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A Program Development and Evaluation Project for Provider Use of Buprenorphine Maintenance

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A DNP	PROJECT
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Abstract

Background: Buprenorphine (BNX) is used in Opioid Use Disorder (OUD) deterrence. Optimal long-term duration with BNX is unclear, but evidence shows that there is a high risk for relapse when medicine is discontinued even if maintenance has been stable for some time. Outcomes: The purpose of this project was to decrease barriers for providers implementing BNX therapy for individuals diagnosed with OUD. Outcomes measured included: (1) knowledge of and barriers to implementing current guidelines, (2) factors preventing use of guidelines, (3) recommendations for BNX maintenance as per guidelines.

Methods: Using a pre-post intervention design, participant knowledge on BNX guidelines, factors preventing use and motivation for practice change were measured using non-standardized questionnaires. Participants were instructed on current guidelines and recommendations to overcome barriers.

Results: Both providers completed surveys in full. Both providers showed consistency and knowledge in the field. DEA limitations with lack of resources and poor treatment models contributing to poor guideline adherence was a concern for both providers. One provider believed it is beneficial to discontinue BNX at some point while the other encourages more long-term use. The clinic was pursuing expansion of resources and more providers to alleviate barriers.

Conclusions: Adhering to BNX guidelines have implications on quality of care impacting clinical, policy, leadership, and ultimately safety levels placing relapse wellbeing states at risk. Results were of value as they discussed important factors necessary to address and ways to improve such thus improving outcomes. Greater attention to guidelines and continuous advocation is vital for sustainability.

A Program Development and Evaluation Project for Provider Use of Buprenorphine Maintenance

Since 1999, opiate-related overdose deaths have increased by six-fold on a national scale (Centers for Disease Control and Prevention [CDC], 2019). Deaths have also tripled in the state of Utah since the dawn of the 21st century surpassing the national rate (National Institute on Drug Abuse [NIH], 2019). The term "opidemic" has become a phenomenon indicating the rapid rise in use of these substances often leading to addiction and death. Pain was once considered the fifth vital sign and various academic institutes nationwide were instructing providers that pain is what the patients say it is. Concurrently, opioid prescriptions have reached an all-time high where 130 Americans die each day from an overdose.

Therapeutic modalities such as psychotherapy and rehabilitation programs have been available to help outcomes for these patients in addition to MAT (medication assisted therapy). These medicines are methadone, naltrexone, and BNX. Positive and encouraging outcomes from BNX have been shown in published evidence and its usage is expanding. It appears to be generally well tolerated and has demonstrated comparable and at times superior benefits to other agents.

This DNP project consisted of pre-post intervention interviews around BNX guideline barriers with provided education. Using the best evidence, recommendations to address barriers were developed to transition into practice. An education module was provided on eliminating barriers to administering BNX maintenance and management followed by second interviews to medical providers assessing if education made a difference in practice.

Background and Significance

In 2017, death rates reached 456 by overdose involving opiates making up 70% of overdose-related deaths escalating Utah to above the national average (National Institute on Drug Abuse [NIDA], 2019). A near tripling of opioid prescriptions dispensed, and opioid related deaths in the United States occurred between 1991 and 2011 (National Institute on Drug Abuse [NIH], 2018). Locally, Utah has ranked 7th in the nation for drug poisoning related expirations which has outpaced deaths by motor vehicle crashes, firearms, and falls between 2013-2015 (Utah Department of Health, n.d.). Addiction has frequent relapses with one study reported as many as 91% of those in recovery will relapse at one point. In the first week, 59% will use substances, and 80% within a month will do so of discharging from detoxing (American Addiction Centers, 2019).

About 2.1 million individuals in this country have a substance use disorder. Misuse of prescribed opioids will include 20-30% of individuals, and 10% of those misusing opioids will become addicted with 5% trying heroin (Yerby & Hampton, 2019). Unfortunately, the problem has escalated to a point where people are losing jobs, families, obtaining criminal records, cycling through treatment, and becoming homeless. Many times, an individual goes for a routine procedure such as wisdom teeth removal, and short-term opioid treatments become an addiction. These people are generally healthy, normal persons with families, careers, and good credit scores that fall victim to opioid addictions.

Opiate misuse is a problem that involves many age groups ranging from early adolescence to geriatrics. In 2016, 3.6% of adolescents in this country misused an opioid (Yule, Lyons, & Wilens, 2018). Kids aged 12-17 in 2015 requiring substance use treatment reached 1.3 million (Lipari et al., 2016), and 2.9% of local Utahn teens aged 14-17 had misused prescription drugs (Utah Department of Health, n.d.). Between 2009 and 2016 persons aged 55-64 saw rates of overdose deaths rise by 52% while those 65 and over also rose by roughly 20%. Geriatrics carry more risk factors as they have higher prevalence of pain compared to younger populations (Blow, n.d.).

Medication Assisted Therapy is a treatment method used in OUD to decrease drug use, cravings, criminal activity, and infectious disease transmission while increasing quality of life, treatment retention and outcomes (National Institute on Drug Abuse [NIH], 2016). Options include Methadone, BNX, and Naltrexone. Methadone is a full opioid agonist, while BNX is a partial opioid agonist. Both replace the properties of previous receptor binding from opiate use to suppress troublesome symptoms of addiction. Naltrexone is a opioid antagonist blocking receptor properties promoting deterrence from opiates and aims to suppress symptoms of withdrawal. While it is difficult to make direct comparisons on superiority between the medications, methadone and BNX appear to have greater amounts of evidence for success rates (Bart, 2012).

This issue is chronic thus there is no cure. Until recently the concepts of detoxification and stand-alone psychological therapy had been the standard for treatment in which relapse rates have staggered around an alarming 90% or higher (Velander, 2018). In the 1960s and 70s, trials and legal acts such as the Controlled Substances Act of 1970 and Narcotic Addict Treatment Act of 1974 helped pave the way for Methadone improving outcomes. However, limitations such as restricted access and visiting specialty clinics on daily bases has made it difficult for people to receive treatment contributing to relapse rates.

Buprenorphine was developed in the 1970s fueling the Drug Addiction Treatment Act of 2000 (Velander, 2018). Due to prevalence and risk among varieties of populations, any individual with opiate misuse or carries the diagnosis can potentially benefit from this medicine.

Optimal duration of MAT with BNX is unclear, but evidence shows that there is a high risk for relapse when MAT is discontinued even if maintenance has been stable for some time (Clinical Tools Inc [CTI], n.d., 1 section).

Needs Assessment

A SWOT analysis was performed examining the strengths, weaknesses, opportunities, and threats of implementation of the project at the project setting (Appendix A). While the location for the project had some reservations in terms of longevity and had challenges due to its new establishment, it also had its advantages as a location for the DNP project. It was a privately owned clinic with a flexible owner, therefore a virtual blank canvas was provided giving the freedom to conduct the project as needed. Because substance use is at an all-time high especially in the local area, and resources are not as available, the demand is also expected to be high so opportunity for a successful project was apparent. With supportive and motivated staff, freedom to conduct the DNP project, and baseline funds and resources at disposal, it was expected to be a successful endeavor at this location.

Problem Statement

Despite national efforts, the failure and dropout rates of treatment have been high for people with OUD as between 4 and 6 people out of ten will relapse upon treatment of OUD (National Institute on Drug Abuse [NIH], 2018). Various treatment modalities exist with this disorder most often involving a variety of multidisciplinary wrap-around services. These include counseling, behavioral intervention, community and group services, long term treatment planning, inpatient acute detoxification, and use of medication (American Psychiatric Association [APA], 2018). Despite ongoing approaches to treating OUD continual rising rates of opioid-related deaths and overall poor rehab retention continue to occur with notable lack of consistencies in treatment.

An issue in treatment has been consistently suppressing the physical craving needs for opioids. Buprenorphine has been available in oral and sublingual forms and has now evolved into injectable depot formulations which has shown improved outcomes when compared to Methadone and other treatments (Hser et al., 2016). Products containing BNX have shown greater outcomes in those with OUD including increased abstinence and treatment retention when compared to no medication use (Mokri et al., 2015).

Current guidelines for BNX management consist of accurate assessment prior to any treatment with special considerations of chronic illness or pregnancy. Regimens are to be individualized based on opiate usage history and genetic implications. Initiation should not take place until 12-48 hours from previous opiate usage to avoid precipitated withdrawal (American Society of Addiction Medicine [ASAM], 2015). Optimal duration of maintaining BNX therapy is unclear, however there is high risk for opiate relapse when treatment is discontinued (CTI, n.d., 1 section). However, if circumstances arise for discontinuation such as employment implications or patient preference, a slow tapering potentially over multiple months with close monitoring is recommended.

The purpose of this project was to decrease barriers for providers to implement buprenorphine (BNX) therapy for individuals diagnosed with opioid use disorder (OUD).

Aims and Objectives

The aims of this study were coordinated to direct feedback from providers therefore questions were framed to match the needs the study was attempting to answer. The project was also attempting to promote change to guideline adherence in BNX maintenance by using evidence, education, and follow up assessments. By assessing knowledge and barriers prior to intervention with interviews, baseline data was able to be established for later comparison. Immediate follow up feedback after education module provided response data from presentation and aims exploring motivation for change. The 6-week follow up assessment helps give insight into the long-term impacts made on the providers from the project assessing the retainment of the knowledge and obtaining direct feedback on any changes in place or in motion for the future pertaining to the intervention. By interview questions with the aims of the study, responses were able to meet expectations of the project.

The objectives included:

- To explore underlying factors preventing use of guidelines to BNX maintenance within the study period.
- To assess provider knowledge of and barriers to implementing current guidelines.
- To propose recommendations to clinic providers for practicing standards of care for BNX maintenance as published by clinical guidelines.
- To re-examine knowledge of providers after intervention.

Review of Literature

A systematic review was conducted to assess the evidence of BNX in the treatment of OUD. CINAHL and PubMed databases were searched. Terms used included "opiate addiction or opiate dependence and buprenorphine not methadone not alcohol", "addiction, opiate and buprenorphine". Number of applicable articles found were 147 following removal of duplicates. The articles are appraised using McMaster University's Quality Assessment Tool for quantitative studies. The evidence is summarized in Appendix B. BNX products appeared to be helpful according to the majority of RCTs and quasiexperimental studies and demonstrated usability in opiate use. Overall abstinence from other opioids was improved compared to placebo and other treatment modalities sometimes by a significant margin as described by Wang et al (2019). and Haight et al. (2019). Greater adherence to treatment with use of BNX compared to naltrexone and placebo showed improved rehab potential in these patients with the help of this agent as opposed to psychological based therapy alone and/or with pure antagonist treatment.

Common barriers in the workforce included insufficient training, experience, and education for providers to practice and prescribe BNX for OUD. These included the required waiver from the DEA, however majority of physicians in Primary Care and Addiction surveyed in New York City cited that earlier, and more reinforced education is needed for successful care (Haffajee et al., 2018). There are widespread negative attitudes towards opiate replacement in addiction medicine due to its high-risk nature further limiting availability. In addition, there are only a certain number of patients the DEA allows at one time to be managed on BNX for addiction per provider (Molfenter et al., 2019). Because of these quantity limitations, providers may be more likely to be bias towards discontinuing BNX sooner than appropriate.

Behavioral health and addiction medicine are often linked and is difficult to find substance use patients without a mental health diagnosis. This can be a barrier as many payer providers fully endorse mental health support systems such as use of psychotherapy and a medication manager for patients to be prescribed BNX. In fact, in Washington State, Medicaid will only pay for BNX treatment if the patient also receives substance use counseling (Hutchinson et al., 2014). Reimbursement thus can be a challenging barrier while there is better coverage than years prior, certain qualifications specifically around Medicaid make it burdensome for some providers (Haffajee et al., 2018). While generic BNX is cheap, the BNX/naloxone combination (Suboxone) is often preferred due to its deterrence abilities but can be costly.

Coverage has improved since the Affordable Care Act and Medicaid expansion, but continues to be a barrier for those without payer benefits and those with poor insurance plans (Molfenter et al., 2019). Like all medicines, BNX has risks of side effects and interactions short and long-term. Most common ones include decreased/altered mood and motivation with changes in appetite, energy, liver changes, adrenal suppression, headaches, and lightheadedness. Patient tolerability varies greatly (Zoorob et al., 2018).

Expansion of BNX use and acceptance is a general recommendation among addiction professional. This includes more providers, greater resource and care coordination, institutional support, adequate training, and decreasing negative perceptions of patients with OUD with or without BNX treatment (Haffajee et al., 2018). Ongoing efforts to legislate provider caseload expansion granted by the DEA would lessen the burden by increasing availability of services to above 270 patients per provider. This and further provider recruitment would greatly benefit the barriers to BNX guideline usage (Molfenter et al., 2019).

Limitations and Gaps in Knowledge

With the recent evolution of BNX where it is becoming available in a depot injectable form, further time and studies are going to be needed to assess the long-term success and safety as opposed to oral agents (Timko et al., 2016). The chemical compositions are different enough along with the mode of entry where further examination will be needed to assess its efficacy and tolerability. A limitation of oral buprenorphine is the concern of drug diversion (Saloner et al., 2017), thus sparking the combination of buprenorphine/naloxone to divert from intravenous use. However, because of its agonistic properties, abuse of the agent is still possible.

A major limitation to the use of BNX includes the policy and DEA-based regulations for the use of this agent and its requirements for providers being able to prescribe it for OUD. Currently additional training hours are needed to receive the "X" waiver for physicians and midlevel providers. The first year of practice, only 30 patients can be treated at one time and 100 is the limit for the following year (Drug Enforcement Administration [DEA], n.d.). While this number increases to 270 by the third year and beyond, these restrictions on treatment numbers further binds providers in assisting those with the illness and limiting further progress in the national crisis.

Common limitation themes among appraised evidence included variation and diversity among patients/recipients, treatment programs and concurrent treatment regimens such as psychotherapy that may impact results as well as sociodemographic factors. Because OUD is multifactorial it is often difficult to bottle all aspects of factors into a given report. Another theme included some inconsistencies in follow up such as missing data and dropouts with clients.

Limitations regarding the guidelines of BNX is that there is no clear timeframe on when and if to discontinue the use of the medication. The literature more so gives input that many patients need to stabilize for many years, and even after doing so the risk of relapse is high when discontinued (CTI, n.d.). No concrete numbers exist for optimal doses, nor timeframe leaving management open to much interpretation to providers. However, the evidence is clear that poor outcomes follow the trend of discontinuation and longer-term use is widely recommended.

Implications for Practice and Recommendations

The literature showed consistency in the effectiveness of BNX in diverse groups of adults of multiple ages and ethnicities, as well as multiple forms of BNX formulations including oral and injectable forms. BNX is effective when compared to other evidence-based treatments and showed similar safety, tolerability, and efficacy (Timko et al.), (Hser et al.), (Feelemyer et al.). Given the adequate quality and strength of the evidence, this review supports the translation into practice.

While limitations by the DEA and gray areas in literature exist making generalizability difficult, BNX helps lower relapse rates both short and long term (Hser et al., 2016). SAMSA (2016) has declared that discontinuing BNX is not required, and that therapy can continue indefinitely if there are no complications, and they adhere to protocols. The VA/DOD guidelines recommend providers to strongly advise patients to continue BNX maintenance long-term due to the failure rates when discontinuing (Department of Veterans Affairs, & Department of Defense, 2015). There are appropriate times for discontinuation of treatment which include hypersensitivity, adverse reactions, and mishandling of the medicine.

As with all other areas of medicine, patient preferences, availability, and provider experience and their comfort are factors to consider when prescribing treatment which is why having treatment options is important. When it comes to treating those with OUD and as per best evidence, BNX should be considered. Its short- and long-term efficacy data combined with its tolerability and safety profiles give clear indicators that it can help improve quality of life.

Methods

Interviews were conducted in a pre- and post-intervention design to gather data. Two medical providers practicing in outpatient addictionology participated in the study. Pre intervention aims were to explore current evidence-based guidelines of BNX maintenance, and to assess provider knowledge of and barriers to implementing current guidelines. Responses were recorded and inputted into software for later analysis. This data then was compared to literature on best practice and barriers to follow recommended guidelines. Post-intervention aim was to assess provider thoughts on education of BNX guidelines and motivation for any change in practice. Information was collected by same means of surveying providers via interviews. Analyses were made in reflection to intervention as well as prior knowledge to look at impacts made from education. The final outcome measured 6 weeks following intervention was to reexamine knowledge of providers and assess any movement in practice changes. This data gives further insight into motivation, retainment of education and impacts pertaining to BNX guidelines and barriers translating into practice.

Excel was the software used to store and analyze data. Providers were given a nonidentifiable number along with their role and years in addictionology practice. Responses to interview questions were directly inputted into the spreadsheet and placed side-by-side for comparison. To ensure accuracy of entry, initial data was transcribed by hand onto paper during interview process. Each provider had their own paper with questions and answers written out to ensure correct obtainment, as well as their names written at the top to differentiate. Data was then transferred to the Excel spreadsheet under the respected provider rows with paper copies kept to backup information. Data was double checked for accuracy by providers giving responses. All data was entered by project lead, care was taken to keep all data confidential and non-identifying. No significant outliers were noted.

There were no standard instruments available unique to this pilot project, therefore new ones were created to meet the needs consisting of pre- and post- questionnaire surveys. The prequestionnaire survey collected demographic information of the participants including education, race, sex, and years in practice. It was designed to gather baseline data information of the provider's knowledge of current guidelines of BNX management in OUD, and their attitudes and opinions on factors preventing the guidelines being followed properly in practice. PowerPoint software was utilized in creating the educational module the project lead presented to the providers while giving resources and data supporting evidence to information. The post-survey assessed provider attitudes and feelings and most importantly motivation toward any potential change in practice after the educational session. Finally, a 6-week follow up survey included assessment of any changes in the practice or upcoming means in reflection to the project's impacts. Due to the originality of the tools to this project, validity, and reliability could not be properly determined and is recognized as a weakness to the project.

Participants and Recruitment

Both clinic providers were certified in treating addiction medicine and been doing so since the opening of the clinic. They ran the BNX management of the clinic and had full control of the operations with any changes as they felt appropriate. Both participants were recruited via direct approach by the project lead.

Consent Procedure and Risks/Harms

George Washington University IRB was consulted, and as this was a QI pilot program involving addictionology providers and minimal risk to participants, the project was deemed IRB exempt. No patient data was collected. Participation was fully voluntary, and withdrawal could occur at any time without consequence. Study was minimal risk, and consent was implied when participants became involved in the intervention. See Appendix F for implied consent form. Both providers were individually asked for willingness to participate in the project with full disclosure of its contents with benefits around the continuing education of their specialized field, and resources, and increased interdisciplinary collaboration in their clinic and community. Risk to the participant was potential peer pressure to participate and potential psychological distress when dealing with mental health and addiction concerns of patients. There was some degree of bias in this project as participants may have known the project lead. Additionally, because this study was not blinded, participants were aware of the purpose and may have unintentionally been swayed to respond favorably to the intervention. It was emphasized that honest responses on the multiphasic surveys were expected with participation.

Costs and Compensation

No additional resources were in need for tasks and interventions for this project. Educational materials were all electronic with surveys done orally. Because the clinic was equipped with computer software, data management systems was able to be utilized via provided equipment by the clinic as well free of charge. Compensation was not provided.

Project Interventions

Initially, providers were interviewed assessing knowledge of current clinical practice guidelines for BNX maintenance and factors contributing to barriers for implementation. They were asked to provide their policies and procedures of the clinic when it comes to BNX therapy. The purpose of the initial interview was to determine baseline knowledge and their perception of barriers for later comparison, analysis, and recommendations.

Education was provided via an educational module. PowerPoint slides discussed surveyed topics in detail with national and state level implications. Traditional lecture style with interaction to engage and encourage participation helped intervention remain relevant and interesting for participants. Estimated time needed was roughly 45 minutes. Post-intervention interviews analyzed provider views on updated practice guidelines while addressing previously mentioned barriers. These sessions assessed impacts from the education sessions and any potential changes to the clinic in the future for practice.

Outcomes Measured

Outcomes to be explored included knowledge and barriers from the feedback given by the medical providers around the educational session on BNX maintenance guidelines. Initial interviews gave their baseline knowledge and barriers to implementing guidelines. Following the educational sessions, re-interviewing providers seeing if education made a difference on elimination of barriers and views of management was documented. After six weeks, final interviews took place regarding the recommendations of guidelines assessing any differences made in practice and elimination of barriers. Survey processes measured the knowledge and barriers for data collection.

Timeline and Resources

The projected timeframe for this initiative was 6 weeks of field work in total. The justification for this timeframe was to assess the impacts and changes in practice following the educational session, and data management. Assessment and education took place on week 1 with outcomes interview on week 6. See Appendix C depicting on-site timeline.

Several resources for the project were already in place. These included working staff, software systems, and office infrastructure. Other working office hardware and computer programs were available for creation, management, and implementation of education materials. Ensuring of a working data application was a necessity upon initiation to ensure confidentiality, reliability, and consistency.

Evaluation Plan

The premise of evaluation was to analyze the data as they related to the goals and outcomes. The data collection process was ongoing and conducted by the student DNP. Pertinent data came from the interview processes and direct responses from the providers. Data were collected via handwritten responses and transcribed by the project lead into Microsoft Excel. Data resided on an excel spreadsheet saved to a firewall and virus-protected computer which was password protected leaving access to only the project lead. Data was deidentified giving participants codes instead of personalized information prior to examination and publication. To ensure all necessary data made it to the software from handwritten notes, organized and individual pieces of documentation were done separately for each provider per interview session lessening risk of missing data.

Data Analysis, Maintenance & Security

For data analysis, responses were listed for each provider in summaries in pre- and postintervention columns – as well as a 6-week post intervention survey column. Common themes were explored and compared to best evidence. Finally, feedback from providers on their changes of practice pertaining to guidelines were inputted assessing impacts from the project.

No formal assistance in data analyses and sorting processes were used as they were all performed by the student project lead. Formal plan for sorting pertinent data, coding for common quality improvement themes, and plans for processing for specific key points were in place ahead of time.

Maintaining and securing pertinent data was trusted via software and firewall systems. Spreadsheet software was utilized in creating data visuals depicting transcribed nominal, interval, ordinal, and ratio data. Regular viral scans and security checks were done to ensure no security threats in addition to email monitoring for potential harms. IT support systems were in place for as needed software troubles.

Results

Of the two targeted participants, both fully completed the project in its entirety with no dropouts or missing data. One was a male Physician certified in Addictionology with 8 years' experience using BNX therapy, and whom of which was the owner of the clinic. He had original certifications in general medicine and practiced for 15 years in long-term care settings before obtaining secondary certifications in addiction medicine where he has managed detox and maintenance programs on inpatient and outpatient levels of care. Second, was a female APRN with greater than 5 years' experience in the field starting as an RN working inpatient with OUD patients and eventually becoming a prescriber in the clinic doing so now for 2 years. Most of her nursing background consisted of both addiction medicine and mental health care doing inpatient detox and maintenance while obtaining her master's degree and transitioning to an APRN. They varied on education levels, certifications, and experience, however, shared similar histories in practicing in mental health and addictionology whether it be nursing or provider levels in multiple counties serving different types of patients.

Pertaining to the guidelines both providers appeared to be well-versed in today's recommendations and they agreed on multiple aspects. Pertaining to the safety of the drug, both providers agreed that people can use the medicine long term for opioid deterrence and without the help of pharmacotherapy people are at risk for relapse. Like any medicine it has its risks and side effects, and the ratio of risk vs benefit needs to be weighed for each patient. Both providers said that BNX helps outcomes and multiple aspects impacts outcomes.

The DEA plays a vast role in limiting the number of patients managed on BNX per provider for maintenance (i.e., 275 at one time). A common barrier in guideline adherence is that opiate use is viewed as a behavioral issue and not a medical based condition impacting stigma leading to less resources, difficult reimbursement, and lesser compliance from patients.

While both providers agreed BNX is safe most of the time, they differed on long-term opinions. The Physician (Provider101) believed that people can benefit from eventually coming off the medicine as it can increase their overall cognitive abilities and generalized function despite the risk of relapse. He also discussed the lack of medical providers and resources impact guideline adherence and interferes with maintenance. The APRN (Provider102) differed believing that if BNX is helping a patient stay sober then they should be taking the medicine as long as possible unless there is a good reason to come off and great caution should be used. Provider102 went on to say each patient is individualized in their care and will make their own decisions, but risks of discontinuing should be fully advised. She also discussed that BNX in its Brand form Suboxone can be expensive without payer coverage which can impact one's compliance to treatment.

Both participants in the post survey were wanting to expand the clinic in hopes of better overall patient care with BNX therapy. They agreed that greater resources, hiring more providers and continued use of the medical model can help the problem. At 6-week follow-up the clinic was in the process of finalizing agreements with several insurance carriers and hiring more help. Both were motivated to providing optimal care and keeping people sober. Provider101 still believed there were benefits to coming off BNX if possible, however if they choose to come off and relapse, they can be put back on BNX maintenance right away. Provider102 still encouraged patients to remain on treatment if the benefits were present and if the desire to come off was there then close follow up needed to occur. Provider101 then proceeded to offer the project lead a working provider position at the clinic. See Appendix F, Table 5 for complete data analysis.

Analysis of Aims/Objectives

To evaluate Objective 1: explore underlying factors preventing use of guidelines to BNX maintenance. Survey questions were asked to providers pertaining to the lack of adherence to established evidence done often in practice and what contributions exist. Feedback established baseline data to the providers knowledge and opinions for later comparison in post-intervention surveys. Many similarities between the two providers exist including lack of resources, federal limitations, and reimbursement issues. However, there are differing opinions on timelines with usage of BNX among the two due to potential side effects.

To evaluate Objective 2: assess provider knowledge of and barriers to implementing current guidelines, pre-survey interviews conducted consisted of questions assessing evidencebased practice for BNX and further exploration deviating from these guidelines. Answers and data indicated responses from reliable, professional sources with respected experiences and opinions of which are up to date on current evidence and problems in the field. Further baseline data provided for later comparison.

To evaluate Objective 3: propose recommendations to clinic providers for practicing standards of care for BNX maintenance as published by clinical guidelines, a slideshow educational presentation was given to both providers showing best evidence on BNX management and guidelines for practice. The resources used indicated that while there no clear objective instructions on BNX therapy, guidelines exist that have determined best care and greater outcomes. Finally, to evaluate Objective 4: re-examine knowledge of providers after intervention, questions assessing motivation for any change in practice immediately following presentation as well as 6 weeks later were asked. This data indicated knowledge adherence, and motivation for change in accordance with best practice. Both providers depicted passion for the field, wanting to expand their practice in hiring more providers believing that getting more help is the key to breaking through some key barriers to BNX guideline adherence and expanding coverage. While some differences still exist in the belief of if/when to discontinue BNX, both believe these patients are to be managed very closely and safely while always striving to keep sobriety.

Discussion

This project served as a powerful tool for practice emphasizing that OUD treatment and BNX maintenance struggle to adhere with what the guidelines recommend. Clinically, the needs for BNX therapy are high and are projected to stay that way therefore the demand for quality care is going to maintain. While each patient is unique and deserves individualized care, generally the more the guidelines are shied away from, the less optimal the outcomes will be. For example, poor practice resources and support coupled with too great of demand of patients leads to medical provider burnout causing them to resign from practice therefore leading to patients coming off BNX for non-personal reasons.

While the success rates for BNX have been encouraging when regimens are complied with, barriers will be ongoing challenges in the form of finances, resources, compliance, and longevity. The decision whether to come off BNX will vary on the patient and the provider, and while the evidence is clear that relapse rates escalate when off the medicine, there is argument that other potential improvements can be seen with discontinuation and they are worth the risk. This variation in opinion can impact sobriety rates and place more patients at risk, and when this situation comes in practice a full safety plan is vital to the patient's chances of success including if they can re-initiate BNX upon relapse.

A focal point in health policy pertaining to BNX therapy is the DEA waiver and limitations set on providers. The expansion of such has allowed APRNs and PAs to now prescribe BNX which has benefitted more individuals in keeping sober, however capping loads at 275 at one time is inhibitory – and that load is only achievable at year three. Other controlled substances schedule 2-5 do not have limitations similar to BNX for OUD, and this limitation further restricts accessibility and optimal guideline adherence for medicine usage. Furthermore, the varying degrees of reimbursement and payor plan coverages threaten ongoing outcomes whether it be financing limited amounts of OUD treatment or restricting altogether. These types of policies largely impact optimal adherence to guidelines by patients and providers and can contribute to poor patient outcomes including relapse.

Executive leadership can help lessen the barriers for BNX guidelines by helping ensure proper resources are in place for practices and providers. Optimal communication and agreements with insurance carriers and financial plans are vital for thriving of the practice, while also consideration for those patients less fortunate. Whether it be having a pro bono funding program or contracting with fellow practices can help bridge the reimbursement challenges while avoiding going against BNX treatment guidelines and patient treatment.

Leadership in practice must ensure enough medical providers given the DEA limitations and in consideration of natural provider burnout. Changing the stigma of OUD from a behavioral based problem to a medical issue can help anchor greater success rates and gather more attraction from patients, the community, resources, and payor plans. The more consistency attracted to treatment regimens means greater guideline adherence and outcomes. Ongoing advocation for legislative and financial support on the state and federal levels along with further general resources would help nurture the addictionology staff as well as increase generalized urgency on the problem.

Guidelines for BNX like majority of others were created for best quality use of care and patient safety. When barriers are seen in practice, safety risks such as patient sobriety and revolving circumstances including psychosocial, financial, and legal consequences are at stake. Inconsistent use of guidelines can also lead to patient hospitalizations for withdrawal or medical decompensations related to opiate use, such as vascular and skin infections related to intravenous opiate use.

Lessening barriers will assist in consistency in patient care in BNX therapy thus bettering overall quality. Addiction is extremely difficult for an individual to overcome by itself without barriers in treatment. To optimize quality of care, patients need to be fully informed of the medication specifically risk of discontinuation despite opinions of provider. Possible benefits are pertinent to discuss as well in addition to strong safety plans if the subject were to approach to help overcome barriers and improve outcomes.

Plans for Sustainability and Future Scholarship

As demonstrated by the individuals that participated in this study, ongoing expansion and advocation of such is pertinent for complying with guidelines to BNX and maintaining good outcomes. By optimizing reimbursement opportunities with private and federal insurance carriers, further expansion of resources such as more providers and case workers can then in turn attract more business. Designated personnel for each practice need to maintain relationships with payor plans while enforcing requirements made for reimbursement. Providers and medical staff need to be fully informed of guidelines for BNX management and will need to maintain continuing education requirements demonstrating ongoing competence. Setting standard schedules for patient follow up visits with or without being on BNX with adjustments accordingly promotes consistency in treatment. Strong treatment plans with ample education components help to lessen non-compliance thus interrupting care. By creating optimal care plans and performing high quality, evidence-based care, business in turn improves thus strengthening the ability to obtain more resources furthering helping comply with guidelines.

Conclusion

Opiate use disorder is a largely prevalent problem nationally and locally in the state of Utah. Relapse and failure rates are high, resource availability is low, and the great need for treatment resources is growing by the year. This project focused on provider identification of barriers to treatment of adults with OUD in an outpatient clinic, the barriers in implementation of established guidelines showing high relapse rates when discontinuing BNX, and education in overcoming such.

While there are multiple barriers to following all elements to BNX guidelines, changes can be made to help adherence bettering outcomes for patients. DEA limitations, reimbursement challenges, and poor general resources are ongoing challenges and strong advocation is important. Greater investment in multidisciplinary approaches and medical providers while consciousness of best evidence in treatment can help with outcomes in sobriety. Individualized care and preferences continue with respect to patient choice, however strong encouragement in supportive discussion has shown to help compliance rates in BNX therapy thus lowering relapse rates, hospitalizations, and bettering outcomes. Adhering to guidelines play important roles in patient safety in clinical practice infrastructure, contributions from health policy, advocation needed from leadership, and are key to best-evidence quality care. The value of these results reinforces the importance and urgency of attention needed to addictionology, particularly OUD, given the large increase in usage with expected needs continuing to rise. These recommendations can assist in the great impact of the 21st century opioid epidemic and its death tolls.

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Appendix A

Figure A: SWOT Analysis

	Helpful To achieving the objective	Harmful To achieving the objective
Internal Origin {Attributes of the organization}	 Strengths Strong, experienced leadership Motivated, supportive staff with strong values Networking and resources Flexible operation 	Weaknesses Smaller establishment Newer practice Lack of reputation Funding in progress with payor sources
External Origin {Attributes of the organization}	 Opportunities Favorable treatment models Support from stakeholders Need for substance use treatment Open-minded, patient oriented practice 	Threats External competition Payer sources Vulnerable population Staff buy-in

Appendix B

Table 1: Evidence Table - Research Studies

Article #	Author # Date	Evidence Type	Sample, Sample Size, Setting	Study findings that help answer the EBP question	Observable Measures	Limitations	Evidence Level and Quality
1	Feelemye r et al.	Systematic review	58 MAT program studies, 27,047 participants	Average 12-month retention was 54.3%, was moderately good for both methadone and buprenorphine 56% and 48%. MAT can achieve treatment retention rates in the lower to middle class income communities	Treatment retention rates	Variation in MAT program designs and studies, diversity in program characteristics such as eligibility, staff trainings, and additional services. Potential location gaps, some locations included in review had advocacy services and additional treatments such as acupuncture possibly contributing to results.	Level I - High
2	Hadland, Scott et al.	Retrospectiv e cohort study	2.4 million youths aged 13-22 from 11 states between Jan 2014 – Dec 2015	Most youths received only cognitive therapy with 23% receiving MAT, median retention rates in those receiving cog therapy only was 67 days compared to MAT ranging between 123-324 days	Treatment retention rates by individual drug and without MAT	Retention of care was MAT vs clinical systems themselves; cog therapy services were diverse among recipients therefore categorization is difficult, potential unmeasured sociodemographic confounders	Level IV - Low
3	Hser, Yih-Ing et. al.	Secondary analysis of Phase IV clinical trial	1,269 from 9 treatment programs across US randomized	74% methadone patients completed tx and went to 80% with max dose, 60% on	Treatment retention rates, urine drug screen,	Limited measures of participant motivation and program characteristics,	Level III - Moderate

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				from 2006- 2009' majority	buprenorphine were retained and had sig lower positive urine	medication doses related to	reasons for dropout coarsely recorded, unblinded	
				middle-aged	tests	outcomes		
	4	Jarvis et al.	Systematic review	34 studies included out	XR naltrexone (NTX) has shown	Induction success,	Limited number of studies on XR-	Level I - High
				of 270 assessed patients of various characteristi cs across the	comparable success to buprenorphine after detoxification but has some limitations such as induction protocols	compliance rates, treatment adherence, opioid use	NTX	
	5	Pashaei et al.	Retrospectiv e cohort study	198 patients over 17 years of age in Tehran, Iran in an outpatient methadone maintenance program	Methadone maintenance therapy improves overall treatment retention and increase in dosages correlates with improved rates and outcomes	Methadone doses, treatment retention rates	Couldn't analyze impact of social and family support on relapses, sample sizes were relatively smaller, homogenous population	Level IV - Low
	6	Sullivan et al.	RCT	60 adults enrolled dx with OUD at outpatient clinic in New York area	Extended release naltrexone (XR- NTX) showed significantly more patients retained in treatment for 6 months than oral NTX 57% vs 28%; XR-NTX combined with cog therapy is an effective option to preventing relapse	Treatment retention rates, opioid use	Study not powered by hypothesis testing and was designed as pilot study to evaluate effect sizes of differences between two groups. There was a high rate of missing urine samples, time burdens in oral NTX group, relatively small sample size.	Level III - Moderate
	7	Timko et al.	Systematic review	55 retained studies of 285 consisting of RCTs, quasi- experimenta	Varying results of retention rates with MAT across one- year time period; higher dosings of buprenorphine may help efficacy in	Treatment retention rates in varying settings and protocols	Authors relied on 2 search databases and did not review grey literature, only included English language studies, authors did	Level I - High

			ls, cohorts and case controls.	treatment but methadone appears to continue to show some superiority. It is critical to combine MAT with behavioral therapies for positive outcomes.		not report attrition rates by condition or effect sizes pertaining to strength of interventions.	
8 Wan e	Veinstei et al.	Retrospectiv e cohort study	1605 outpatient buprenorphi ne (BNX) programs among 1237 patients aged 18 or older in large urban hospital established in 2002	Over half of patients, greater than the national average of substance use retention rates, were successfully retained for >1 year in the office-based model of BNX treatment. Disparities did exist including poorer rates for younger, black and Hispanic and Hep C positive patients.	Retention rates in office- based setting	Potential limited generalizability due to one location, some missing data such as in reasons for disengagement, death records not verified	Level IV – Very low

1	Haffajee, Rebecca L.; Bohnert, Amy S.B.; Lagisetty, Pooja A.	Qualitative, Grounded Theory	History, policies, persistent barriers, pathways, and provisions for improvement examined	Most common barriers to adequate guideline and BNX treatment include insufficient training and education, lack of institutional and clinical support, poor care coordination, provider stigma, inadequate reimbursement, and burdensome regulatory policies. Bettering availability for resources, support and removing constraints are vital for expansion of BNX	Discusses barrier themes to BNX treatment and recommendations on addressing them.	None mentioned	Level VI - low
2	Hutchinson, Eliza; Catlin, Mary; Andrilla, C. Holly; Baldwin, Laura-May; Rosenblatt, Roger	Qualitative, Narrative	92 physicians interviewed – prescribing statuses, clinic characteristics, precepted barriers to prescribing buprenorphine	Most had positive attitudes towards BNX but only 22 practiced prescribing the medicine. Reasons included lack of institutional support (36%), lack of	Barriers to BNX implementations leading to recommended changes.	Limited to Washington State physicians, mostly rural based providers over urban.	Level VI - low

Table 2: Evidence Table - Non-research Studies

				psychosocial support (64%), time constraints (50%), lack of specialty backup (54%), lack of confidence (41%), resistance from partners (42%), and financial concerns (28%).			
3	Molfenter, Todd; Fitzgerald, Maureen; Jacobson, Nora; MacCarter, Dennis, Quanbeck, Andrew; Zehner, Mark	Qualitative, Time-Elapsed Narrative	27 Ohio counties, 44% of the state's SUD treatment providers – asked what barriers were present in BNX treatment	Common thematic responses included insufficient funding, negative attitudes, diversion concerns, and lack of prescribers.	Barriers to adequate BNX therapy and subsequent recommendations to improvement.	Generalizability sample taken from one state and did not include all of Ohio, possible bias to towards payer sources.	Level VI - low
4	Sordo, Luis; Barrio, Gregorio; Bravo, Maria J; Indave, B Iciar; Degenhardt, Louisa; Wiessing, Lucas; Ferri, Marica; Pastor- Barriuso, Roberto	Systematic review and meta-analysis of cohort studies	19 cohorts, 122,885 people treated with methadone over 1.3-13.9 years and 15,831 people treated with buprenorphine over 1.1-4.5 years, varied settings	Retention in treatment in Methadone and buprenorphine treatment is associated with improved treatment outcomes, and substantial reductions in risk for all cause and overdose mortality.	Mortality rates, overdose-related deaths, retention rates	Potential for confounding variables in comparisons of crude mortality risk in and out of treatment, differential loss to follow-up, highly variable length of follow- up, no data on illicit market with overdose deaths	Level V - Low

5	Smyth,	Qualitative,	120 patients –	Opiate	Treatment	Power limited	Level
	Bobby P.;	observational	51% female	abstinence at	retention, relapse	by relatively	VI -
	Elmusharaf,	study	mean age	month 3 was	rates of heroin,	small sample	Low
	Khalifa;		17.3, 39 total	21% and was	use of other	size, very	
	Cullen,		patients	46% at month	drugs, unplanned	routine drug	
	Walter		through entire	12.25% of	exits	screenings	
			period,	participants			
			outpatient	had unplanned			
			treatment	exit by 120			
			center in	days. Program			
			Dublin,	of psychoed			
			Ireland	only – no			
				MAT.			
6	Zoorob,	Qualitative,	BNX –	Side effects	Risks short and	None mentioned	Level
	Roger;	grounded	pharmacology,	include	long-term to use,		VI -
	Kowalchuk,	theory	safety,	changes in	costs, and		low
	Alicia;		dosages and	mood, hepatic	guideline for		
	Mejia de		formulations,	function,	timeframe of use.		
	Grubb,		costs, at-risk	drowsiness,			
	Maria		populations,	headache,			
			guidelines for	sedation, and			
			use	respiratory			
				depression in			
				those with			
				pulmonary			
				conditions.			
				Costs can vary			
				between \$50-			
				\$500 monthly			
				formulation			
				and desing			
				and dosing.			
				interact with			
				other sedating			
				agents			
				stimulants and			
				CYP 450			
				affected drugs			
				No time limit			
				on treatment.			

Appendix C

Gantt Chart

Tasks	Week					
	1	2	3	4	5	6
Pre- Intervention Interview						
Education						
Post- Intervention Interview						
Outcomes Assessment						D

Appendix D

Table 3: Data	Collection/Evaluation	and Analysis	Methods

Aims/Evaluation Questions	Measures	Measure Type	Data Source	Recruitmen t Method/ Population	Timing/Freque ncy	Calculati on/ Statistics	Goal/ Benchma rk
Knowledge of current BNX maintenance guidelines	Subjective interview responses from providers assessing knowledge on recommended practices	Process	Provider Interview	Both providers in outpatient clinic	Pre-intervention interview with each provider	N/A	N/A
Identify barriers to implementing BNX management guidelines in treating patients for OUD	Provider responses to practices deviating from recommended guidelines	Process	Provider Interview	Both providers in outpatient clinic	Pre-intervention interview with each provider	N/A	N/A
Provider motivation in implementing change in practice	Achievements from intervention to following guidelines closer	Outcome	Interview	Both providers in outpatient clinic	Post-intervention interviews with each provider	N/A	N/A
Re-examine knowledge of providers and assess changes	Provider feedback and practice changes	Outcome	Provider survey	Both providers in outpatient clinic	6-week re-visit following intervention	N/A	N/A

Appendix E

Table 4: Data Dictionary

Data Element	Data Label	Data Type	Definition/Purpose	Data Values &
				Coding
Provider Identifier	Prov#	Alpha- numeric	Unique identifier	Alpha-numeric
Gender	gender	Numeric, continuous	Age in years	1, Male; 2, Female; 3, Transgender; 4, Other; 5, Prefer Not to Disclose
Race	race	Categorical	Identified race	1, White; 2, Hispanic or Latino; 3, Black or African American; 4, Native American or American Indian; 5, Asian/Pacific Islander; 6, Other.
Role	clin_role	Categorical	What is your clinical role?	1, Physician; 2, Nurse Practitioner; 3, Physician Assistant
Years practiced	years	Numeric, continuous	Number of years worked with patients in opiate use/with BNX	Alpha-numeric
Knowledge of current BNX maintenance guidelines	know_guide	Text	What is your knowledge of current published guidelines for BNX maintenance therapy for OUD?	Verbal responses to open-ended question
Barriers to implementing guidelines to OUD patients	fact_prevent	Text	What are factors and barriers preventing use of	Verbal responses to open-ended question

			these guidelines in	
			medicine today?	
Provider	prov_motiv	Text	What is your	Verbal
motivation in			feedback and	responses to
implementing			thoughts on the	open-ended
change in			information given	question
practice			and what	
			consideration do	
			you have for any	
			practice changes?	
Re-examine	post_change	Text	What are your	Verbal
knowledge of			thoughts on our	responses to
providers and			previous session	open-ended
assess changes			and any new	question
			considerations or	
			changes in	
			practice?	

Appendix F

Informed Consent for Participation in a Research Study

Title of Study: A Program Development and Evaluation Project for Provider Use of Buprenorphine Maintenance **IRB #:** N/A **Principal Investigator Name:** Kyle Olson, APRN **Version Date:** 4/4/2021

You are invited to participate in a research study under the direction of Kyle Olson, APRN of the Department of Nursing George Washington University (GWU). Taking part in this research is entirely voluntary, and you may decide to withdraw from the study at any time. Further information regarding this study may be obtained by contacting Kyle, the principal investigator at telephone number 801-201-8001.

The purpose of this study is to decrease barriers for providers implementing buprenorphine therapy for individuals diagnosed with opioid use disorder.

What are the reasons you might choose to volunteer for this study? Continuing education of their specialized field, and resources, and increased interdisciplinary collaboration in their clinic and community.

What are the reasons you might not choose to volunteer for this study? Potential peer pressure to participate and potential psychological distress when dealing with mental health and addiction concerns of patients.

If you choose to take part in this study, you will be presented an educational module with pre- and post- intervention surveys as well as a 6-week follow up survey. The total amount of time you will spend in connection with this study is 90 minutes. You may refuse to answer any of the questions and you may stop your participation in this study at any time.

Possible risks or discomforts you could experience during this study include: loss of confidentiality or psychological stress.

You will not benefit directly from your participation in the study. The benefits to science and humankind that might result from this study are: Spread awareness to the barriers of opioid addiction treatment and recommendations to improve outcomes.

Every effort will be made to keep your information confidential, however, this can not be guaranteed. You will be given non-identifiable numbers in data collection and interviewed independently. If results of this research study are reported in journals or at scientific meetings, the people who participated in this study will not be named or identified.

The Office of Human Research of George Washington University, at telephone number (202) 994-2715, can provide further information about your rights as a research participant.

To ensure anonymity your signature is not required, unless you prefer to sign it.

Your willingness to participate in this research study is implied if you proceed. *Please keep a copy of this document in case you want to read it again.

Appendix G

Table 5: Data Analysis

A Program Development and Evaluation Project for Provider Use of Buprenorphine Maintenance								
Prov# 💌	gender 💌	race 💌	clin role 💌	years 💌	know guide	fact prevent 💌	prov motiv 🔽	post change 💌
							· -	
101	Male	White	Physician	8	Many patients, in fact 2/3 of them, use BNX	The DEA waiver has large impact.	Clinic is looking at expansion in	"I still encourage people to come off
					long term for pain as well.		OUD management.	BNX if possible. People have better
								access to their emotions and
								cognitive
								abilities."
					People can be on BNX indefinitely.	Capping BNX patient load at 275 limits	"The relapse rates for opiates are	Risk of relapse is there, but benefits
						abilities to treat patients with	so high and our all around goal is	are also worth trying.
						maintenance BNX.	to meet people's needs."	
					If patients are on BNX maintenance for OUD,	Reimbursement is still challenging	As practice continues to develop,	Clinic follows patients closely
					the concept of coming off should be brought up	with a number of insurance plans.	wants to hire more providers to	enough that if there are relapse
					at some point. It can cause side effects, and		help treat more patients with OUD.	concerns than they can go back on
					many that come off have brighter moods, more			BNX.
					motivation, and all around more energy.			
					It's the mainstay for detox and opiate	The lack of practitioners for OUD	Want to include clinic Case	Close to finalizing agreements with
					withdrawal, and keeps people sober, and is all	patients often leads to relapse	Manager for continual close follow	major insurance carriers to expand
					around safe.	interfering with their maintenance	up on all patients to provider well	clinic practice.
						regimens.	rounded care despite not getting	
							reimbursed.	
						OUD is often looked at as a behavioral		"Would you be interested in doing
						problem rather than a medical problem		some part time work for us?"
						leading to stigma, poor reimbursement,		
						poor motivation, and less resources		
						such as providers to treat patients.		
102	Female	White	Nurse	5	Patients each need their own unique dosage,	Suboxone can be expensive out-of-	Want to continue encouraging	Continuing to encourage safe use of
			Practitioner		of BNX and despite what guidelines say,	pocket.	patients to stay on their BNX as	BNX maintenance.
					research backs up dosages above the "max		long as it's effective and safe.	
					And just like how doses are individualized,	Because OUD has been looked at as a	The clinic is looking at hiring more	If people are wanting to come off
					coming off BNX is an individualized decision.	behavioral model instead of a medical	providers with expansion to help	BNX they need to follow up with us
						model, it's impacted many aspects.	treat more patients.	very closely.
					People benefit from staying on BNX long term,	Poor compliance and follow up, and	Current clinic medical model	Clinic continuing to expand and to
					and those wanting to come off need to be fully	lack of strong medical resources often	appears to be effective in helping	hire more help.
					aware of the risks.	leads to patients coming off BNX.	people stay sober.	
					For the most part it's a safe drug to be on long-	DEA limits number of patients able to		
					term.	treat with maintenance.		
					If tapering off, it needs to be a slow process			
					with close observation.			