of the medication.