A QUALITY IMPROVEMENT PROJECT

by

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Abstract

The worsening opioid crisis and the concomitant fewer number of primary care providers who treat addiction disease result in reduced access to methadone maintenance treatment programs for opioid use disorder. Nurse practitioners (NPs) have been delineated "qualified practitioners" to prescribe schedule III, IV, and V in the treatment of Opioid Use Disorder since the passage of the Comprehensive Addiction and Recovery Act (2016). The purpose of this Capstone Project is to evaluate the NP-Physician shared care model in an Opioid Treatment Program (OTP) as a quality improvement initiative. The effect of the implementation of the shared care model is assessed using Donabedian's framework for healthcare quality on structure, process, and outcomes on increased provider access, improved patient satisfaction, and increased provider efficiency. The findings of this study show an increase in patient access, patient satisfaction, and improved provider efficiency thus supporting the NP-Physician shared care model in OTP in clinical support roles and as leaders to develop and implement policy in combating the unrelenting opioid crisis.

(Keywords: nurse practitioner, outpatient, opioid treatment, quality, shared-role, effectiveness)

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Acronyms

AAFP	American Academy of Family Physicians
ACA	Affordable Care Act
AMA	American Medical Association; against medical advice
APG	Ambulatory Patient Groups
APP	Advanced Practice Provider
APN	Advanced Practice Nurse
APRN	Advanced Practice Registered Nurse
CARA	Comprehensive Addiction and Recovery Act
CDC	Centers for Disease Control
CEO	Chief Executive Officer
CMSS	Council of Medical Specialty Society
CRNA	Certified Registered Nurse Anesthetist
CSAT	Center for Substance Abuse and Treatment
CTP	County Treatment Program
DATA	Drug Abuse and Treatment Act
DEA	Drug Enforcement Administration
DNP	Doctor of Nursing Practice
FPA	Full Practice Authority
FTC	Federal Trade Commission
HCAHPS	Hospital Consumer Assessment of Healthcare Provider and Systems
HHS	Health and Human Services
HIPAA	Health Information Portability and Accountability Act
H&P	History and Physical
ICP	Interprofessional Collaborative Practice

IDC	Interdisciplinary Committee
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
IMF	Illicitly manufactured fentanyl
IRB	Institutional Review Board
MAT	Medication assisted treatment
MEPS	Medical Expenditure Panel Survey
NIDA	National Institute of Drug Abuse
NP	Nurse Practitioner
NYS	New York State
OASAS	Office of Alcohol and Substance Abuse Services
OTP	Opioid Treatment Program
OUD	Opioid Use Disorder
PA	Physician Assistant
PCP	Primary Care Physician, phencyclidine hydrochloride
PDSA	Plan, Do, Study, Act
PrEP	Pre exposure prophylaxis
PICOT	Population, Intervention, Comparison, Outcome, Time
RC	Relational Coordination
RCT	Randomized Controlled Trials
ROI	Return on Investment
RWJF	Robert Wood Johnson Foundation
SAMHSA	Substance Abuse and Mental Health Services Administration

SOP	Scope of practice
SPO	Structure Process Outcomes
TEDS	Treatment Episode Data Set
VA	Veterans Administration
VP	Vice President

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OPERATIONAL Definitions

In order to provide clarity and comprehension, the following terms are used throughout this document. "*Admission"* means the determination to admit an adult for treatment in an OTP, such determination accepted by all parties upon satisfaction of all criteria, with the first induction dose of the approved medication. "*Accrediting Body*" refers to an organization granted approval by the federal Substance Abuse Mental Health Services Administration (SAMHSA) to accredit all OTPs utilizing opioid agonist treatment medications. "*Opioid treatment program"* (OTP) means certified sites where methadone or other approved medications are employed to treat opioid dependency. It includes medical and support services such as counseling, educational and vocational training in the appropriate settings. "*Medication assisted treatment*" (MAT) refers to the treatment of opioid dependence and abuse with federally approved medication, dispensed as an order or prescription from an authorized professional. *"Medication management"* refers to the face-to-face or telemedicine service with a prescribing provider for the purpose of a complete medication review of a new or existing patient to assess the eligibility for a dose adjustment (increase, decrease, withhold dose, or continue current dose). "*OASAS"* refers to the New York State Office of Alcohol and Substance Abuse Services which is the designated single state agency responsible for coordinating state-federal relations concerning addiction services. The agency promotes the prevention, treatment and recovery needs of individuals with drug, alcohol and/or gambling addictions. "*Interdisciplinary conference*" (IDC) refers to treatment team and patient meeting to assess and address any issues concerning the patient and the OTP.

INTRODUCTION

Since their inception in the mid-1960s, NPs initially provided primary care to underserved children and their families in urban and rural areas (Pulcini et al., 2019). Currently, NPs are found in diverse settings such as acute care, school health, mental health, women's health, ambulatory care, and long-term care settings while uniquely blending the specialties of medicine and nursing in a manner which benefits patients and families (Vasquez and Onieal, 2002). The roles of NPs include health promotion, disease prevention, screening, treating disorders, teaching and counseling individuals, families, and groups. NPs focus on psycho-social and physical aspects and are skilled in educating and advocating for patients.

The acceptance of NPs was not always the case. In the United States, westernized medicine has been physician-centric for more than a hundred years (Wasan et al., 2017). Historically, the shortage of primary care providers during the 1960s presented the opportunity for the NP role development. Since their introduction to the new role, NPs have increased their numbers annually. During the period 2010-2016, the graduating rate of NPs has far exceeded the rate of physicians entering primary care (Wasan et al., 2017; Moldestad et al., 2019; Neprash et al., 2020). NPs work independently and collaboratively with physician providers (Norful et al., 2019; Kraus et al., 2016; Mundinger et al., 2000 & Neprash et al., 2020).

However, the NP role has been affected by the scope of practice (SOP), and the 'reduced and restricted practice' states. The Institute of Medicine (IOM) (2010) recommends in order for NPs to achieve the most significant impact, is their ability "to practice at the maximum of their education and training" (Neprash et al., 2020), especially since the passage of the ACA, which endorses and accredits NP-led health clinics. In a shared-care role model, NPs typically

(dependent on the collaborative agreement) manage patients with fewer challenging coexisting conditions, allowing physician-providers to focus on the more complex cases and being available for collaboration/consultation. According to McCleery et al. (2014), a report from the Federal Trade Commission (FTC) based on information from the IOM, counters against physician supervision or collaborative practice agreement, as they may inadvertently limit competition. These agreements, the authors conclude, can be detrimental to health services consumers and adverse public health outcomes, evidenced by decreased access to health care services, costly health care, reduced quality of care, and lesser experiments in health care delivery. Currently**,** 28 states and Washington, DC, allow NPs full practice authority (FPA).

The benefits of the NP-MD shared-care model type practice include improved access, improved quality, improved efficiency (D'Afflitti et al., 2018; Norful et al., 2017), and the facilitation of inter-professional collaboration. Over the last twenty years, the NP-MD shared-care model is evident in inpatient and outpatient settings. However, according to Neprash et al., 2020, NPs and physicians manage different patient populations.

NPs are more economical than physicians in training and remuneration; hence NPs are more likely to treat populations covered by Medicaid. However, as the literature demonstrates, despite the initial NP role development by a physician (Dr. Silver), the expansion of NPs' role and scope of practice (SOP) has not been without controversy, explicitly concerning whether NPs are capable of quality healthcare without the authority of a physician. McCleery et al. (2014) found although the American Medical Association (AMA) supports team-based care, they contend medical doctors should lead teams in integrated systems such as the Veterans Administration and the Kaiser Permanente Geisinger systems have been established.

Evidence-based **s**tudies have shown better patient outcomes and satisfaction (Neprash et al., 2020; Moldestad et al., 2020; Cimiotti et al., 2019) in patients managed by NPs. Nevertheless, according to the American Academy of Family Physicians (AAFP) and the Council of Medical Specialty Societies (CMSS) vigorously opposed the expansion of the NPs scope of practice. Despite the fraught relationship between physicians and NPs initially, there is now mutual respect as providers recognize each team member's contributions (Gittell et al., 2012; Kraus et al., 2015). Providers concede NPs and physicians emerge from vastly different educational foundations, different theoretical viewpoints, and different practice surroundings (Donelan et al., 2013 & Neprash et al., 2020), yet can collaborate to achieve quality patient outcomes.

Again, in history, the contributions of NPs are essential and are requisite in the specialty of addiction services. However, their impact can only be perceptible and appreciated if NPs are members of addiction treatment teams. Currently, a few OTPs have physician-only providers, including the CTP since its inception. The physician-staff turnover results in increased patient wait times of an average of ninety minutes for provider encounters; while nationwide, the wait time is an average of forty-five minutes. The passage of the CARA (2016) facilitated improvement in patient access to OTP significantly as more NPs and PAs filled these roles in rural (and urban) settings in Medicaid-eligible populations **(**Hafferjee et al. 2018**).** There is room in certain OTPs for the addition of NPs in a shared-care model type of practice.

Background of the Problem

In the United States, the opioid epidemic has affected approximately 2.4 million individuals who have a diagnosis of Opioid Use Disorder (OUD), according to the American

Society of Addiction Medicine (ASAM 2015; Jackson and Lopez, 2018; SAMHSA, 2014). The ASAM and the National Institute on Drug Abuse (NIDA, 2018) reports prescribed narcotics (opiate painkillers, benzodiazepines) and heroin (oral, nasal, and intravenous) are the modes of use, abuse, and overdoses. According to the Centers for Disease Control (CDC, 2021), since 1999-2018, 450,000 people have died from overdoses attributed to prescribed and illicit opioids; the Health and Human Services (HHS, 2019) reports 760,000 people have died from overdoses. The United States is the world leader in the use and abuse of narcotics and is the global supplier of hydrocodone (99%) and oxycodone (83%) (Chisholm-Burns et al 2019).

According to the (ASAM, 2015), there are three available FDA-approved medication-assisted-treatments (MAT) for OUD. MAT as defined by OASAS "as the treatment of chemical dependence or abuse and concomitant conditions with medications requiring a prescription or an order from an authorized prescribing professional." The available MAT are: Methadone, buprenorphine, and naltrexone. Methadone (Dolophine) is an opioid agonist dispensed in Opioid Treatment Programs (OTP) approved by the SAMHSA. Despite these available medications, only 25% of individuals with OUD receive treatment. OTP clinics are open and easily accessible by private or public transportation or within walking distance. However, as reported by Jones et al. (2019), barriers to accessing addiction treatment are fewer OTPs and long waiting lists in the rural areas, and fewer addiction and primary care providers are available. This quality improvement project focuses on methadone only.

Significance of the Problem

Methadone is the gold standard for treating OUD in the United States (Jackson and Lopez, 2018). Methadone is available in many safe OASAS) certified OTPs with multidisciplinary staff

to assess patients, provide counseling, and refer patients for acute, chronic medical or psycho-social problems. County Treatment Program (CTP) is a well-established hospital-affiliated, small, community OTP treating opioid addiction using methadone (Dolophine) orally for more than 40 years). CTP admits patients with polysubstance abuse and severe chronic co-occurring comorbidities; whereas OTPs in the proximity are selective and have rejected those patients who are prescribed benzodiazepines, have coexisting alcohol use disorder, and currently are under the care of (opioid) pain management specialists.

To meet our working population's needs, the CTP, as do other OTPs, provides early morning dispensing hours beginning at six-fifteen A.M. to accommodate the actively employed clients' various shifts. In the CTP, approximately 100 clients are medicated at opening until nine A.M. daily. In 2017, the CTP physician staff turnover impacted the clinic's operations and its ability to provide the quality patient-centered care experience for which it is known. Due to the OTPs' remaining full-time medical provider in-hospital medical teaching rounds and an office practice obligation, the OTP experienced provider staffing challenges for the early morning coverage. The absence of the provider for the early OTP attendees creates delays for clients who need provider evaluations. The provider encounters comprise of "medication management" which is defined by OASAS as a face-to-face service with a prescribing professional for the purpose of a comprehensive medication review of a new patient or a patient requiring a more extensive review of medications or the induction to a new medication requiring a period of patient observation. Medication management includes reinstatement to the program, take-home doses, interdisciplinary conference (IDC) sessions, and dose adjustments. The completion of the history and physical assessments and the review of laboratory results, while relevant, are outside

of the purview, are equally important but less urgent and are (can be) rescheduled within a reasonable time.

More importantly, delays can negatively impact the vulnerable and unstable patients' work, family, groups, and law enforcement obligations. Patients' responses on the patient satisfaction survey in 2017 cited "long wait times for providers," "rude and unkind doctor," "disagreement with a treatment plan" as some of the reasons for dissatisfaction. According to the Agency for Healthcare Research and Quality (AHRQ), patients' experiences with care and communication with providers correlates with adherence to medical advice and treatment plans and is a fact among patients suffering from chronic conditions.

The lack of an available provider impacted the operations of the OTP. During the scheduled certification audit by OASAS, the auditors discovered significant patient findings and deficits which warranted immediate corrective action. Some of these findings were: The lack of pre-admission screenings by intake for potential patients, initial laboratory tests not done, and the absence of (or partially completed) comprehensive patient physical exams on new admissions within the established time frame, unsigned verbal orders, granting of take-home medications without patients meeting the eligibility criteria, the failure to address positive urine toxicology for illicit substances, and involuntary discharges lacked multidisciplinary team input. Consequently, the findings' enormity and frequency resulted in a six-month-provisional accreditation instead of the usual three-year accreditation. The independent monitor's recommended corrective measures were (i) the provision of additional licensed independent providers, (ii) improve the ratio of counselors to patients, (iii) implement case conferences, (iv)

the addition of a quality improvement officer for chart review and (v) the addition of a peer counselor.

Evidence of Scope of Problem

The overall goal of the OTP is to provide treatment for the management of OUD and to assist in the restoration of 'individual normalcy' in line with patients' personal goals. The OTP staff is dedicated and provides unwavering support to clients to maintain sobriety, everyday lifestyle, and family relationships. However, having one physician provider has resulted in the inability to meet the certifying body's criteria for operations and ultimately, negatively affects the quality of patient care. The historical data on provider encounters is limited. However, the available information reviewed shows an average of five patients who are logged-in between 06:15 to 08:00 AM for a provider encounter but had to be rescheduled after receiving a low-one-time-dose by telephone orders, without a provider's evaluation. Additionally, an excessive number of exception doses, the absence of Prescription Monitoring Program Registry (PMPR) (also known as I-stop) screenings, delays in IDCs, and medication management. However, the CTPs' receipt of the six-month provisional certifications twice and the assignment of an independent monitor for corrective actions were indicative of the quality issues and the catalyst for change.

Effect on Individuals

In the patient satisfaction survey conducted in 2017, 50% of the respondents were dissatisfied with the provider's long wait time. Patients who have not attained the opiate-blocking dose (70 mg or higher), or those experiencing cravings and withdrawal symptoms will continue to use illicit (opiates) substances to satisfy their cravings. These patients require a medical

provider encounter for a dose evaluation to assess and justify an adjustment (increase/decrease) in their methadone dosage. The inability to receive an increase in methadone dose when needed may result in an accidental overdose, because a patient will seek illicit substance(s) to satisfy their cravings and 'dope sick.' This action has and may lead to unintentional death, and severely impacts family, finances, housing, and jobs. As the opioid crisis evolves, there was significant overdose deaths from prescribed opiates in the first wave (Chisholm-Burns, 2019; Denis, 2019), then later, transition to synthetic and illicitly manufactured fentanyl (IMF) which is more potent because it combines heroin, counterfeit pills, and cocaine. In 2018, 67,367 overdose deaths occurred, of which two-thirds represented synthetic opioids, including fentanyl and its analogues (CDC, 2019).

OTPs are responsible for providing quality care, which includes an evaluation by a medical provider whenever indicated. The individual struggling with addiction is likely to have encountered family violence, child abuse, and legal problems. Individuals with substance abuse disorder are generally stigma recipients, whether internalized, perceived, or experienced. Widespread, common stigma regarding substance abuse and addiction is profound in contrast to the stigma directed to mental illness (Birtel, 2017). The individual diagnosed with an addiction disorder is considered unpredictable, untrustworthy, and usually encounters prejudice in housing, healthcare, and employment (Burda, 2020). The individual positive effects derived from MAT are reductions in the rates of transmission of HIV, hepatitis C, abscess formation from needle-sharing (Moore, 2019), and the opportunity to become functional and maintain family relationships.

Effect on the healthcare system

According to the Drug Abuse Warning Network (DAWN, 2011 now retired), approximately 1.25 million emergency room visits were related to illicit substance use. According to SAMHSAs' data, as of 2019, 19.3 million or 7.3% of individuals aged 18 years and older is diagnosed with substance use disorder. The New York State Opioid Annual Report 2019 data shows in 2017, more than 25,500 hospitalizations were related to opioid overdose and abuse. Additionally, in 2017, emergency room visits for opioid overdoses in New York State were 12,301; and 62,000 NY residents required admission to an opioid treatment program. Individuals who experience chest pain, withdrawals, and drug-seeking behaviors usually seek emergency room treatment. Most medical providers easily recognize drug-seeking behavior. The patient walks out or leaves against medical advice (AMA) upon the denial of opiates, which compels the patient to satisfy their cravings and physical withdrawal symptoms (nausea, abdominal cramps, and diarrhea) through illicit substance use.

The illicit use of heroin and fentanyl can result in an accidental overdose, altered mental status, or inappropriate behavior requiring medical provider evaluation in an emergency room. Heart failure, a direct sequela of a substance use disorder, is a significant contributor to morbidity and contributes to emergency room visits and hospital admissions (Nishimura et al., 2020). Ultimately these repeat episodes lead to frequent emergency room visits and increased burden on emergency resources (potentially self-destructive behavior requires one-to-one observations). Additionally, illicit substance use may precipitate or result in criminal activities, such as motor vehicle accidents and driving while impaired, and necessitate the criminal justice system's involvement. According to NIDA, the annual cost of methadone treatment per person

per year is $126.00/weekly or $6,552.00 annually. When taken into context, the costs associated with untreated OUDs include criminal justice, hospital treatment of overdoses, treating addicted newborns, the transmission of infectious diseases, injuries related to driving while impaired, and the costs associated with hospitalization care prosecution (jail, legal defense).

National Guidelines

The Drug Addiction Treatment Act (DATA, 2000) allows doctors who have completed eight hours of buprenorphine training to prescribe this treatment for OUD in private offices, primarily to reduce stigma while increasing access (Tierney et al., 2015). However, the DATA (2000) prohibited mid-level practitioners (NPs and PAs) from prescribing buprenorphine despite having controlled prescription privileges and the DEA authorization. Evidently more vital national legislation was needed. On July 22, 2016, Congress passed the Comprehensive Addiction and Recovery Act (CARA, 2016), (P.L.114-198), which was signed by then President Obama to address addiction through prevention, education, increase access to substance abuse treatment, recovery support, criminal justice reform, overdose reversal (naloxone), and law enforcement (Parrish, 2017).

Under CARA's auspices, the Department of Health and Human Services (DHHS) provided funding to states, non-profits, and treatment facilities to improve access to MAT for women, families, and veterans. Further, under Section 303, CARA revised the Controlled Substances Act and delineates nurse practitioners and physician assistants to prescribe MAT until 2021 through inclusion in the definition as "qualified practitioners." The passage of the Affordable Care Act of (2010) has enabled access to health insurance coverage and healthcare services. The result is an expanded demand for healthcare during primary provider shortage

(Donelan et al., 2013). This delineation was necessary given the consensus of 'inadequate addiction specialist' (St. Marie, 2016), the inclusion of psychiatric NPs to prescribe buprenorphine (Parrish, 2017), and the shortage of primary care providers (Donelan et al., 2013; Carryer & Adams, 2016); Norful et al., 2019; Moldestad et al., 2020; Neprash et al., 2020).

Market Analysis

Nationwide, the ongoing opioid crisis is a testament to the need for improved access to evidence-based opioid treatment in all areas and the expansion of medicine in correctional facilities. With the unrelenting opioid crisis, this is not the time for curtailing OTP services. The shortage of available physician providers and the recognition NPs are competent in filling provider gaps (AANP, 2018) underscores the urgent need for additional and accessible services. In 2019, the federal grants allocated two billion dollars to combat the opioid epidemic. In NYS, 2015, funding for the opioid crisis increased from 168 million to 247 million in 2019**.** These facts are sobering. Despite the increased funding to combat the problem, more innovative programs to address poverty and access in rural areas are necessary.

Strategic Analysis

With the recognition the opioid crisis is relentless, the need to meet the accreditation bodies criteria is urgent, to remain operational and continue to provide a needed service to this population. The corrective measures include ascertainment of an onsite medical provider, which can be fulfilled by an NP or PA. NPs emerged as a feasible and economical substitute after issues with provider coverage, the quality of patient care, patient dissatisfaction, and the failure of the CTP to meet the standards of regulating and certifying bodies. The short-term plan entails

implementing an interim NP to cover the vulnerable early morning hours for approximately eight weeks while actively recruiting an ideal NP candidate(s) during this period in a permanent role.

Readiness for Change

According to the World Health Organization (WHO, 2020), globally, approximately one-half million deaths result from drug use. About 70% of these deaths are caused by opioid use, while 30% overdosed. The WHO (2020) reports 269 million (or 5.3% of the global population aged 15-64 years) used illicit drugs at least once in 2018; 58 million used opioids, and 35.6 million individuals in 2018 as having a drug use disorder. The CTP stakeholders recognized the OTPs extensive history of contributions to the institution's community through its mission of commitment, providing quality care, and addressing the evolving opioid crisis. The CTP acknowledged the importance of capitalizing on the strengths of the dedicated staff, long-standing clients, and positive staff-patient relationships. In order to remain a reputable, relevant, competitive, and an ubiquitous part of the solution of the unwavering opioid crisis, practice change is inevitable to serve their population on the basis of improved accessibility, increased patient satisfaction, and provider efficiency.

Statement of the Problem

Timely, available, and effective treatment for OUD is equivalent to improving the patient's self-care function and maintaining employment, reducing infection risks and drug overdoses. During the period 2000 to 2017, the most significant spike in opioid overdose deaths occurred. The causes of the high death rate were likely attributed to an increase in prescribed opiates, the ease of access to illicit opiates, the use of illegal opiates after a period of incarceration, the reduced access to MAT in the rural areas, personal/individual denial of an OUD, and limited

authorized providers. Multiple studies have shown MAT programs can effectively reduce overdose-related deaths (Villegas et al., 2020; Moore, 2020; Turner et al., 2018); however, the strain and limited physician-only providers impacts the OTPs ability to provide access and improve outcomes. The CARA now allows advanced practice providers (APPs), i.e., NPs and PAs prescribe MAT, thus increasing access to treatment.

Purpose Statement

The purpose of this quality improvement Doctoral Capstone project is to evaluate the NP-MD shared care model delivery by integrating the nurse practitioner in the opioid treatment team to increase provider-patient access, improve patient satisfaction, and improve provider efficiency.

PICOT Question

The PICOT question's focus is to evaluate how the NP-MD shared care model's implementation will increase patient access to the provider, improve patient satisfaction, and improve provider efficiency. The research question will employ the PICOT literature review. The PICOT (population, intervention, comparison, outcome, and timeframe) question: In an opioid treatment program with limited physician-provider coverage (P), does the implementation of the NP-MD shared care model in the OTP improves provider-access, increase patient satisfaction and improve provider efficiency (I), physician-provider only (C), increased provider access, improved patient satisfaction, and improved provider efficiency in six months (T).

Conceptual Framework

The adaptation of two conceptual frameworks provides the foundation to facilitate the change process: The interprofessional collaborative practice (ICP) and relational coordination (RC) (Gittell, Godfrey, and Thistlethwaite, 2012), and Donabedians' Structure, Process, and Outcome (SPO) framework (Ayanian and Markel, 2016). The ICP and RC provided the basis for this evaluation, as both concepts are similar (Gittell et al., 2012). ICP is a four-dimensional construct which incorporates roles, interdependence, knowledge exchange, and goal ownership. The ICP concept recognizes equality in roles. NPs in New York State are independent practitioners, and it is thus crucial to evaluate the providers equally**.** According to the WHO Framework for Action, by implementing interprofessional collaboration, learning to work together, and respecting one another's healthcare perspectives, multiple disciplines can work more effectively as a team to help improve patient outcomes. In its simplest form, interprofessional collaboration is the practice of approaching patient care from a team-based perspective and is fully supported and meets the objectives of the Essential VI inter-professional collaboration for improving patient and population health outcomes of *The Essentials of Doctoral Education for Advanced Nursing Practice by the American Association of Colleges of Nursing (AACN).* Implementing an NP-MD shared-care role in OTP allows the doctoral-prepared NP to demonstrate and apply leadership skills in managing issues unique to individuals with addiction disorders.

As discussed in Gittell, 2002 (as cited in Gittell et al., 2012), relational coordination is "a mutually reinforcing process of communicating and relating for task integration." The first dimension, understanding of roles, encompasses the clarification of strength, appreciation, and

ultimately, mutual respect, contributes to patient care quality. The second dimension, interdependence, promotes the scheduling of a patient encounter commensurate with the provider's level of expertise (e.g., the admission of a medically complex patient by the physician provider) to prevent intake delays. The third dimension, knowledge exchange, promotes comprehension while education differs; each role is vital and offers to learn through observation, referrals, and consultations. The fourth dimension, the ownership of goals, involves understanding, participation, and team members' collaboration to work toward patient-centered care outcomes. With all dimensions' application, providers have improved efficiency and increased satisfaction, and the patient outcomes in safety and quality are improved.

The Donabedian's SPO framework for healthcare quality is the source used in assessing the quality and evaluation of NPs performance (Wong et al., 2017; Gardner et al., 2012). In this process improvement, Donabedian's structure-process-outcome model provided the foundation for the addition and appropriateness of adding nurse practitioners to the opioid treatment program team. Donabedian's framework for healthcare quality evaluation involves using the triad of structure, process, and outcome to evaluate healthcare quality and is appropriate for this evaluation. Ayanian and Markel, 2016, defines Donabedian's framework as the *structure* represents the setting: Outpatient opioid treatment, qualifications of providers, and the administrative systems through which care takes place; the *process* is the components of the care delivered to patients, e.g., treatments, counseling, and referrals; and the *outcome* is the recovery, the restoration of function, and survival of patients. Structure-what were the stakeholders' expectations, and how prepared are they to implement NP-Physician shared care model? Process-how will the NPs transfer's clinical background to the effective management of opioid treatment, and will the NPs require additional training? Outcome - will the NPs' leadership and

management be safe, appropriate, improve patient satisfaction, meet the certifying bodies' criteria, and reduce provider workload.

Definition of Terms or Variables

Patient Access: According to Healthy People 2020, one of its goals is improving access to comprehensive and quality healthcare. According to Healthy People (2020), patients' access to health services means "the appropriate and prompt use of health services to achieve the best health outcomes." It requires access to the healthcare system through insurance coverage, obtaining healthcare in a preferred location, and establishing trusting and open communication with a provider. Whether it is specialized, primary or inpatient care, patients should access healthcare whenever needed. However, multiple variables can affect access to opioid treatment and include but are not limited to few addiction providers, rural areas, and OTP waiting lists for entry.

Patient Satisfaction: Patient satisfaction in healthcare is a significant and frequently used indicator for quality based on a patient's assessment of the care rendered compared to their care expectations. Essentially, patient satisfaction impacts clinical outcomes, patient retention, and quality healthcare delivery (Alcaraz et al., 2018). Patient dissatisfaction can be the result of multiple factors. However, a significant cause of dissatisfaction is the wait time in healthcare settings such as the doctors' offices, emergency rooms, and clinics. The Press Ganey Outpatient Medical Practice Survey is frequently used to estimate patient satisfaction with outpatient healthcare. According to the Press Ganey survey, the average wait time in the United States is 17.8 ± 19.4 minutes in 2016. The OTP's patient satisfaction survey conducted in 2017 indicated 35% dissatisfaction because of the provider's long wait time. These metrics have influenced

healthcare organizations implementing throughput processes to reduce wait times and increase efficacy.

Improve provider efficiency: Healthcare providers, both inpatient and outpatient, are burdened by the sheer volume and complexities of patients' medical management. As reported in D'Afflitti et al. 2018, a survey of 1,000 physicians, NPs, and PAs, in 2015 found two-thirds reports being "very stressed," one-third reports "burnout," and one-quarter reports "poor job satisfaction." To combat the issue, the shared-care model is an approach to patient care using the knowledge and skills of multiple healthcare team members who deliver different aspects of their care needs (Norful et al., 2017; D'Afflitti et al. 2018). Implementing the NP-MD shared care model to provide care effectively improves patients access, reduces wait times, increases patient and staff satisfaction, meets healthcare metrics, and improves providers' efficiency. The bonus benefits are ultimately reduced burnout and stress.

SECTION II: CRITICAL APPRAISAL OF EVIDENCE

Inclusion/Exclusion Criteria

While there is an abundance of information accessible on substance abuse treatment, there is a shortage of research on nurse practitioners' role, effectiveness, quality, and shared care role in treating opioid addiction. Inclusion and exclusion criteria used to identify studies appropriate for this project include randomized controlled trials comparing NP-MD versus MD-only management in adult primary care and analyses of the NP role. A review of the most current literature using the search terms “opioid use disorder," "nurse practitioner," "opioid treatment," "effectiveness," "healthcare access," "role," "shared-care model," and "patient satisfaction" in Cinahl, PubMed, Ebsco, and Google Scholar databases for pertinent publications over the last

five years. We excluded studies on inpatient settings, focused on physician-provider only, pediatrics, and non-English speaking. The search returned approximately 56,100 articles. Of this number, 380 were applicable, but only 34 peer-reviewed articles in 2009-2020 were appropriate. For shared-care model, ten articles; improving access, sixteen articles; patient satisfaction: seven articles.

Level of Evidence

The Oxford Level of Evidence identifies relevant evidence related to the PICOT question using the classification levels of Ia to V. The studies which meet 1a criteria are systematic reviews (meta-analyses) of randomized controlled trials (RCTs). In the level of evidence, 1b consists of RCTs. The level of evidence II is cohort studies. Case-control-studies are level III evidence, whereas case-series are level of evidence IV, and lastly, level of evidence V are those of expert opinion.

Review of Literature

Despite data which indicates NPs and PAs are the frontline providers in opioid addiction treatment, there are very few studies available on their roles in addiction treatment. According to Haffajee et al. (2018), NPs and PAs most often manage patients with OUD in collaboration with mental health therapists/counselors and physician collaboration. Approximately one-third of Haffajee study's respondents were familiar with methadone, while fifty percent were confident in their ability to treat or manage the disorder. Because of the paucity of research on NPs' roles in OTP, the author adapted research conducted in primary care settings because the OTP patient population, characteristics, and provider-shared roles are similar.

The literature review supports the shared-care NP-MD role in various primary care settings (D'Afflitti et al., 2018; Norful et al., 2019; Mundinger et al., 2000; Kraus & DuBois, 2016; Swan et al., 2015; Moldestad et al., 2020 and Neprash et al., 2020). Other settings demonstrate improved quality of care and positive outcomes, such as long-term care, (Lovink et al., 2017; Kilpatrick, 2020). Other studies in various setting supports the NP-MD shared roles: NP-model of care in prison setting by Wong et al. (2017); Moldestad et al. (2020) and McCleery et al. (2014) evaluated the NP role quality in the VA system, while McCormick et al. (2019) explored a quality improvement project in a VA substance treatment program. Ying et al., (2015) evaluation of NPs' scope of practice found they have increased access to primary care in vulnerable areas. Bates and Martin-Misener (2021) found the stigma and complexities of patients living with OUD as the barriers to NPs prescribing methadone in Nova Scotia. In contrast, Cimiotti et al., (2019) suggests consistent administrative staff support improves the quality of primary care provided by nurse practitioners.

In the early phase of NPs' addition to multiple settings, Masso & Thompson (2015) assessed NPs roles and found a lack of consistency in the evaluation of the NPs on care provided and the patient outcomes. The authors recommended the use of a checklist of eight characteristics for use in future studies to improve the decision-making process on implementing NP models of care, enable comparison, and increase the capacity to make informed decisions about the prospects for expanding the NP roles. These findings prompted further research to compare the NPs autonomy and patients' outcomes.

Early studies depicted the simmering and polarized conflicts between the proposed expansion of NPs SOP and primary care physicians (Moldestad et al., 2020; Donelan et al.,

2013; Mundinger et al., 2000). Donelan et al., (2013) national post-mail survey from November 23, 2011, through April 9, 2012, consisted of 505 physicians and 467 NPs in primary care to explore their attitudes and primary care experiences. The authors selected NPs in specialties aligned with physician specialties such as adolescent and adult medicine, family medicine, general practice, geriatric medicine, internal medicine, pediatrics, and women's health). In the study, most NPs were female, older Caucasian, and possessed fewer years of experience (likely as an NP), worked fewer hours, and earned less. The physicians were male, senior, and worked longer hours. In the study, 80.9% of NPs worked in collaborative practice, whereas only 41.4% of PCP worked with an NP. The response rate was 61.2%. The findings support the restricted practice of NPs at the time of the study. The analysis revealed the NPs provided the bulk of patient care for annual physicals, complex chronic coexisting conditions, acute illness, care coordination, patient/family teaching, and follow-up lab results in a collaborative setting. In the findings, approximately 95.6% of the NPs and 76.3% of the PCP agreed NPs should practice to the full extent of their education but disagreed NPs should lead medical homes and receive equal pay. In our OTP, NPs perform 100% of annual physicals, whereas the physician provider performs 100% lab results review. It is difficult to coincide with the assertion that PCPs work longer hours, as the breakdown does not correlate with the workload of PCP.

Kraus and DuBois (2018) qualitative study found the participants' perspectives were not aligned with professional organizations or the media. However, the findings demonstrated physicians were supportive of the diverse NP roles, had confidence in the notable levels of NP independence and autonomy. The NPs and physicians agreed on the criteria for NP independence, the episodic need for physician collaboration, and access in the interest of patient

safety. The researchers conclude qualitative studies are applicable in developing theory, describe relationships between variables, and identify queries in need of further research.

Norful et al., (2019) compared NP-MD co-management versus an individual physician in primary care in a synthesized review of six studies, (n=4) randomized controlled trials (RCT), (n=1) cross-sectional study, and (n=1) case stud. The researchers examined the (a) primary care provider adherence to recommended care guidelines, (b) observed changes in clinical patient outcomes, and (c) patient/caregiver quality of life. Four studies evaluated and compared how NP-MD co-management of patient care impacts compliance with completing recommended care guidelines. The researchers found significantly more completed evidence-based policies in the NP-MD co-management; whereas some findings of the patient clinical outcome favored the co-management model and demonstrated very little difference in patients' quality of life. Norful et al., (2019) recommends institutions investigate co-management process and implementation for its feasibility, review relevant qualitative research on co-management roles, the communication between providers, the delegation of tasks, and their interactions. Additionally, investigation should concern if each provider is willing to work in a co-management environment (Norful et al., 2019).

Some researchers have focused their investigations on the outcomes of primary care patients treated by physicians or NPs (Mundinger et al., 2000; Moldestad et al., 2020) and practice patterns of physicians and NPs in primary care, Neprash et al., (2020). Mundinger et al.'s (2000) RCT investigated the outcomes of patients randomly assigned to an NP or physician for follow-up care after an emergency room or urgent care visit from August 1995 through October 1997. It consisted of patient interviews six months after the initial appointment and data

utilization one year after the initial appointment. The trial involved four community-based primary care clinics with 17 physicians and one primary care clinic with seven NPs at an urban academic medical center. The researchers screened 3397 individuals, enrolled (n=1316), has a mean age, 45.9 years, 76.8% female, and 90.3% of Hispanic patients had no primary care provider, and kept their initial appointment and were randomized with either physician (n=510) or an NP (806).

All providers have equal authority to prescribe, consult, refer, and admit patients. The investigators measured patient satisfaction using a 15-item questionnaire, health status Medical Outcome Study Short-Form 36), and physiologic test results six months later. Service utilization (accessed through computer records) is checked for one year after the initial appointment. The results revealed no significant differences in patients' health status in NPs vs. Physicians' care at six months (p=92). There was no difference in health service utilization or satisfaction after one year. Physicians were rated higher (4.2 vs. 4.1 on a scale where 5=excellent; P=0.5) in one of four criteria (physician attributes); however, the difference is minimal. The study's limitations include the urban setting, the population, Medicaid patients, Hispanic-speaking recent immigrants, and faculty providers, limiting its applicability to various locations such as private practices, ambulatory clinics, and specialty clinics. The study's population was not randomized in equal proportions to reflect diversity. However, the rationale suffices, as the NP clinic was established after, which allowed for greater patient capacity. However, areas of similarity align and are thus applicable to this study's population and its affiliation with a small community teaching medical center.

Moldestad et al. (2020) found the primary care provided by NPs and physicians in states with restricted and full practice authority (FPA) as 'comparable yet distinct in their qualitative exploratory study in a Veterans Affairs Healthcare System involved 14 NPs, 17 physicians, and 28 patients. The researchers found NPs provided more holistic care when compared to physicians, and patients were satisfied with NPs, but the provider's professional experience outweighed the provider type. Reassigning the participants to new providers after the termination of the prior relationship reduced the potential for bias. The VA approved FPA in 2017 across the states despite the study being conducted in the previous year. The authors opine the VA's FPA approval suggests the reduced likelihood of the results being affected by differing NP practices. The limitations were the size, the setting, and the selected population was not reflective of the general population. The authors conclude the acceptance of NPs has increased, and those states without FPA should consider their expansion to the FPA.

In contrast to Moldestad et al. (2020), Neprash et al. (2020) cross-sectional analysis consisted of 29,048,405 electronic patient visits to 12,272 physicians and 5953 NPs practice at 3146 primary care clinics. The age range of patients 15 to 65+years with most patients being older, female, and are Medicare recipients, Medicare Advantage, Medicaid, commercial, and the uninsured. However, while the demographics are diverse, it was skewed to majority Caucasian and female. The findings reveal NPs treated younger, healthier, female, non-white patients covered by Medicaid, commercial insurance, or no insurance when compared to the physicians. The NPs scheduled longer appointments and treated more patients on a same-day basis or after-hours, whereas physicians managed complex patients. The average 'overlap services'- those provided by both NPs and providers represented 92% of all service volume. This study's

strengths show that in states with full FPA, the NPs provided care that closely reflects the care provided by a physician.

D'Afflitti et al. (2018) assessed how team-based care in primary care impacts improvement in provider experience and patient access through NP-physician direct care teams in a safety net clinic staffed by 50 physicians and eight nurse practitioners. The pilot study had eight physicians and two NPs co-managing seventy medically complex patients through providing consistent appointments and supporting the physicians in their management. The authors measured patient access to care "as the number of days to the third next appointment with the NP or physician." The findings of study showed reduced wait time of nearly 20 days for appointments, and 79% of the physicians report the model was 'very or 'extremely helpful in reducing the burden of work, and 100% of the NPS reported they were 'very or extremely satisfied in their job. It appears the additional "two protected sessions per week" by the NPs were instrumental in the NP Anchor model being adapted by leadership because losing primary care physicians is expensive and disruptive. The model allows for an increase in capacity and in revenue, improves performance on quality metrics, and undertakes co-management of complex patients. This study's limitations include the lack of a comparison/standard group and an evaluation of patients' experience and outcome; however, these were not the intended variables. The primary objective was to address patient access and provider stress, which aligns with this doctoral capstone quality improvement evaluation.

As the healthcare industry expanded the scope of practice for NPs, additional studies evaluated their effect and safety and compared the outcomes to physicians' management in primary care. The systematic review of studies by Swan et al. (2015) to evaluate the NPs'

potential in alleviating primary care provider shortages consisted of ten articles: seven were RCTs, two were economic evaluations, and one, a two-year follow-up study, involved 10,911 patients. The authors found there were few differences in primary care provided by APRNs and physicians. Evidence suggests NPs consultations lasted longer (without an increase in costs), NP providers adhered to guidelines, engaged in more patient education, and scheduled more follow-up. Further, for some measures, APN care was superior. The study's limitations include English-speaking only studies. RCTs affected the size, which increased the risk for type II errors and the variation in measuring the process and outcomes. Despite being a small RCT, the findings are consistent with co-management study by Norful et al., 2019; perceptions and comparison of NP-MD by Moldestad et al., 2020; and the practice patterns of NPs and physicians by Neprash et al., 2020, as all studies evaluated primary care settings.

According to McCleery et al. (2015), the VA system uses NPs (and other advanced practice registered nurses (APRNs) in the delivery of healthcare in primary, specialty, acute, and home care after the integration of the Veterans Integrated Service Network (VISN) and the Veterans Healthcare Eligibility Reform Act in 1996. This integration resulted in an increase in ambulatory and primary care, and a concomitant rise in the number of veterans seeking primary care. Because of the ongoing debate on the comparison of health outcomes of autonomous APRNs' SOP and physicians, the investigators conducted a systematic review to re-evaluate recent and original studies of reported health outcomes. The authors evaluated four RCTs in urgent care settings, three controlled trials in primary care settings, and three observational studies in inpatient anesthesia care. The urgent care practices included rural and urban areas; total patients served from 3,000 to 16 000 with one to five partners. The results found no difference in

management; however the researchers recommended additional studies of longer duration. The authors did not include the study's findings on CRNAs due to the lack of relevance.

The quality improvement study by McCormick et al. (2019) found the redesign of a substance abuse treatment program for veterans resulted in increased access to MAT. Additionally, the termination of wait times guarantees same-day treatment for patients with alcohol addiction and OUD to receive pharmacotherapy in managing substance use disorders. This program's similarity and applicability lie in the concept of quality improvement to address treatment access for individuals with substance use disorders. A comparable yet different quality assurance study by (Wong et al., 2017) in June 2015 for two months using Donabedian's structure, processes, and outcomes framework, reviewed the nurse practitioners' care model's implementation in a male correctional facility. The researchers collected data on staff attitudes on the implementation of primary and mental health NPs, (n=21), consultation records of clinical process and time use (n=289), and a patient satisfaction survey (n=29). The most common encounters for the primary health NP were musculoskeletal complaints and medication management. In contrast, the most common encounters for mental health NP involved depression and Axis II disorders (personality disorders). The researchers found the services provided were necessary, safe, met the patient's need, and reduced treatment delays. The limitations are the study's setting, the homogenous prison population, and the exclusion of a breakdown of the participants' demographics. The quality assurance study's similarities and applicability rest in the implementation of NPs, Donabedian's SPO's use, and "freed the physician's time" in a correctional setting.

In an assessment of the expansion of healthcare access by the addition of NPs and PAs in the geriatric population in primary and long-term care, Lovink et al. (2017) performed a systematic review of two RCTs and eight studies of comparative designs. The findings in the two RCTs in primary health care showed the substitution of NPs and PAs for the physician were equal when compared to physician-only care for about half of the patients. Additionally, the researchers found with appropriate funding, adequate NPs and PAs; geriatric education should include the PAs. The research is limited as only two RCTs were reviewed, while two of the comparative studies addressed cost, the researchers were unable to draw specific conclusions. A gray area exists regarding substitution vs. supplemental as it requires clarification and would benefit from additional research. Provider outcomes were not measured, and there is a concern for attrition bias and contamination (the control group received the intervention). While the evidence for support is limited in long-term care, NPs function competently in a shared-care role and a substitute role in substance abuse treatment.

Conversely, Kilpatrick et al. (2020) expands further on the roles of NPs in long-term care (LTC) in a mixed-method quality improvement study to identify NPs integration in LTCs. The researchers conducted a prospective cohort study in six LTC facilities in Quebec and collected data between September 2015 and August 2016 on all residents (n=538) and NPs interventions (n=3798). The variables reviewed were related to medications, polypharmacy, falls, restraints use, pressure ulcers, and monitored all transfers to acute care. The NPS (n=6) worked half-time in LTC with an average caseload of 42 to 80 residents. Three sites offered shared-care, two locations offered consultations only, and one place offered the combination shared care/consultative model. The average age of residents was 82, with the most common diagnosis was dementia (62%=331), and two-thirds were female.

Kilpatrick et al. (2020) found the average number of interventions per resident was (range 2.2 – 16.3) and depended on the care model. The findings revealed a reduction in the number of prescribed medications per resident by 12% or 10% for every 30 days over 12 months. Overall, polypharmacy falls, restraint use, fewer pressure ulcers, and transfers decreased. Despite the positive results, the researchers were unable to compare outcomes due to the inability to access the previous year's paper-based data. The assessment did not include the residents' and their families' input; however, their opinions are necessary and should be included in future analysis. The long-term care setting's common factors are the shared-care model and the NPs, has shown to improve care quality in varied health care settings utilizing NPs.

Studies have researched how the NPs' SOP regulation has impacted health care delivery. Ying et al. (2015) conducted a systematic review to examine the impact of state SOP regulation on three key areas: NP workforce, access to care, and health care utilization and associated costs. The researchers reviewed 15 studies and found states with full SOP increased the numbers of NPs, an increase in healthcare provided by NPs, and expanded health care utilization, primarily in rural and underserved populations. While the review reveals the impact of NPs when SOP regulations are relaxed, the study's sample is small and did not categorize by specialty. It appears approximately half of the NPs studies reviewed occurred in specialty care. However, subsequent studies have examined NPs roles in primary care and have found the care provided to be comparable to physicians, good quality, and cost-effective, especially OUD treatment (Jackson Lopez, 2018; Denis, 2019).

The number of primary care and specialty physicians decreased because fewer doctors enter primary care and physician specialists retire (Cimiotti et al., 2019). The coexisting dilemma

is individuals are living longer with more complex illnesses. NPs are ready and available to fill healthcare gaps; however, reduced and restricted practice states impact NPs SOP. Additionally, Cimiotti et al. (2019) report studies have revealed despite being employed in full SOP states, institutions have policies and regulations, which inherently limit NPs ability to exercise full practice authority. Subsequently, Cimiotti et al. (2019) conducted a cross-sectional survey to provide a current description of the NP workforce and identify the professional and organizational factors associated with NP care quality in reduced or restricted practice states of California, Florida, New Jersey, and Pennsylvania. Regression analysis measures the odds ratio. The researchers found NPs in primary care settings reported higher organizational climate scores on professional visibility (3.1 vs 2.9) and NP-administration (3.0 vs. 2.7) compared to acute care NPs. The acute care NPs reported higher scores on independent practice and support (3.6 vs. 3.4), while in acute and primary care settings; the NPs scored the same (3.4) for the subscale of NP-MD relations. While the research was intentionally limited to four states with restricted/reduced practice, the results should encourage organization leaders and states to find ways to support NPs complete SOP. Their impact is crucial, especially in a primary care setting with the increased need for quality healthcare services.

In contrast to previous studies, (Traczynski & Udalova 2018) examined changes in the utilization of health care and outcomes in states which allowed FPA without any physician oversight. The investigators used the medical expenditure panel survey (MEPS) and difference-in-difference approach to investigate NPs independence. The researcher found that with increased healthcare NP providers with FPA, especially in underserved populations and rural areas, the outcomes show improved care quality, increased frequency of checkups, and decreased

emergency room utilization for primary care (Traczynski & Udalova, 2018). Other patient benefits derived were easy access, flexibility, and follow-up appointments.

Globally, challenges to meet the populations' healthcare services equitably with primary care providers are ongoing. Many new, complex, and evolving illnesses, coupled with the long-term needs of a diverse population co-mingled with poverty, the emergence of new infectious diseases, and health disparities, places great demands on the limited number of medical providers. The NP role, as multiple studies have demonstrated, has proven to be the ideal solution to manage the gap in healthcare services. However, except in settings with new graduates, experienced NPs must demonstrate their competence and ability to provide care comparable to primary care physicians. Carryer & Adams (2016) examined the NPs' role alignment in New Zealand with countries concerned with sustainable healthcare by interviews with thirteen NPs and three management staff in private general practices, public health clinics, not-for-profit clinics, and community/indigenous health clinics. The findings demonstrate NPs have competently managed medical tasks but usually fill roles as a substitute, thus limiting their practice. Additional RCTs or systematic reviews should be conducted with data analysis to demonstrate validity and guide healthcare policy.

Patient satisfaction is a significant driver in hospital consumer assessment of healthcare providers and systems (HCAHPS). Some of the issues contributing to patients' dissatisfaction in our OTP include program rules and the long wait time for the doctor. In her assessment of patient satisfaction, Kelly et al. (2010) assessed how satisfied new admissions (n=283) to methadone treatment were with their counselors and the program at three months. Regression analysis was used to measure the relationship between satisfaction and drug testing at three months to predict

retained participants in treatment at 12 months. The authors found the satisfied participants had lower drug and addiction severity index and remained in treatment at 12 months.

Gryczynski et al. (2011) found the primary causes of delay to OTP admission included racial/ethnic minority status, lower education, criminal justice referral, prior OTP treatment experience, secondary cocaine or alcohol use, and co-occurring mental health disorders. Conversely, IV drug users, self-pay patients, and those referred from acute health care and addiction providers encountered fewer delays. The findings reveal delays were frequently associated with communities with significant population uptake of methadone whereas in communities offering alternative MAT has fewer delays in admissions. The treatment episode data set (TEDS) data system consists of statistics that are routinely collected by various states, programs and the federal level in monitoring their individual substance abuse treatment systems. However TEDS has limitations, because the data collection is voluntary. Programs with long waiting lists may not reveal this information, thus data may be skewed. The study reports that programs should report delays based on program requirement or inadequate capacity, however individual programs may interpret instructions differently.

Livingston et al. (2018) qualitative study found the barriers to physicians providing MAT in primary care were concerns regarding methadone expertise support, skills, support from allied professionals, and their personal experiences. The patient factors were perceptions of the non-OUD patients on the OUD patients. Practice related concerns included threats to the physician's careers, surveillance duties, unfair compensations, and practice disruptions. Conversely, Bates and Martin-Miseners' (2021) qualitative study of Canadians NPs perceived barriers to prescribing methadone found four distinct concepts: inescapable barrier of stigma, discernment

of complexities of individuals living with OUD, the NPs' education and practice supports, and the healthcare context and execution of the NP role.

An assessment of current opioid treatment programs is necessary to determine the need for improvement in service and access. Jones et al. (2019) national survey found majority OTPs (95.8%) administered methadone, 61.8% dispensed buprenorphine, 43.9% administered naltrexone, and an overall 32.4% dispensed all three medications. The researchers found some OTPs offered hepatitis testing (60.9%), hepatitis A (14.9%) and B vaccinations (15.3%), hepatitis C treatment (12.6%), HIV testing (60.7%) and treatment (8.4%), pre-exposure prophylaxis (PrEP) (9.5%), treatment for alcohol use disorder, and telemedicine. While OTPs should be standardized nationwide, the services provided reflect population demographics, health needs of individual communities, funding, and oversight by SAMHSA. The inadequate response of 31.0% may be negatively impacted because SAMHSA conducted the survey, thus the element of non-response bias has to be considered. Further, the poor response rate is less than 50% of the United States OTPs and does not accurately reflect the practice characteristics of all OTPs, thus affecting the 'need perception' and should be interpreted in this context.

Bourion-Bedees et al. (2017) conducted an exploratory, cross-sectional study to assess the relationship between patient and physician characteristics and early outpatient satisfaction with care for alcohol and opioid dependence. The researchers utilized a multi-dimensional, self-administered, and validated questionnaire after recruiting 249 outpatients with a 63.8 % response rate, majority male 76.1%, and mean age 39.5 years old, married 37%, and 17.7% completed high school or university degree. The researchers found patients without a history of substance use treatment were more satisfied with the appointment process (b=7.2; P=0.029) and doctor's

encounter (b=10.3; P=0.003) than those who had previous treatment. It is unclear why the study did not include individuals who had long-term exposure to treatment. Patients' perspective in any long-term treatment is beneficial, objective, and transparent, given their length of time in the program and experience. The completion of the questionnaire at home reduces the risk of the Hawthorne effect. However, high satisfaction can only lead to positive retention, as it is unlikely a patient will leave an OTP they have rated positively. Additional studies should examine factors affecting satisfaction in opioid treatment using a more extensive study population.

The patient satisfaction survey conducted by Aziz and Chong (2014) in Malaysia with (n=425) participants had a response rate of 80% and reported an overall satisfaction rate of 95% in those single or married, but not those who are separated or divorced. The survey highlights potential improvement in areas such as extended dosing hours, waiting room appearance, and reducing staff shortages, however the study neglects to assign a percentage of respondents who favored these improvements. Improving dosing hours is a common source of dissatisfaction. It is prevalent in CTP, with certain patients frequently missing dosages on weekends because of shorter dispensing hours, overslept, forgetfulness, weekend hours, or traffic-related delays.

In Ford II et al (2007), qualitative descriptive and exploratory study to identify admissions-related problems in 327 applicants to Robert Wood Johnson Foundation (RWJF) and the Center for Substance Abuse and Treatment (CSAT) identifies poor staff engagement with clients, burdensome processes and procedures, the difficulties in addressing the patients' complex lives and needs, and infrastructure problems which aligns with similarities of issues present in our CTP. Generally, the CTP accepts potential clients from inpatient detoxification units as same day admits; however, walk-ins have to undergo a screening process to ascertain their needs and

appropriateness for MAT. The screening process for admission for MAT requires laboratory screening for illicit substance may last three to seven days, unless the potential patient is a former patient. Conversely, Schwartz's et al (2015) two-arm open label randomized trial of 300 newly admitted patients found no significant difference between (patient-centered methadone) PCM and (treatment as usual) TAU conditions in opioid-positive urine screens at 12-month to demonstrate while counselors are essential, relevant, and plays significant roles in addiction treatment and have synergistic relationships with their caseloads, their effect on patient outcomes vary.

CHAPTER III METHODOLOGY AND IMPLEMENTATION

Study Design

The Doctoral Capstone project employed the pre-intervention and post-intervention survey with the addition of the NPs as the intervention. The Plan, Do, Study, Act (PDSA) is the institution's performance improvement methodology model. According to the Institute for Healthcare Improvement (IHI), the PDSA, known as "the Deming Wheel," or ``Deming Cycle," was created by the management consultant Dr. William Edwards Deming in the 1950s. Dr. Deming referred to it as the "Shewhart Cycle" because it was the brainchild of his mentor, Walter Shewhart.

The PDSA is a repetitive four-stage method used for improving processes, products, or services. The PDSA model for improvement asks three questions of stakeholders: What are we trying to accomplish? How will we know change is an improvement? What changes can we make that will result in the progress we seek? In the "Plan" stage, using deduction, the problem is identified; in the "Do" stage, the potential solution undergoes testing, and the effect or results

are measured. In the "Study" stage, the results/effect are reviewed and determined if the hypothesis is supported or not. In the final "Act" stage, if the solution is effective, it is implemented. Plan: The stakeholders meet to discuss and brainstorm solutions to address the limited provider coverage concerns affecting service quality. Do: Assign temporary NP coverage for the vulnerable hours. Study: The interim NP coverage is evaluated based on patients' satisfaction, provider and clinical staff feedback, and ultimately her effectiveness and 'being there.' One hundred percent of the patients, providers, and clinical staff provided positive feedback supporting the shared NP-MD role. Patients and clinical staff were happy a provider was available to assess patients, and the remaining provider experienced improved efficiency associated with their role and responsibilities. Based on this feedback, the stakeholders support the NPs addition using a shared model of care. Act: The stakeholders agree on the recruitment of NPs to provide full-time coverage NP as the feasible and economical solution.

Goals and Objectives

This capstone project's overall goal is to improve patient access to a provider, increase patient satisfaction and improve provider efficiency by 25% through the addition of NPs to create an NP-MD shared care model in our OTP clinic. The NPs will provide appropriate care to the OTP population, demonstrating comprehension of the methadone pharmacogenetics, half-life of the drug, withdrawal, cravings, and the side effects through patient assessment. The NPs will conduct health assessments, provide patient education and counseling in health promotion, maintenance, and disease prevention. NPs will interpret relevant laboratory data and recommend appropriate follow-up care. Additionally, the NP providers participate in team meetings and conferences to embrace the multidisciplinary approach to specialized healthcare. The NPs will

practice within the OASAS guidelines and comply with the OTP and the medical center's policies and procedures after completing a six-week provider orientation.

Measurable Outcomes

Using Donabedian's SPO framework to assess improvement, the *structure* being the OTP, the *process* being the implementation of NP-MD shared-care role, and the *outcomes* as increased provider access, improved patient satisfaction, and improved provider efficiency. We measure the results by comparing the patient-provider encounters before and after the NP-MD shared-care model was implemented. The author used a patient questionnaire survey with responses on a Likert scale to measure the effect of increased provider access and the patients' level of satisfaction. The providers' satisfaction is assessed based on improved efficiency, using a single-question survey. After collecting six months of data on patient encounters, we tallied the total and compared the encounters to the last period of the same duration before the nurse practitioners' addition. We measured the patients' satisfaction by selecting ten patients per week for ten weeks. We chose patients on the program for more than three years (primarily because of their familiarity with the period before implementing NP-MD shared care) for a total of one hundred patients. The participants complete the three-question patient questionnaire on provider access and satisfaction using a Likert chart. The nurse practitioner designed the post-implementation study. To reduce bias and the Hawthorne effect, the survey is completed by the accession desk receptionist and the individual counselors.

Organizational Setting

The Doctor of Nursing Practice Capstone Project 'NP-Physician shared-care model in OTP' transpires in the CTP clinic located in a multicultural and urban community in New York

with a population of approximately 500,000. The OTP is subsidized by OASAS and NYSDOH. It operates under a small community teaching hospital umbrella. In 2014, the CTP relocated to its present location due to the outgrowth of its former site. In 2015, the program accepted 150 transfers from an OTP in neighboring vicinity due to permanent closure. These transfers increased CTP's enrollment to approximately 450 patients, with 500 patients as the certified maximum allowed. The OTP has 22 multidisciplinary team members: A medical director, two newly hired part-time nurse practitioners, a clinic director and clinical program director (social workers), a program manager, office manager, clinical nurse manager, licensed practical nurses, and substance abuse counselors (accounts for the highest number), and an accession desk secretary. The OTP operates seven days per week: Monday through Friday from six AM to two PM daily; on Saturday and Sunday 07:30 AM until 10:30 AM. The medication dispensing hours are six-fifteen AM until 11:00 AM. During the weekend, the OTP hours are seven-thirty AM until ten-thirty AM.

The physician covers Monday through Fridays 08:00 till 11:00 AM; one nurse practitioner is scheduled Monday to Wednesday 06:15 until 2:00 PM. The other nurse practitioner is scheduled Wednesday through Friday 06:15 until 2:00 PM, with Wednesday as the overlap day. For any medication management encounter which requires a provider evaluation, the patient first approaches their counselor for an assessment, discussion, and preparation of the necessary paperwork, then a provider, except in the cases of new intakes or the completion of a history and physical.

Target Population

Currently, the OTP has approximately 400 opiate-dependent adults aged 18-years and older in treatment. The census has hovered at 400 to 450 with attrition due to successful program completion, transfers, incarcerations, discharges, and death. Approximately 50% of individuals with OUD reside in poor, urban, and underserved neighborhoods; however, a small percentage of patients are middle-class and upper classes. There are 245 males and 155 females. The majority age group is older than 51-years of age for both genders. The ethnic breakdown is as follows: Caucasian 58 percent, African Americans 21 percent, Hispanic 19 percent, American Indian, Asian, and Pacific-Islander account for less than point five (0.5%) percent. Approximately 40% of the enrolled patients are employed, 30 % are on social security disability, 20 % are unemployed, and 10% are retired senior citizens. A few of our patients are biologically related and/or partners: Couples, parents/adult children, siblings, uncles, and cousins. We have former inmates and patients with ongoing cases with the criminal justice system. Our patients' education level consists of eight to eleventh grades, high school diploma or GED, incomplete college degree, associates, bachelors, and masters' degrees. Others possess trade certification in carpentry, electrician, plumbing landscaping, and other skills via on-the-job training. Many OTP patients have co-occurring mental illnesses (depression, bipolar disorder, anxiety) and other diagnoses such as asthma, chronic obstructive pulmonary disease, congestive heart failure, diabetes, and hypertension.

Sample/Sampling

The post-intervention survey is conducted twenty months after completion of the NPs' orientation in a two-fold process. During the data collection period of 9/2019 to 2/2020**,** we will

collect the total and types of patient-providers (NP/MD) encounters daily until closure at eleven AM except for holidays and weekends. The data measures the patients' access to providers. The second portion consists of patient satisfaction and provider efficiency surveys.

Project Plan

During the interim NP short-term coverage, permanent NP providers are recruited internally for the NP-MD shared care role in the OTP. The applicants met with the Clinic Director, shadowed the interim NP, interviewed with the Director of Behavioral Services and the CEO, and completed the application and the onboarding process in eight weeks. As the NPs were in-house transfers lacking prior OTP experience and novel to the treatment team, except for short-term NP coverage, a formal orientation program is innovative and experimental. Becoming familiar with the OASAS policy and procedure manual and MAT literature is vital to NP providers' assumption of their roles and responsibilities and the program's processes, thus contributing effectively and efficiently.

The orientation process began with being familiar with the patients' chart organization. We were required to read the *OASAS Office Compilation of Rules and Regulations, the General Service Standards for Chemical Dependence Outpatient and Opioid Treatment Programs, Criminal Conduct and Substance Abuse Treatment: The Provider's Guide* as a part of the orientation process. The orientation design comprised the provider and team's observations during medication management and IDC encounters, the relevant questions asked, and the interventions. We had sessions with the certified addiction nurse, who shared her wealth of knowledge and trained users on the Avatar computer program used by the OTP. The senior LPN offered information and advice concerning medication management. We received teaching and

guidance related to advocacy, consideration and justice from the clinical directors and the licensed substance abuse counselors. After one month, we evaluated patients on our own with routine requests such as dose adjustment, take-home, or reinstatement of treatment/dose. In the application of the interprofessional collaborative practice, complex cases such as diversion and loss of medication were managed by the physician provider until NPs became confident in complex decision-making.

Data Collection /Data Privacy/Procedures

Institutional review board (IRB) and ethics approval and informed patient consent are not needed for a quality improvement retrospective study. The authors exclude all of the participating patients' sensitive and identifying information. The OTP's accession desk clerk is a medical assistant whose 'gatekeeper role' includes entering clients' names in the log record in the order of visit to facilitate client-provider or IDC team meetings. The client's name, the reason for the visit (for ex. dose change) and seen by which provider is entered in the covered logbook/schedule by the accession desk clerk to maintain HIPAA guidelines. Any encounter with a provider or team can last 15 to 50 minutes, depending on the encounter's nature. The schedule/logbook and the ambulatory patient groups (APG) system are the data abstraction tools used. The APG system is the new state-mandated payment methodology for most Medicaid-reimbursed outpatient services at the contracted rate (NYS.gov 2015). The APG is completed daily for each encounter and lists the name, medical record number, type, and duration of the encounter. While computerized order entry is available, it is utilized primarily by nurse practitioners and registered nurses.

Using a retrospective review, the nurse practitioner extracted the number, types, and duration of visits initially entered in the desk clerk's logbook. We collected data on reasons for the patient encounters scheduled in our appointment book categorized by intake, history and physical, dose adjustments, take-home dose requests, reinstatements to treatment after missing doses, and IDC team meetings for six months, September 2019 until February 2020. Data is collected from Monday to Friday. During the weekends and major holidays, providers are not present in the OTP but are available for a telephone consultation. The nurse practitioner designs a staff satisfaction survey unique to the nature of service. Data for the six-month collection period for encounters is entered on a *Microsoft Excel* spreadsheet for analysis. However, the patient satisfaction survey data collection was affected by the declaration of the global Sars-COVID-19 pandemic on March 11, 2020. The guidelines outlined by the NYS, CDC, and OASAS limit the number of patients in the OTP to a maximum of five at any given time. Thus, the patient satisfaction survey was collected over six months.

IRB/Ethical Conflicts

The author identified no conflicts of ethical principles. The Doctor of Nursing Practice Capstone project evaluates a quality improvement practice that does not include patient-sensitive or identifying data or harm. The evaluation does not require an institutional review board (IRB) consent. The clinical and program directors provide permission.

Measurement Tool

Patient Access and Patient Satisfaction Questionnaires

The author compared the effect of the implementation in the difference in the pre-post implementation survey. Dichotomous "yes or no" questions were used for the provider access and workload queries, whereas the five-point Likert scale was adopted to evaluate patient satisfaction. The survey comprises three questions: For patients: (i) Did you see the provider you wanted to see today? The higher tally of "yes" responses is associated with positivity. (ii) Did you wait longer than **t**wenty minutes to see a provider today? The lower count of "no" answers is associated with positivity. Using a Likert scale, the post-intervention survey question to patients: (iii) How satisfied are you with management by the provider today? The scores on the Likert five-point scale: Extremely satisfied (5) Very satisfied (4) Neutral (3) Satisfied (2) Not satisfied (1). Positive responses are associated with "extremely satisfied" and "very satisfied," a neutral selection as "no opinion," and the reactions of "satisfied" and "not satisfied" are considered as unfavorable. The goal score is greater than or equal to five, indicates high satisfaction.

Provider Questionnaire

The shared care model's benefits are evident in the interprofessional collaborative practice (ICP) dimensions of roles, inter-dependence, and knowledge exchange in patient care delivery. This shared care model allows for flexibility in schedules, continued coverage for personal emergencies, and vacation without compromising patient care. Using a three-point Likert scale, the questions for providers: How often did you have to complete encounter documentation the following day? How many times have you felt overwhelmed with your workload in the last 30

days? The responses: Frequently (3) occasionally (2) never (1). The goal is less than three occurrences in any thirty days.

Risks, Benefits Analysis, Potential Barriers

The benefits of introducing new and enthusiastic team members with fresh perspectives often outweigh the risks and uncertainty associated with new hires/transfers. The risks identified include difficulty recruiting the ideal team members because of the program's location, competition, recruitment costs, and low return on investment (ROI). The potential for unconscious bias affecting our patient interactions had to be acknowledged and addressed. As former registered nurses in the emergency room, we had encountered and cared for a diverse population with substance abuse disorders and possessed unconscious bias. The potential benefits include low NPs recruitment cost and shorter orientation period as the NPs were internal transfers, assisting in meeting the regulatory body's three-year operating certificate criteria, and improved quality of service.

The adaptation of the shared-care NP-MD model for the OTP, while exciting and readily accepted, did expose our limited knowledge on specialized addiction treatment. A fragmented orientation compounded our learning curve, role adjustment, and acclimation to an entirely different work setting, further enhanced by an unwilling and distant physician-provider. We made a few minor errors, such as initiating a lower or higher dose, which contributed to our learning. We had to adapt our training to specialized rather than primary care, which means, we cannot order a chest radiograph, instead, the patient must be referred to his provider, urgent care, or the emergency room. As our addition was innovative, we had no blueprint to follow for orientation. Gender bias pervaded some patient interactions (mostly encountered through

manipulative male patients), but as our awareness and education progressed, we handled these encounters well. As former Registered Nurses in an inpatient unit, our main concern centered on the necessity of confirming the last actual date and dose of methadone administered because the ubiquitous, hospitalized OUD patient prioritizes their methadone and demands it 'doggedly' above anything else. It was only after assuming provider roles in OTP; we could appreciate the significance of and the potential adverse effects of MAT. Other barriers includes reticence from the physician providers, who perceive being responsible for NPs' teaching as time consuming, unfamiliarity with the NP qualifications and role, and ultimately, the burden of signing a collaborative agreement (at the time) as onerous. The resistance was short-lived after the physician-provider(s) recognized the NPs providers as valuable and beneficial.

The NP-MD shared-care roles allowed for flexibility, early morning, vacation, and unexpected coverage. The NPs provide the bulk of the co-management for medication management and history and physicals. Remuneration was initially budgeted for one full-time NP from Monday through Friday; however, the recruitment process returned few respondents; hence the two part-time NPs are hired internally to fill this role. Negative patient outcomes result from various factors (individual and care delivery systems), including the lack of patient-centered care, evidenced by low-quality care, due to decreased provider access. The opportunity to improve service and patient satisfaction through the shared model of care is a win. The most significant external threat is the failure to institute corrective measures necessary to attain the three-year operating certificate.

Ethical Implications

The author obtained organizational approval for this retrospective pilot study from the Chief Executive Officer (CEO) and the Vice -President (VP). The author submitted a DNP statement of non-research determination to the college's governing body. The study was deemed exempt from IRB approval as a non-research, service improvement, and a practice change project.

In accordance with the CTPs' philosophy of treatment and its mission, it strives to provide treatment "in such a way that each person either serving or being served, is reminded of the value and dignity of all human life." The principles of healthcare ethics autonomy, beneficence, justice and confidentiality are practiced in our encounters with our patients. Autonomy is the principle of allowing individuals to self-determine their own plans, choices, and actions based on their values and beliefs with the expectation of respect. Many of our patients are 'former patients' who had left AMA and attempted to achieve 'sobriety on their own.' While there are patients who need to be rescued such those mandated as part of legal court proceedings, some do 'self-refer' when he/she is ready to enter/re-enter treatment, usually after lacking the funds to maintain their addiction or truly recognizing the benefits of MAT. Beneficence is the ethical principle of doing good and preventing harm. The nature of our service dictates the ultimate belief in making a difference in the individual with addiction through offering a low-cost service with the end goal of achieving sobriety and preventing untimely deaths. For example: If a patient who has OUD was admitted to a hospital for syncopal episodes, the hospital providers confirm the patients' status with the OTP and notify of reason for admission. Upon the patient's return to the OTP, (with or without a discharge summary), the OTP staff must contact the hospital

providers or pharmacy to establish the last dose. It was determined the patient left the hospital AMA and methadone was reduced to one-half dose because of QTc prolongation. Despite patient's frustration because of the delay in dose confirmation, the goal is to 'do no harm,' and as providers we recognize the potential risks for harm associated with methadone and the QTc prolongation. Justice is the ethical principle of treating individuals who are equal in the same manner. Confidentiality is a right granted to all patients in an OTP. It means clients' records and information will not be shared without the patient's consent except in legal, medical, and mandated reporting.

Our patients benefit from the principles of ethics when our clinical nurse allows flexibility when scheduling the annual history and physical. The practice of beneficence is demonstrated when a client who is ineligible for a take-home-dose privilege who plans to miss treatment for two days due to work obligations and off-site visit with a supervisor. The alternative is to arrange for guest dosing, which creates suspicion (as the patient has to leave for dosing) and the patient wishes to maintain confidentiality. The best option is to grant the take-home-doses to maintain stability in dosing, thus preserving her confidentiality. The take-home-bottles or guest-dosing options are considered whenever a patient has scheduled vacation or a family emergency. However, the nearest OTP is 30 miles away, and he relies on public transportation or family members, and has to pay a daily fee for methadone. In this context, the reasonable and fair alternative is to approve the vacation bottles. If a similar situation involves a middle-class patient who has access to a private car and is able to pay the fee but expresses concerns about confidentiality (family may inquire of plans, whereabouts) and the location of the OTP clinic presents challenges, the provider grants the take-home privilege to a middle-class patient who

does not encounter these barriers. In these scenarios, justice is practiced (evident) and patients' confidentiality is maintained.

Evaluation of Outcomes/Results/Analysis of Data

The Doctoral Project's primary objective was to evaluate NPs in a shared-care model using Donabedian's structure, process, and outcomes by applying the inter-professional collaboration in an OTP. The NP-MD shared care model integration results in improved provider access, evidenced by the 1280 encounters compared to 610 to the same periods three years prior. There is a 30% (was 50%, now 80%) improvement in patient satisfaction as opposed to 50%. The reduced and practicable provider workload has directly contributed to improved access and patient satisfaction and is a positive consequence of the shared-role concept. The results show a mean of 10 encounters daily, with the lowest at five and the highest at eighteen, with 73% of encounters fulfilled by the nurse practitioners. Of these 73% encounters, 50% occur between the hours of six-fifteen to nine O'clock. The majority of the encounters addressed medication management and history and physicals.

The surveys were scheduled for twenty-six months after the addition of NPs to allow completion of orientation, acquisition of knowledge relevant to addiction management, and exposure to various situations unique to an OTP. However, due to the global COVID-19 pandemic, the survey's completion was delayed. The OTP has implemented and utilized telehealth practice however, its use was not applied during the survey to prevent the halo effect. The impact of the NP-MD shared care implementation on patient satisfaction was compared to the difference in the pre-and post-implementation survey.

The post-implementation 2020 survey (n=100) with 90% respondents shows improvement in providers' access and patient satisfaction compared to the 2017 results. In the 2017 survey, the question "Did you see the provider you wanted to see today?" 50% (n=90) responded "no," 30% responded "yes," and 10% provided a neutral response. In the 2020 survey, 80% responded "yes," while 20% responded "no." In the 2017 survey, the response to the question: "Did you have to wait longer than twenty minutes to see a provider? 60% of respondents answered "yes," 35% answered "no." In 2020, 75 % responded "no," while 15 % responded "yes." In the 2017 survey, the response to the question: "How satisfied are you with the provider management?" was associated more with negative provider attitude at 60% in 2017 whereas in 2020, the provider availability improved the patient satisfaction to 80 % extremely satisfied, 10% satisfied, and 5% not satisfied, and 5% provided neutral responses. For providers, there is no comparative data. The responses: Frequently (3) Occasionally (2) Never (1) assess provider workload: How often did you have to complete encounter documentation the following day? Two-thirds responded "occasionally," and one-third responded "never." How many times have you felt overwhelmed with your role in the last 30 days? Two-thirds responded, "Never." The response: Frequently (3) Occasionally (2) Never (1).

Sustainability

The CTP is funded through an OASAS grant of two million annually. The OTP is licensed to treat 500 patients. The addition of NPs has improved provider access, increased patient satisfaction, and reduced provider burden in the OTP. As a result, there is an increase in the number of encounters with the resultant increase in billing, reduced the episodes of missed encounters, and decreased wait times. The opportunity to increase patient enrollment exists

without compromising patient care as the NPs augment healthcare quality in the shared model of care through improved patient access. NPs educate, advocate and facilitate care for their patients whenever indicated. It is economical to retain NPs whose salaries are commensurate with their experience. NPs provide exceptional service with competence and can cover medical leave, vacation, or any other unforeseeable event. The NPs salaries of $90,000 each annually are in the OASAS grant and the umbrella hospital. The increase in billing and funding leads to the continuation of the shared care model for the foreseeable future.

Budget

The NPs salaries of $90,000 each annually are under the central hospital budget and the SAMHSA/OASAS funding of the program. The prior budget covered two physician providers, whereas the current budget covers the medical director and two NPs with increased provider hours. Before the NPs' addition to the team, there were reduced encounters and thus fewer daily billing. The stakeholders intend to continue with the current staff of two part-time NPs and the physician provider, who also functions as the medical director. This staffing assures consistent provider coverage and has guaranteed a $50,000 surplus annually, reflecting a positive ROI.

Discussion

The findings of this qualitative improvement project demonstrate the implementation of NP-MD shared-care role in an OTP proves beneficial. The research question inquires whether NPs addition increases provider access, improved patient satisfaction, and improved provider efficiency is demonstrated in the 1280 encounters, compared to 610 in the same period three years prior. It is imperative to clarify that the onset of the COVID-19 pandemic confounded the execution and outcome of the quality improvement, as the state of emergency was issued on

March 07, 2020, by the NYS Governor. The Centers for Disease Control recommended gatherings of 50 or less on March 15, 2020. The "blanket waiver" was issued by the OASAS as part of mitigating the spread of the COVID-19 virus. During the first phase of the lockdown in March 2020, those patients on a daily schedule were reduced to an alternate pick-up schedule (Monday-Wednesday-Friday or Tuesday-Thursday-Saturday) instead of daily attendance reduce crowding and potential exposure. The CTP implemented telehealth practice to continue service, facilitate crowd control, and the reduced risk for exposure. Whereas all patients were easily accessible via telehealth, not all patients possessed a smartphone to access telemedicine for video calls.

Increased Provider access in an OTP setting/Structure Data collection reveals 1280 encounters and 73 rescheduled appointments during the six months of data collection. Compared to 2016-2017, during September to February, before the NPs addition, the estimated total is 610 encounters, reflecting a mean of 5 daily encounters. Most of the rescheduled encounters were for history and physical (H&P) completion and medication management (dose reductions and schedule change). The rescheduled encounters are done the following day or at the patient's convenience. One caveat with OTP workflow, inherently, days with just one provider, the H&P is electively not scheduled to allow for access, the flow of patients, and avoid delays.

In the immediate period post-NP-orientation, the application and relevance of the ICP model dimension of interdependence are evident. The MD-provider determines eligibility for MAT and completes the new admissions. The MD-provider manages cases involving suspected medication diversion (loss or stolen medications require a police report). The MD-provider usually evaluates patients with multiple acute and chronic comorbidities such as

cardiomyopathy, congestive heart failure, and end-stage chronic obstructive pulmonary disease to assess the MAT dose and the adverse effects of methadone, i.e., prolonged QTc. Over time, with knowledge and experience, NPs are now capable of managing new admissions and complex cases.

During the pandemic, NPs were granted a "blanket waiver" for admission completion. The NPs account for a higher volume of patient encounters due to longer provider hours in the OTP. We have implemented patient-centered scheduling for annual H&P to include patient participation based on availability and convenience and improve adherence. Completing the H&Ps and annual laboratory screen is essential as they allow us to monitor the effect of methadone on patients' liver function, screen for HIV, Hepatitis C, infection, pregnancy, diabetes (new onset or uncontrolled), or underlying bleeding disorder. We are availed the opportunity to assess and inquire on coping skills with chronic conditions such as asthma, diabetes, hypertension, mental illness, and the opportunity to educate patients on the rationale for continuing medications, lifestyle adjustments such as smoking cessation, dietary adjustments, and the inclusion of physical activities in daily routine to combat weight gain.

During the H&P completion, some patients have disclosed self-discontinuation of prescribed medications for various reasons: "I have stopped taking the medication because my blood pressure is better." (The blood pressure is high). "My doctor stopped it." (The patient did not return for a refill). Or "I did not know I am supposed to take it forever)." Others report self-discontinuation because of side effects such as erectile dysfunction (ED). It is at this point the realization dawns on us (NPs) the patients lack insight and knowledge which warrants education and instructions to initiate a discussion with their primary provider for an alternate medication.

Our patients' education includes the recommendation for primary care evaluation (PCP) for dysuria, elevated blood pressure, and the need for routine age and gender-appropriate screening for known familial risk factors. Other times, a patient fails to disclose signs of infection (such as an abscess from intravenous drug use), wheezing, or abdominal pain, are usually discovered during the physical examination. Other times a patient may present and 'appears' impaired, for which the appropriate actions are to with-hold the methadone and transfer to the nearest emergency room for an evaluation. In non-life-threatening scenarios, the NP educates and persuades the patient to seek treatment.

While the OTPs' history and physicals are not substitutes for the PCPs' physical examination, it is especially significant for our patients without an established primary care provider. Upon an abnormal critical lab notification, the provider must notify, educate, and instruct the patient to have an immediate (usually a referral to an emergency room for acute management or subsequent follow-up care. The increase in provider access is clinically significant because much more is derived, while the initial objective is to assure provider access in the early mornings. It promotes patient safety, the assurance of licensed professional evaluation, timely encounters, and reassures patients they are valued and respected. Additionally, if there is an unscheduled provider absence, having NPs on the team allows for continuity of care.

Improve Patient Satisfaction/Process: Improvement in provider access translates to an increase in patient satisfaction of 90%. The patient dissatisfaction of ten percent relates to the provider medical-decision-making to selectively reduce a patient's MAT dose when issues such as concurrent alcohol ingestion, suboxone use, prolongation of QTc, severe cardiac comorbidity,

and obvious impairment are evident. Patient satisfaction is notably improved when life events such as acute illness, weddings, or death in the family render consideration for emergency take-home bottles for clients who have not met the criteria for take-home privilege. Still, guest-dosing arrangements place an excess burden on the patients. Conversely, the revocation of take-home doses for high-risk patients results from diversion (loss of medication), polysubstance abuse relapses (includes alcohol), and confusion (more common in the older patients who take more than prescribed or forgets to take). Typical angry responses from patients are: "Why do you have to cut my dose?" "It is just going to make me use it more!" "This is messed up!" "They never did this at my other program!" Verbal threats directed at staff is not tolerated, and the OTPs response is detoxification or transfer to another OTP. The need to engage law enforcement is rare. Generally, whenever providers follow the established guidelines, patients are more dissatisfied.

The NP providers reiterate patient safety is our goal. We educate and encourage patients to be transparent in their illicit substance use, to allow us to provide safe and appropriate management. Many patients are honest and inform us of their relapse (usually confirmed on urine drug screens. However, urine toxicology never lies, yet some patients will vehemently deny illicit use. The OTP can request a laboratory breakdown of the positive specimen and send a repeat urine screen for confirmation.

Respectful language is employed in conversations to convey consideration, dignity, avoid labelling, and reassure our patients the overwhelming concern is for their well-being. Initially, the patients were pleasantly surprised when they realized NPs would become permanent team members because they found us approachable and communicative. Overall, the counselors' morale has improved because most of our patients are satisfied with the treatment and have an

excellent relationship with their counselors. Counselors feel fulfilled and satisfied when able to assist their vulnerable patients. The weekly case conference offers the team an opportunity to present, share, and brainstorm the appropriate interventions for their complex and most challenging cases.

Improve Provider Efficiency/Outcome The addition of the NPs in a shared care role survey reveals two-thirds of the providers (NPs) occasionally have to complete documentation the following day. The incidence is low and occurs whenever there is a high volume of patients and just one provider due to personal emergency, sick leave, or vacation. The use of telehealth and telemedicine during the pandemic allowed for a false sense of improved efficiency, because charts are sometimes completed after the telehealth session.

Nursing Implication and Actual Impact

The improvement project results align with the knowledge NPs are known to provide competent care in multiple acute and outpatient settings and culturally diverse populations. The addition of NPs to the OTP team has improved the quality of service to our patients. The patients have benefited from empathetic and professional care. Additionally, the nurse practitioners' impact was positive among stakeholders, patients, and colleagues. Overall, we provide constant, reliable, and professional yet kind and considerate care for our patients. We provide education and counseling on harm reduction; have made recommendations to seek urgent, acute, and chronic conditions, routine age/gender appropriate screenings (breast cancer, colonoscopy), and smoking cessation. We have educated and referred patients for hepatitis screening and treatment. The NPs addition has contributed to the issuance of the three-year certification by OASAS as stakeholders perceived an overall improvement in service and documentation. The NPs can have

a potentially significant impact if the OTP adapts the full 'medical home' model to facilitate patient-centered care through convenient access to primary, mental health, women's health, dental care, and pharmacy services.

The following are a sample of patient's comments to the NPs:

"I have never been asked these questions before." (*Inquiry/Concern*)

"My physicals never last this long." (*Favorable*).

"I like talking to you guys." *(Compliment*)

"Now I understand why I should still take my blood pressure medication."(*Education*)

"I am the office aide in a doctor's office, and I overheard a patient's complaint: "The doctor did not call in my colonoscopy prep, what is that?" (*Education*)

Why do you want to talk to my psychiatrist about my meds?" (*Collaborate*)

"I cannot give urine today. I have a shy bladder." (*Negotiate for an oral swab instead*).

"I spilled my methadone." *(Evaluate for partial re-dose)*

I do not need you to talk to my pain management; I am not giving any consent!" (*Collaborate)*

DNP candidate: "Your lab results show your fasting blood glucose is 600 mg/dL. You need to go to the emergency room for treatment to lower your glucose. *Patient: "I just relaxed. I can't do it right now."*

DNP candidate: I had to persuade the patient to seek care through education, consequences, offering to call an ambulance (he declined), and ER notification.

The evaluation of quality practice demonstrates the improvement project as a success and can be adapted, especially in rural communities with limited providers.

SECTION V SUMMARY

Strength and Limitations

The NP-MD shared-care model in OTP demonstrates the management provided by NPs is professional, high quality, and cost-effective. NPs are approachable, spend more time assessing and providing relevant patient education. The NPs are 'a welcomed presence' felt by patients and staff. Strength of this project included the mixed population and age groups. It was challenging to randomize for the survey because the pandemic forced alternating schedules. The findings in this quality improvement project is limited to this OTP, as there is variation in OTP practice, population, services offered, staffing, and operating hours. The small sample size is a limitation. New York State is one of the States supporting collaborative practice agreement; hence there are no NP-led OTP clinics. The SAMHSA and OASAS's governing policy and procedures outline denote the 'medical director' as a physician. It mentions APP (NPs), however, in supporting and substitute roles. Of note, the Sars-Covid-19 pandemic allowed for the emergency 'blanket waiver approval' for NPs to complete admission assessment and the initiation of treatment precisely because of the increased demands during the 2020 pandemic on all healthcare providers.

Implications, Recommendations, and Conclusion

This evaluation's findings apply to this program only as other programs' operations may not be identical or comparable. The evaluation results support OTP's need to improve patient access to substance abuse, mental health, primary care, women's healthcare and advocacy by integrating these services, commonly known as 'medical homes.' The 'medical home model' of healthcare provision exists in NY State but has room for further expansion to meet the vulnerable population's healthcare needs. Additionally, these clients have encountered stigma because of their socio-economic status, co-occurring mental health disorders, criminal justice history, refusal and reluctance to seek medical care, and OUD. For these reasons, it would be ideal if the patients' primary healthcare needs are available in a 'medical home' setting.

A doctoral-prepared NP can advocate and lead the integration of medical homes to meet patients where they are while allowing for easy access to quality healthcare and collaboration among providers. Approximately eighty percent (80%) of the patients requiring MAT are covered under New York State Medicaid insurance; the remainder is on a sliding scale, thus limiting a patient's access to quality healthcare. OTPs should be standardized nationwide; however, the services provided reflect population demographics, health needs of individual communities, funding, and oversight by SAMHSA.

Despite the affiliated hospital operate an OTP in a different borough, the opportunity did not arise for the new NPs to observe, learn, and adapt portions of their approach towards improving this OTP. Further, as a community teaching institution, collaborating with an institute of higher learning at the Masters' level should be facilitated to offer NP-student clinical hours to become familiar with the management of addiction disorders. The NPs orientation for OTP lacks

a standardized process and should be considered for future NPs. Haffajee et al. (2018), supports the standardization of the graduate programs for NPs and PAs to include addiction training and education to facilitate a good foundation. At the time of publication, the Haffajee reports SAMHSA is sponsoring a grant for the PAs programs. A similar program should be introduced for NPs.

Because the CTP serves a diverse population, a language-translation line should be available for use if specific (more frequently Spanish-speaking) staff is unavailable to facilitate translation. This issue has involved only Spanish-speaking patients; however, the possibility exists for other non-English speaking patients to encounter this barrier in treatments. The hospital leadership should apply for and accept Medicare and commercial insurance in the treatment of OUD, as addiction is a recognized diagnosis for which treatment is available. I believe if the CTP accepted commercial insurance, more working patients would likely seek care.

The need for OTPs in rural areas is urgent. The New York State government has allotted $25.2 million in federal funding to identify new initiatives in combating the opioid crisis. It is imperative additional funds are allocated for addiction research as there is a need for new strategies. As leaders in the healthcare field, it may be practical for MAT to be distributed in rural communities by pharmacies in collaboration with primary care providers or mobile treatment clinics; however, a mobile clinic may present safety and security concerns. The operations' intricacies would be structured to meet the setting, such as daily medication dispensing for the first week, then automatic every three to four days administering, coupled with

weekly urine, its duration to be determined by the provider. With federal funding, legislators and hospitals in the underserved areas should explore how best to provide addiction services.

Based on CDC statistics on opioid addiction, treatment will be necessary for the foreseeable future. For this reason, nurses and advanced practice nurses must be prepared to meet the needs of communities with OUD in all aspects of care, including the prevention, identification, treatment and education, and rehabilitation of the affected population. Experienced nurses and advanced practice nurses who pursue advanced degrees and certification in specialty fields promote the IOM objective of doubling the number of nurses with doctoral degrees. For academic faculties and advanced clinical practice nurses to demonstrate knowledge and expertise in a chosen specialty, institutions must utilize them at their highest education level (Finnell et al., 2019).

AACN Essentials of Doctoral Education for Advanced Practice Nursing

This quality improvement evaluation aligns closely with selected competencies set forth by *The AACN Essentials of Doctoral Education for Advanced Practice Nursing* (2006), which expects the doctoral-prepared graduate to apply scientific underpinnings for practice (I) through the use of organizational systems thinking. Leadership acumen is needed to improve healthcare outcomes through applying and analyzing artificial intelligence (AI). The advanced practice doctoral-prepared provider endeavors to enhance inter-professional collaboration for vulnerable patients and population health outcomes (VI). The DNP-NP is prepared to advocate and institute policies geared to improve health access in underserved populations, educate healthcare systems on evidence-based practice (III), and disseminate relevant research to effect change (V).

The promotion of the medical home's full use to meet the needs of individuals with addiction and mental illness in medically underserved areas can significantly impact healthcare access and utilization. In providing healthcare, the doctoral-prepared graduate demonstrates competence in completing the comprehensive physical assessment (VIII), using a culturally sensitive approach, appropriate language, and reducing the appearance of stigma to encourage patient utilization and maintain retention in treatment.

Role of DNP in Capstone

The DNP program prepares the advanced practice provider for leadership, health policy, and global health. Ideally, the role involves an innovative change to impact the underserved and vulnerable population's lives, such as those struggling with addiction, gender identity, mental illness, physical disabilities, children and elder abuse, un-domiciled population, and incarcerated individuals. The DNP-prepared NP is competent to explore, implement, and lead new programs to address health care disparities.

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Table of Evidence

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Alcaraz et al, (2018). Heroin-dependent patient satisfaction with methadone as a medication influences satisfaction with basic interventions delivered by staff to implement methadone maintenance treatment	Exploratory Spain	Completion of a 15-point SASMAT-METHER to assess their satisfaction with methadone for heroin treatment.	A sample of 210 heroin dependent resistant to methadone treatment (mean age =41.66 years, SD = 6.50; 75.7 % male) participated voluntarily.	The aim of the study was to test a structural equation model of patient satisfaction with different key facets of methadone maintenance treatment. In this study the 3 dimensions of patient satisfaction with methadone on personal functioning and well-being, anti-addictive effect on heroin, and anti-addictive effect on non- opioid substances	Results shows patient satisfaction with the compatibility of methadone with personal functioning, wellbeing, and anti-addictiveness effects of methadone on non-opioid substances predicts satisfaction with basic interventions (®=0.191 and (® =0.152,) respectively). It also suggests that understanding of patient satisfaction could help better understand patients' perspectives and experience.	Level IIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Andrilla et al, (2018). Projected Contributions of Nurse Practitioners and Physicians' Assistant to Buprenorphine Treatment Services for Opioid Use Disorder in Rural Areas.	Survey and State scope of practice regulations	Using existing public data sources, data and results from a prior national survey of rural physicians with a DEA waiver conducted by the WWAMI Rural Health Research Center, estimates were made of a variety of factors which contribute to the number of NPs and PAs who get a DEA waiver and how they use it. The # of NPs, PAs, and MDs in each US county with a DEA waiver were estimated.	NPs, PAs, and MDs	The study was conducted to project the potential increase in MAT availability provided by NPs and PAs for rural patients.	NPs and PAs are projected to increase the number of rural Patients treated with buprenorphine by 10,777.	Level IIIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Aziz, Z and Chong, N (2014). A satisfaction survey of opioid - dependent patients with methadone maintenance treatment.	Cross-sectional Malaysia	This cross-sectional study was conducted in 11 centers in central, north, east, and south regions that were methadone-dispensing centers for at least 3 months. The survey included participants who have been in the program the month before. The interviews were conducted by two trained interviewers over a two-month period.	502 participants were invited. 425 agreed to participants, which represents a response rate of 85%. The respondents were all males except for 2 females, age range 14 to 74, with a mean age of 39.	The purpose of the study was to examine patient's satisfaction with the MMT services offered by MMT centers in Malaysia to identify factors which predict overall satisfaction	The percentage of respondents who indicated that they were satisfied with the MMT Service at the centers were high 75%-90%, would recommend the program to a friend, and had positive comments about the service provided	Level III

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Barnett et al. (2018). Drug and alcohol treatment providers' view about the disease model of addiction and its impact on clinical practice: A systematic review.	Systematic quantitative and qualitative: USA	Systematic review of quantitative and qualitative studies focusing on DMA	2193 papers, 141 were selected, further narrowed to 63 of which 26 met the final inclusion. Eight additional papers were selected from references in these papers	A review of treatment providers' attitudes about the brain disease model of addiction (BDMA). Examined factors associate with positive and negative attitudes and assessed their views on the potential clinical impact of both modes.	Support for the DMA was positively associated with the treatment provider's age, year of qualification, certification status, religious beliefs, being in recovery, and Alcohol Anonymous attendance	Level IIA

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Bates and Martin-Misener, (2021) (Canada) Facilitators and Barriers to Nurse Practitioners Prescribing Methadone for Opioid Use Disorder in Nova Scotia: A Qualitative Study	Qualitative	Interviews: In-person and telephone	18 Participants: NPs(n=5) MD (n=5) Stakeholders (n8)	To identify facilitators and barriers to NPs prescribing methadone	The barrier of stigma, the perceived complexity of patients living with an OUD.	Level IVC

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Bourion-Bedes et al (2017). The effects of patient and physician characteristics on the early outpatient satisfaction with substance dependence care: results of the SUBUSQOL study.	Questionnaire	Cross-sectional analysis with multiple linear regression was performed to identify the variables associated with satisfaction level.	249 outpatients were included, with 63% completed the questionnaire	This exploratory study assessed the relationship between patient and physician characters and early outpatient satisfaction with care for alcohol and opioid dependence.	Patients without a history of previous care for substance dependence were more satisfied with the appointment making process (®=7.2; *P*+0.29) and with the doctor consultation (®=10.3; *P*=0.003) than those who had received treatment previously.	Level III

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Carryer, J and Adams, S. (2016) Nurse Practitioners as a solution to transformative and sustainable health services in primary care: A qualitative exploratory study	Qualitative Interviews New Zealand	Interviews and observational studies	13 Nurse Practitioners in rural areas in private practice, health clinics by District Health Boards, not-for-profit health providers, and community indigenous health clinics.	To consider the alignment of the Nurse Practitioner (NP) role in NZ with the goals and aspirations of the many countries facing challenges in maintaining health service delivery and reducing health disparities.	The findings demonstrate that NPs have competently taken on a range of previously deemed medical tasks but also practice congruently with a nursing approach to practice. NPs provide complete person and family centered care, focusing on seamless and integrated service delivery. Has roles that limit potential.	Level IIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Cimiotti et al., (2019). Regulation of Nurse Practitioner Workforce: Implications for care across settings	Cross-sectional survey USA	Cross-sectional survey data from a sample of NPs actively employed in four states with reduced or restricted practice. (Florida, California, New Jersey, and Pennsylvania) were used	NPs in the sample (N=21,629), 6539.respondents: 1,263 were acute care; 2,343 worked in primary care; 2,933 were excluded because they worked in other settings/or missing data	To examine the impact of SOP regulations on three key issues: NP workforce, access to care and healthcare utilization, and healthcare costs.	Receiving support from administrative staff and physicians were associated with an increase in the three measures of quality. The greatest effects were seen in primary care settings	Level IIIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
D'Afflitti et al., (2018). USA Improving Provider Experience and Increasing Patient access through Nurse Practitioner-Physician Primary Care Teams.	Case Study	Introduction of the NP Anchor model	Two nurse practitioners, Eight Physicians, and seventy medically complex patients	This purpose of this study was to examine a model of NP-MD care team in an urban safety-net primary care practice to reduce provider burnout.	NP Anchor teams improved access to care for patients with a member of their care team (either NP or MD). The investigators found that most physicians felt the NP Anchor model was helpful in reducing the between-visit workload, a driver of physician dissatisfaction and burnout while maintaining high levels of job satisfaction for the NPS.	Level VB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Donelan et al., (2013). Perspectives of Physicians and Nurse Practitioners on Primary Care Practice.	Postal-mail survey (USA)	A National postal-mail survey was conducted from November 23, 2011 to April 9, 2012 of 972 clinicians.	505 physicians and 467 NPs) in primary care on scope of work, practice characteristics and attitudes about the expanding roles of NPs in primary care with 67% response.	To examine the perspectives on proposed expansion of the NPs role to expand primary care access.	Physicians reported working longer hours, seeing more patients and earning more. 80.9% NPs worked with an MD while 41.4% of physician worked with an NP. 66.1% of physician agreed that 'physicians provide higher quality exam than NPs' 75.3% NPs disagree.	Level VB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Ford II et al (2007). Process Improvement Needs in Substance Abuse Treatment: Admissions Walk-through Results.	Qualitative Study: Descriptive and exploratory.	Walk-through	327 applicants to Robert Wood Johnson Foundation (RWJF) and the Center for Substance Abuse and Treatment (CSAT).	The purpose of the qualitative study was to identify admissions-related problems	The study identified poor staff engagement with clients, burdensome processes and procedures, the difficulties in addressing the patients' complex lives and needs, and infrastructure problems.	Level VD

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Gardner, Gardner, and O'Connell (2012). Using the Donabedian framework to examine the quality and safety of nursing service innovation.	Mixed methods Australia	The Donabedian framework was used to evaluate the structure, process, and, outcome of nurse practitioner service. The investigators used stakeholder surveys (n=36), in-depth interviews (11 patients, and 13 nurse practitioners), and health records data on service processes.	36 stakeholders, 13 nurse practitioners, and 11 patients.	To evaluate the safety and quality of nurse practitioner service using the audit framework of Structure, Process, and Outcome.	The study demonstrates the Donabedian framework of Structure, Process, and Outcome evaluation is a valuable and validated approach to examine the safety of a service innovation.	Level IIIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Gryczynski et al. (2011) (USA). Patterns in admission delays to outpatient methadone treatment in the United States.	National Survey and Data Collection.	Used a combination of national data sources: Treatment Episode Data Sets (TEDS), National Survey of Substance Abuse Treatment Services (N-SSATS), and Core-Based Statistical Area (CBSA).	40 U.S metropolitan areas (N=28,920)	The purpose of this study was to assess what patient and service system factors are related to admission delays that stem from program capacity shortfalls.	The study found patient characteristics associated with admission delays included racial/ethnicity minority status, lower education, criminal justice referrals, prior treatment experience, secondary cocaine or alcohol use, and co-occurring Psychiatric problems. The researchers found increased community use of methadone was associated with delay, whereas delays were less evident in communities which utilized alternative modes of therapy.	Level IIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Jones et al. (2019). (USA). Characteristics and current clinical practices of opioid treatment programs in the United States.	Survey	National Survey of U.S. OTPs using a 46-question electronic survey instrument collected data between August 2018 and October 2018	497 OTPs (31%)	To determine OTP services in characteristics, services offered, and current clinical practices.	The survey found among responding OTPs 32.4% used all three medications for treatment; 95.8% used methadone only; 61.8% used buprenorphine, and 43.9% used naltrexone. The mean (SD) number of patients currently receiving methadone was 383 (20.4); buprenorphine 51 (7.0), and extended-release naltrexone 6 (1.0).	Level IIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Kelley, et al (2010). The Role of Patient Satisfaction in Methadone Treatment	Correlation USA	Completion of the Client evaluation form (CEF) and the Addiction Severity Index (ASI). Regression analysis assessed the relationship between satisfaction and drug testing at 3 months and was used to predict whether a patient remained in treatment at 12 months	283 opioid-addicted individuals newly enrolled in one of six Baltimore area methadone maintenance treatment program.	The aim of the study was to measure the three and twelve – month retention.	Participants who were more satisfied with their programs remained in treatment for at least twelve months	Level IIC

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Kilpatrick et al., (2020). A mixed methods quality improvement study to implement NPs roles and improve care for residents in long-term care facilities.	Mixed method surveys, interview, or focus groups, cross-sectional data, chart audit, and sampling. Canada	Data was collected from 9/2015-8/2016 from all residents in the NH followed by an NP.	6 NPs. Each NP had a caseload of 42-80 residents with an average age of 82	The purpose of the study aimed to identify how NP roles influence care quality for residents in long term care to inform the wider implementation of these new roles in Quebec.	The result reveals a decrease in the incidence of polypharmacy, falls, restraint use, fewer pressure ulcers, and reduced transfers to acute care	Level IIIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Kraus and DuBois (2016). Knowing Your Limits: A Qualitative Study of Physician and Nurse Practitioner Perspectives on NP Independence in Primary Care	Qualitative (based on grounded theory). USA	Semi-structured in-depth interviews with analysis guided by grounded theory.	Thirty primary care professionals. 15 primary care physicians and 15 NPs.	The aim of the study was to explore and describe the attitudes about NP independence among physicians and NPs working in primary care.	Participants had perspectives. that were not well represented by professional organizations or the media. Physicians were supportive of a wide variety of NP roles and were comfortable with high levels of NP independence and autonomy.	Level IIIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Lovink et al., (2017) Effects of substituting NP and physician assistants, for physicians concerning healthcare for the ageing population: A systematic review.	Systematic Literature review. The Netherlands	A combination of RCTs, pre-post design, and cohort studies	Initial search reveals 19,991, then screened to 11,340. Further screening using inclusion/exclusion narrowed to 105	To evaluate the effects of substituting nurse practitioners, physician assistants, and nurses for physicians in long-term care facilities and primary healthcare for the aging population (primary aim) and to describe what influences the implementation (secondary aim).	The two RCTS showed no effect on approximately half of the outcomes and a positive effect on the other half of the outcomes. The results of the eight comparative studies points in the same direction. The implementation was influenced by factors on a social, organizational, and personal level.	Level IIB

Author/Stud	Design	Methods	Participants	Purpose	Findings	CEBM Level
Livingston et al. (2018). USA. Primary Care Physicians' Views about prescribing Methadone to treat Opioid Use Disorder.	Qualitative Descriptive Study	Survey Interviews	20 Primary Care Physicians.	The purpose of the study was to explore factors that primary care physicians consider important when contemplating prescribing methadone to treat opioid use disorder.	The authors found physician-related factors includes access to methadone experts, support from allied professional, suitability of skills, and personal experience. Patient-related factors include perceptions about methadone users as difficult patient group with complex needs. The practice-related factors involve concerns about threats to careers, Surveillance duties, unfair salary, safety risks, and practice disruptions. Contextual factors were knowledge deficits on substance use disorders, primary care as general rather than specialized and opioid prescribing patterns.	Level IIIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Masso et al., (2017). A research investigating the role of nurse practitioners: A view from implementation science.	Surveys, interviews or focus groups, cross-sectional data, chart audit and sampling. Australia	A systematic review of 186 papers/studies.	1,316 patients, 7 NPs, and 11 Physicians.	The purpose of the paper was a rapid review of the literature which identified Australian research on NPs. The paper reports on those studies investigating individual roles framed in implementation science and the 3 stages implementation: Exploration and adoption of the role, initial implementation of the role, and the full operation of the role.	There was no consistency in the way the roles were described, making it difficult to compare what may be similar roles in different studies. Based on the findings, A checklist is recommended for use in future studies which would enhance the ability to make judgements about implementing NPs models of care; facilitate comparison of similar roles and increase the capacity to make informed decisions about the about the prospects for wider implementation of nurse practitioner roles or models of care.	Level IIIC

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
McCleery et al., (2014). Evidence Brief: The quality of care provided by advanced practice nurses (APRN).	Randomized controlled trials and observational studies. USA.	Medical Outcomes Short Survey Form Health Survey (SF-36).	Nurse Practitioners	Assess the strength and relevance of studies comparing autonomous APRNs with physicians in primary care, urgent care, and anesthesia care for four outcomes: health status, quality of life, hospitalizations, and mortality.	The findings revealed little new evidence regarding health outcomes of patients receiving from an independent advanced practice nurse or physician in primary care or urgent care settings. There was insufficient information on whether the quality of care provided by advanced practice nurse varies by the setting of practice to draw any conclusions.	Level IIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Moldestad et al (2020). Comparable, but distinct: Perceptions of primary care provided by physicians and nurse practitioners in full and restricted practice authority states.	Qualitative exploratory	Interviews (semi-structured) in 2016 with primary care providers and patients in states with full practice and restricted practice authority for NPs.	28 Patients, 17 Physicians, and 14 NPs	To understand the patients' and provider's perception of primary care delivered by NPs in the VA healthcare system.	Patients' preferences for NPs (compared with prior physicians) contributed to perceptions of patient centeredness. Investigators found that providers' perceptions suggest NPs and physicians are both viable providers for primary care.	Level IIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Mundinger, et al (2000). (USA) Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians.	Randomized Control Trial	RCT conducted between August 1995 and October 1997, with patient interviews at 6 months after initial appointment and health services utilization data recorded at 6 months and 1 year after initial appointment.	Of 3397 patients screened, 1316 patients (mean age 45.9 years; 76.8% female; 90.3% Hispanic) who had no regular source of care and kept their initial primary care appointments were enrolled and randomized with either a NP (n=806) or physician (n	To compare outcomes for patients randomly assigned to NPs or physicians for primary care follow-up/ and ongoing care after an emergency department or urgent care.	No significant differences were found in patients' health status. There was no difference in satisfaction ratings following the initial appointment.	Level 1A

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Neprash et al, (2020). USA. Practice Patterns of Physicians and Nurse Practitioners in Primary Care.	Cross-sectional Retrospective	First patient characteristics (age, sex, race, payer, chronic condition), visit characteristics (new patient, scheduled duration, same-day visit, after hours visit). Second, procedures performed and diagnosis during visit. Lastly, daily quantity (visit volume, minutes scheduled for patient care, total relative value units billed) of care	29, 048, 405 patients during 2017 to 12,272 physicians and 5953 NPs, practicing at 3146 primary care practices.	To describe the clinical activities of NPs compared with physicians.	Relative to physicians, NPs treated younger, healthier, mostly female, non-white, covered by Medicaid, commercial, or no insurance. NPs scheduled longer appointments and treated more same-day or 'after hours'. Overlapping services (those performed by NPs and Physicians) were 92%.	Level IIA

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Norful et al., (2019). U.S.A. Nurse Practitioner-Physician co-management of primary care patients: The on functional outcomes: promise of a new delivery care model to improve the quality of care.	Systematic reviews of : Four RCTs One cross-sectional and one case study	PRISMA framework This is a review of all available studies that compare the effects of NP-Physician co-management to an individual physician managing primary care	Six studies accepted for synthesis	The purpose of the study was to synthesize all available studies that compare the effects of NP-Physician co-management to an individual physician managing primary care	There was variability of clinical patient outcomes with some findings favors the co-management model. Across all studies, the NP–Physician co-management care delivery model was determined to produce no detrimental effect on measured outcomes and, in some cases, was more beneficial in reaching practice clinical targets.	Level 1A

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Park et al (2020). USA. Patient-centered care's relationship with substance use disorder treatment utilization	Survey Data from 2017 National Drug Abuse Treatment System Survey (NDATSS).	The researchers measured treatment clinics association between patient-centered care and the utilization of methadone, buprenorphine; behavioral treatment, routine medical care, HIV testing, and suicide prevent ion counseling.	730 sampled clinics, with a response of 657 (90%) response rate.	The purpose of the study was to measure clinics practice of and emphasis on patient-centered care on whether the clinic regularly invites patients into clinical decision-making processes and whether supervisors believed in patient-centered healthcare and shared decision-making practices within their clinics.	Only 23% of substance use disorder (SUD) treatment clinics regularly invited patients into care decision-making meetings. Patient-centered care practices are significantly associated with patient's service use. Ten percent of clinics offered methadone, 70% of clients accessed it; for buprenorphine 34% offered, while used by 16%. Behavioral, routine medical care, HIV tests an suicide prevention counseling were available in 63-83% and >50% utilized these services	Level IVB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Schwartz et al (2015). U.S.A. Patient-centered methadone treatment: a randomized clinical trial.	Two-arm open label randomized trial	Newly admitted (methadone treatment programs) MTP patients were assigned randomly to patient-centered methadone treatment (PCM, n=149) or treatment as usual (TAU, n=151).	300 newly admitted MTP patients who were enrolled between September 13, 2011 and March 26, 2014.	The purpose of the study was to investigate whether a PCM approach improved participation outcomes at 12 months.	There was no significant difference between PCM and TAU conditions in opioid-positive urine screens at 12 months.	Level IIB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Swan et al., (2015). Quality of primary care by advanced practice nurses: A systematic review.	Systematic review of random controlled trials	10 studies which represented data from 10,911 subjects who participated in seven RCTs Five studies were in Europe. One study and its two year follow up were conducted in the US. The. subjects were randomized when they presented for a general, or a diabetic-focused primary care visit, or same day consultation for any reason	APRNs and Primary Care Provider	To conduct a systematic review of randomized controlled trials (RCTs) of the safety and effectiveness of primary care provided by advanced practice nurses (APRN) and evaluate the potential of their deployment to help alleviate primary care shortages.	The findings reveal APNs groups demonstrated equal or better outcomes than the physician physiologic measures, patient satisfaction, and cost. APNs generally had longer consultations compared with groups for Physicians' however, two studies report the APNs patients require fewer consultation overtime	Level IA

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Traczynski, J. and Udalova, Victoria (2018). Nurse practitioner independence, healthcare utilization, and health outcome.	Cross-sectional. USA	The investigators used the individual level data on healthcare utilization and outcomes from the Medical Expenditure Panel Survey (MEPS) and used a difference-in-difference approach to investigate the effects of NP independence in primary care and prescriptive authority.	Data on healthcare utilization and health outcomes from the MEPS full year consolidated data files for the period 1996-2012.	The purpose of the study was to estimate the causal impact of NP Independence on population health outcomes exploiting variations in the timing of the state laws passage.	The research shows NP independence increases the frequency of routine checkup, improves care quality, and decreases emergency room use by patients with ambulatory care sensitive conditions. These effects result from decreases in administrative costs for physicians, NPs, and patients indirect costs of accessing medical care	Level IA

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Trujols et al., (2014). Spain. A critical analysis of user satisfaction surveys in addiction services: opioid maintenance treatment as a representative case study.	Literature review of satisfaction surveys in addiction treatment and harm reduction services.	A selective critical review and analysis of the literature on user satisfaction surveys in addiction treatment and harm reduction services	4 types of patient satisfaction scales: PSS-DP (developed by patients); PSS-CP (patient-centered); PSS-VP (developed without direct patient participation); and PSS-IP (developed entirely without any patient participation).	The aim of this paper is to provide a critical overview of user satisfaction surveys in addiction and harm reduction services with a particular focus on opioid maintenance treatment as a representative case	Most studies that have reported results of satisfaction surveys have found that the great majority of users are highly satisfied with the services received. However, when these results are compared to the findings of studies that leave different methodologies to explore the patient's perspectives, the results are not as consistent as might be expected.	Level IIA

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Woodhouse, G. (2009) Exploration of interaction and shared care arrangements of generalist community nurses and external nursing teams in rural health settings	Qualitative Non-experimental Descriptive Grounded theory	10-point Questionnaire completion by six members (100% response rate).	The participants were a generalist health care team consisting of registered nurses in community health, palliative care team and an aged care team.	The purpose of this study was to explore the interaction and shared care arrangements of generalist community nurses and external nursing teams in a rural setting.	Four themes emerged: a lack of understanding of each team's role; difficulties in communication; the importance of setting shared goals in care planning; and the need for collaboration to ensure clarity in case coordination.	Level IIIC

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Wong et al., (2017). Implementing two nurse practitioners' models of service at an Australian male prison: A quality assurance study.	Qualitative Australia	Data collection by survey	21 staff; 29 patients	To evaluate the quality and safety of two newly implemented NP models of care at an Australian prison.	The NPs provided 289 consultations to 208 prisoners. The presenting problems indicated that most referrals were appropriate. Both NPs spent greater than half their time on medication review, management, and individual patient-related care. The findings suggest the implementation of NPs in correctional facilities is acceptable, feasible, and has the potential to improve prisoners' access to health services.	Level VB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Ying et al., (2015). U.S.A. Impact of state nurse practitioner scope-of-practice regulation on healthcare delivery: Systematic review.	Systematic review	Combination of time series, cross-sectional design.	529 published articles were retrieved, further narrowed to 22 and further excluded 7 due to risk of bias, 15 reviewed papers selected from references in these papers.	To understand patient and system characteristics associated with performance on HEDIS, Alcohol and Other Drug (AOD) Initiation and Engagement (IET) measures.	States granting NPs greater SOP authority tend to exhibit an increase in the number and the growth of NPs, greater care provisions by NPs, and expanded health care utilization especially in rural and vulnerable populations. The findings shows promise that removing restrictions on NP SOP regulations could be a viable and effective strategy to increase primary care capacity.	Level IB

Author/Study	Design	Methods	Participants	Purpose	Findings	CEBM Level
Yarborough et al., (2018). Patient and Systems characteristics associated with HEDIS measures of alcohol and other drug treatment initiation and engagement.	Mixed method study linked patients and health data. USA	The investigators used comparison.	44,320 commercial or Medicare insured.	To understand patient and system characteristics associated with performance on the Healthcare Effectiveness Data and Information Set (HEDIS) Alcohol and Other Drug (AOD) Initiation and Engagement of Treatment (IET) measures.	Tailoring treatment, enhancing treatment motivation among individuals with lower severity diagnoses, offering medication treatment of addiction, clinician education, care coordination, co-located AOD and primary care departments, and behavioral medicine specialists in primary care may improve rates of initiation and engagement in AOD treatment.	Level III

APPENDICES

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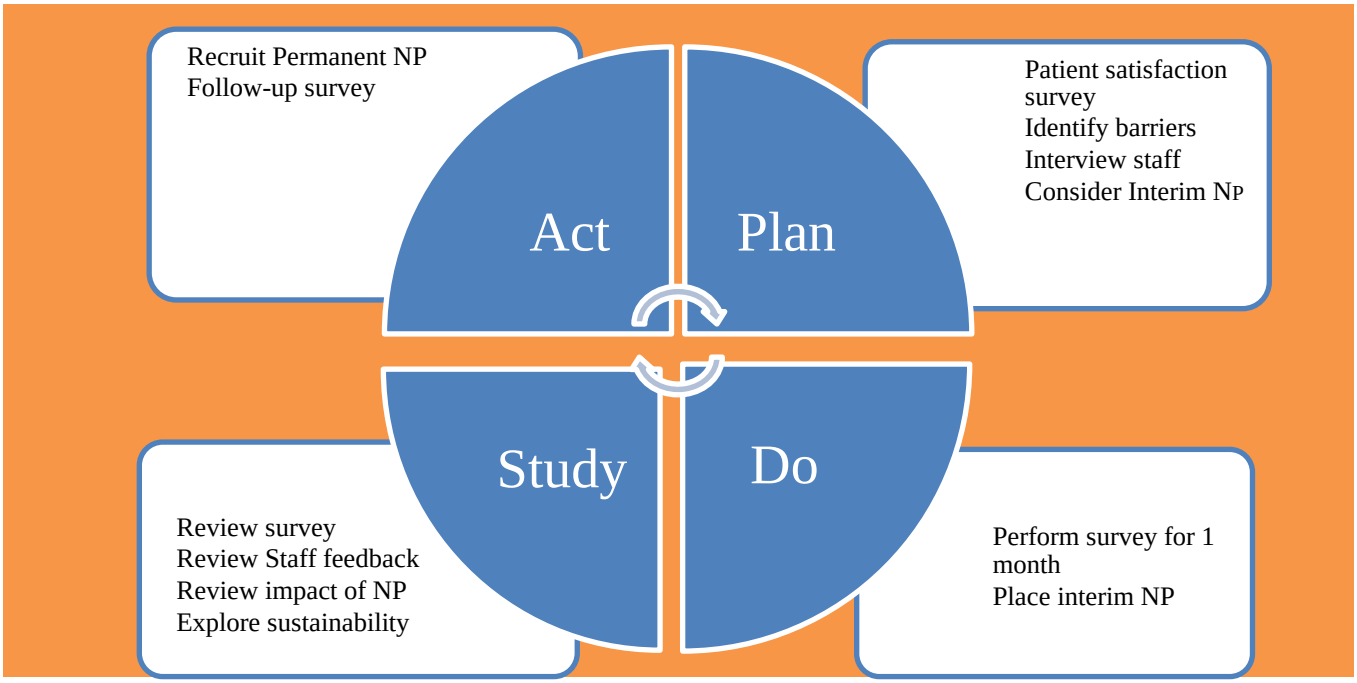
Appendix A.201 Classification of Level of Evidence and Quality Guide

Strength of Recommendations	Level of Evidence	Study Design
A	I	Large randomized controlled studies (RCT) (N>100). Systematic Review of RCTs
B	II	Systematic Review of Cohort studies, Randomized Controlled Trial, Observational study with dramatic effect. Inception of cohort
	III	Systematic Review of Case Control Studies, Non-randomized Cohort study
C	IV	Case Series, Case Control Studies
D	V	Expert opinion Case study Bench research Anecdotal evidence

Appendix B. SWOT Analysis

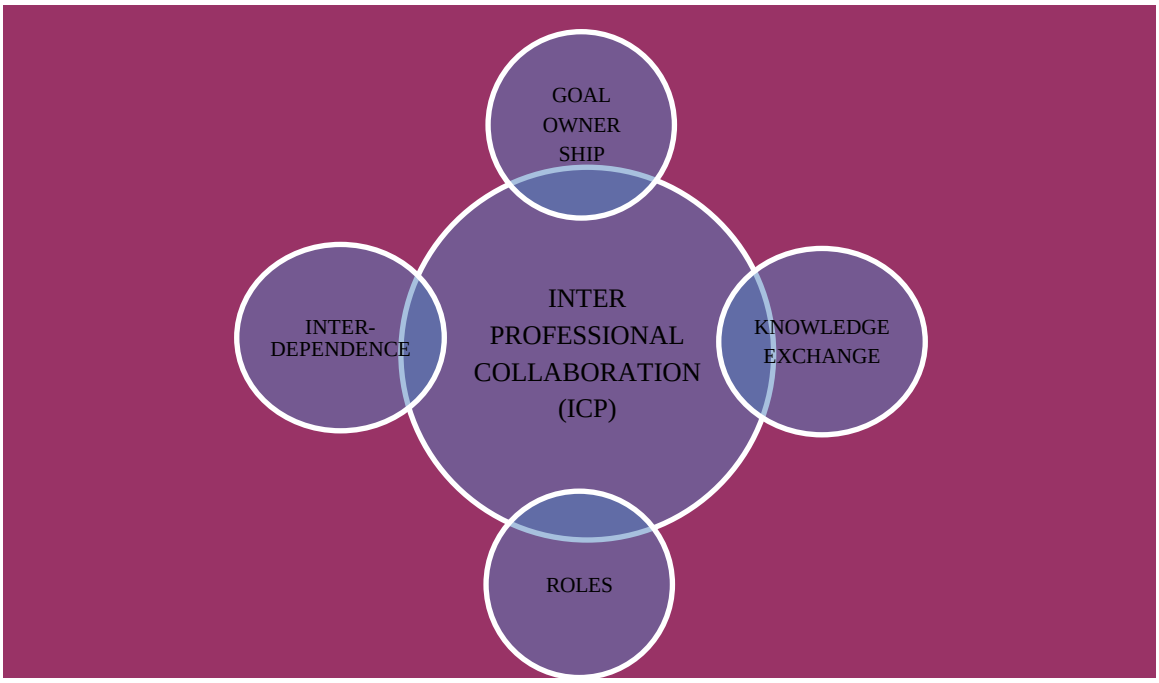
Appendix C. PDSA Cycle



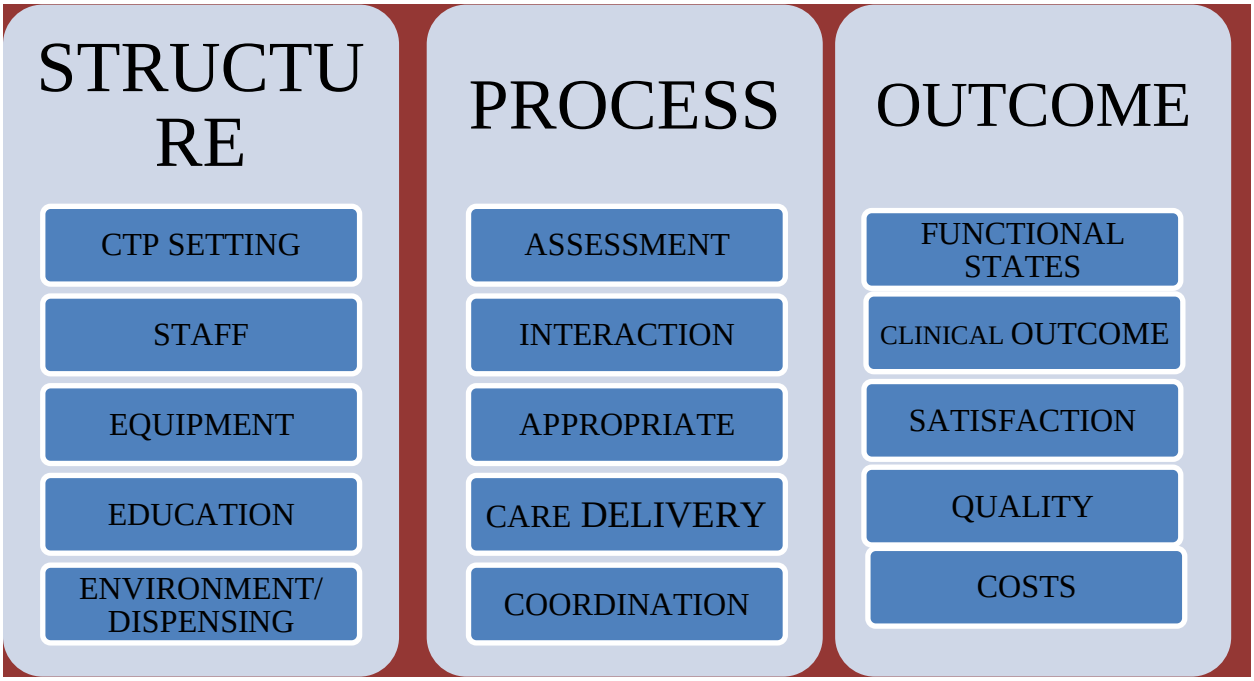
Appendix D. Project Conceptual Framework

Structure	Process	Outcome
County Treatment Program (CTP)	Addition of nurse practitioners to improve service	Improve service to clients Improve provider efficiency
The availability of NP provider	Timely access to NP/ Provider	Improved quality of service Reduced delays in treatment
		Improved ROI

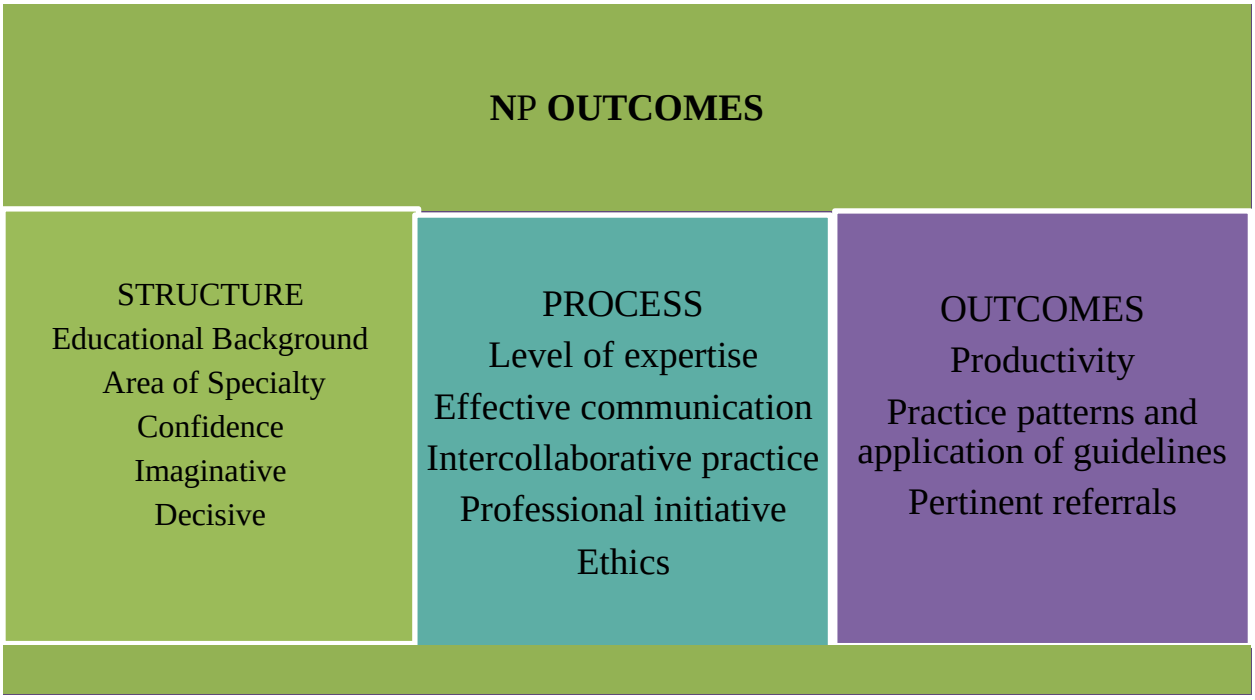
Appendix E Inter-professional Collaboration



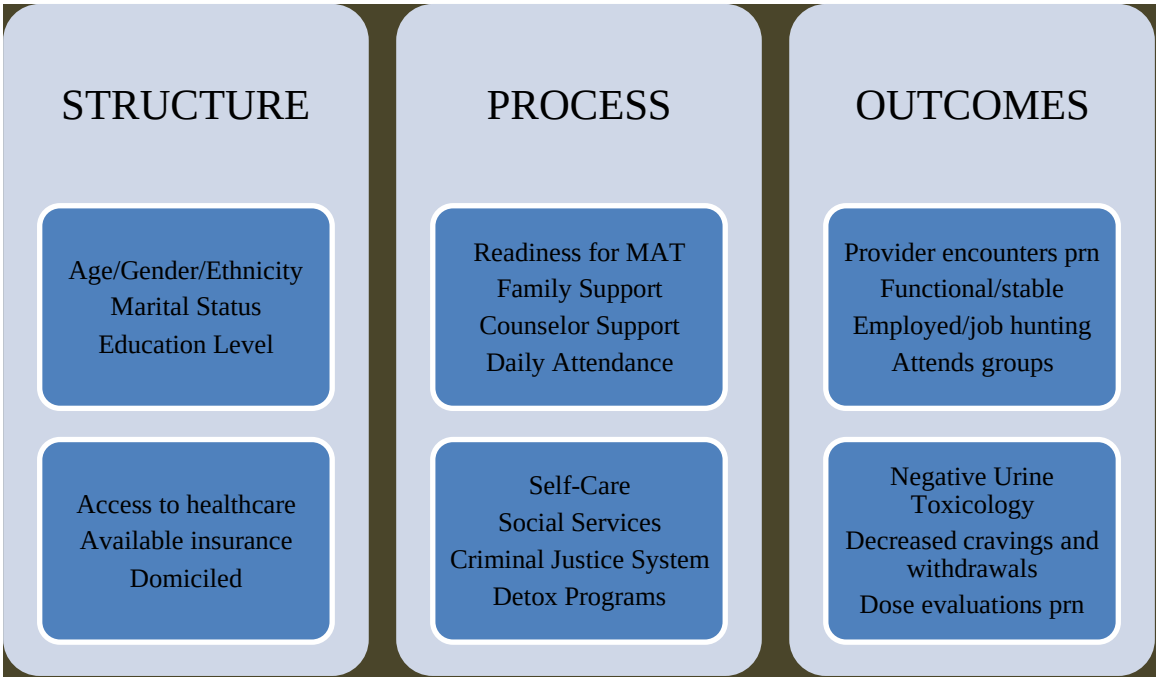
Appendix F **CTP OUTCOMES**



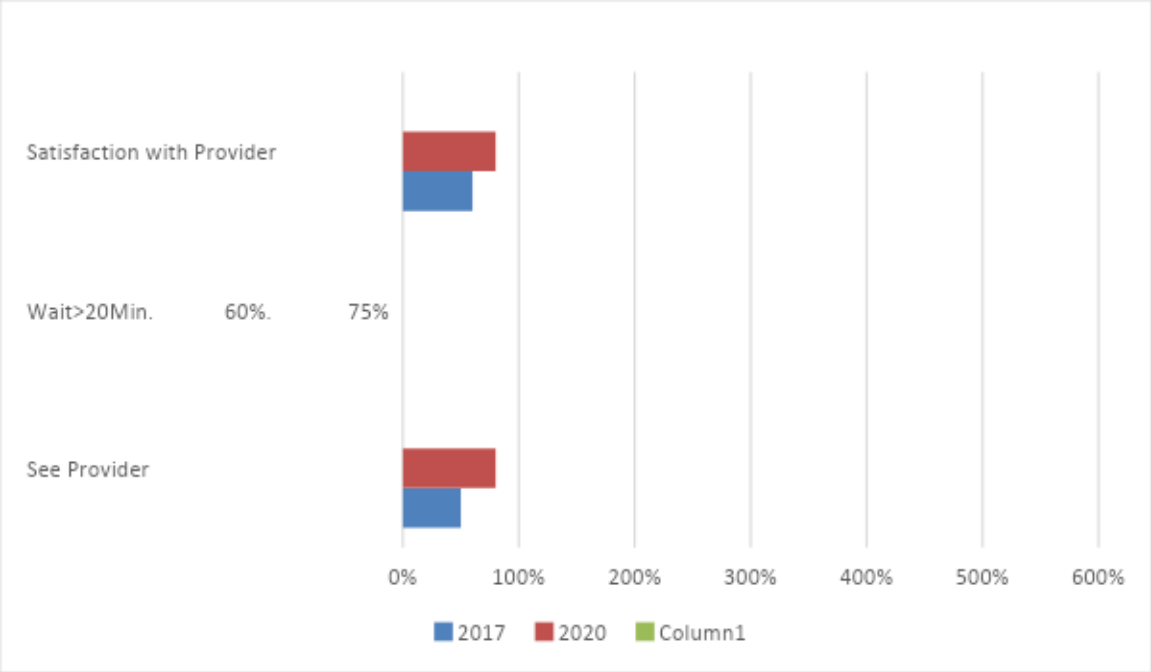
Appendix G NP OUTCOMES



Appendix H. Patient Outcomes



Appendix I Pre and Post-Implementation



Appendix J. CTP Patient Satisfaction Survey

Please respond to the following question regarding your personal experience in treatment by circling the number that corresponds to your experience.

1. Have you seen the provider you wanted to see today?

The scoring is based on the Likert five-point scale:

(5) Always

(4) Almost Always

(3) Frequently

(2) Sometimes

(1) Never

2. Did you have to wait longer than 20 minutes to see a provider?

(1) No

(2) Yes

3. How satisfied are you with the provider management?

(A) Extremely satisfied

(B) Satisfied

(C) Dissatisfied

(D) Neutral

Provider Satisfaction Survey

Please respond to the following question regarding your daily workload: How often did you have to complete encounter documentation the following day?

Frequently (3)

Occasionally (2)

Never (1)

Appendix K **Job Description: Nurse Practitioner**

County Treatment Program, Yonkers, New York Opioid Treatment Program

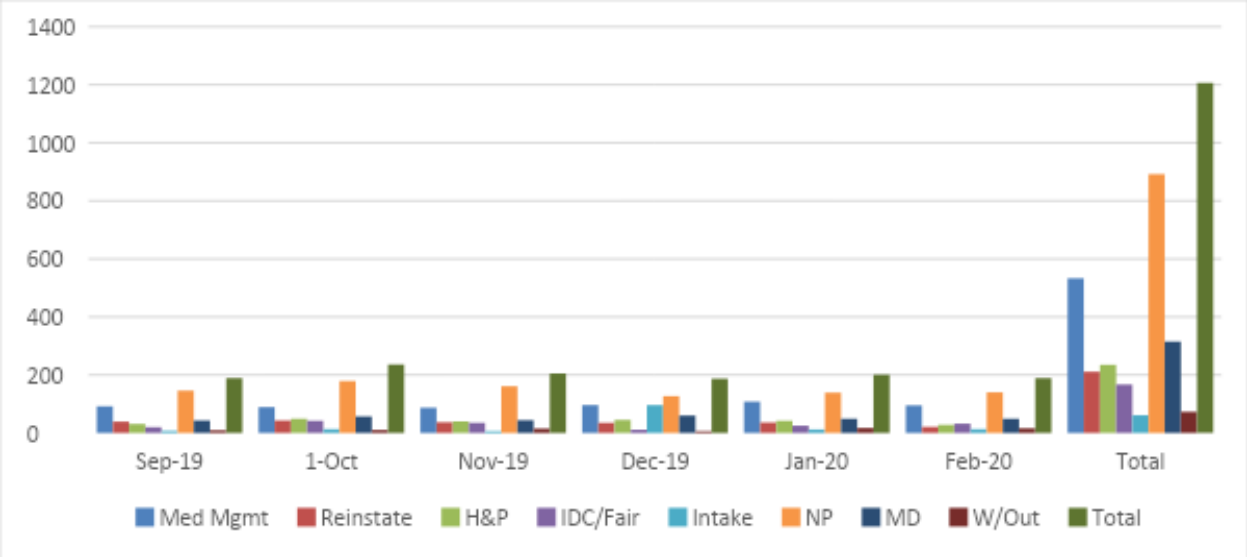
Job Summary: Performs a variety of functions necessary for the admission of patients through assessment, diagnosis, treatment, follows-up and outcome evaluation.

NURSE PRACTITIONER COMPETENCIES	Met	Not Met	Comments
Conducts initial and annual comprehensive health assessments & physical exam of patients with acute and/or chronic health problems. Initiates referrals to specialty services and fosters continuity of care.			
Provides patient/family education and counseling in health promotion, maintenance, and disease prevention.			
Adjust MAT according to OASAS guidelines. Consult the NYS PMP site as necessary.			
Reinstatement of patients to treatment.			
Assess patients for eligibility criteria for take home dose privilege and vacation doses.			
Participates in multidisciplinary team conferences for patient review (IDC and case conferences).			
Completes intake of new patient, screening and the initiation of induction of medication-assisted -treatment.			
Assess in the effectiveness of MAT.			
Review of laboratory examination and patient referral to specialist services.			
Ensures compliance with regulatory agencies by maintaining of proper documentation, the preparation for and the participation in audits and survey.			
Identifies quality improvement issues and develops relevant improvement programs			
Acts as a resource to staff and implements educational programs.			
Participates in approved medical and nursing research studies.			
Maintains a current level of knowledge relative to professional practice.			
Collaborate with team and medical provider for advice and input as defined by Policies and Protocols.			
Use of effective communication with patients and colleagues.			

Qualifications:

- Master's Degree as Nurse Practitioner in Family Health and/or Adult.
- Current license to practice as a Registered Nurse and a Nurse Practitioner in New York State.
- National Board Certification in specialty area. Certification to be attained prior to next credentialing.
- Completion of an advanced pharmacology component of three semesters or the equivalent and instruction on New York and federal laws relating to prescription and record keeping.
- Collaborative practice agreement with a physician and designated protocols, both filed with New York State Department of Education.
- Previous experience relevant to the area of clinical practice, preferred.
- Full-time day, 6:00AM-2:00PM.
- Environmental Setting: Indoors
- Expected to wear gloves. Exposure to electronic equipment such as computers, fax and copy machine.

Appendix L Table of Encounters



Appendix M QUALITY IMPROVEMENT PROJECT CHECKLIST

Instructions: Answer YES or NO to each of the following statements:

Project Title: Addition of NP to an Opioid Treatment Team Using a Shared Care Model	yes	no
The aim of the project is to improve patient access, increase patient satisfaction, and reduce provider workload through established standards.	X	
The specific aim is to improve performance or a specific service or program and **is a part of usual care.** All participants will receive standard of care.	X	
The project is NOT designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control. The project does NOT follow a protocol that overrides clinical decision-making.	X	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does NOT develop paradigms or untested methods or new untested standards.	X	
The project involves implementation of care practices and interventions that are consensus-based or evidenced-based. The project does NOT seek to test an intervention that is beyond the current science and experience.	X	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has **an agreement with CTP**	X	
The project has NO funding from federal agencies or research focused organizations and is not receiving for implementation research.		X
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., not a personal research project that is dependent upon the voluntary participation of colleagues, students, and/or patients.		X
If there is an intent to, or possibly of publishing your work, you and your supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: This project was undertaken as an Evidence-based quality improvement project at an Outpatient Treatment Program, and as such was not formally supervised by the Institutional Review Board.	X	

Appendix N IRB Declaration

OTP RESEARCH TRANSFORMING THE FUTURE OF SUBSTANCE TREATMENT PROGRAMS

Date: 12/18/2020

Subject: IRB

Title: Addition of Nurse Practitioners to Opioid Treatment Program

Dear: Program Director

As a Research Determination Official for the Methadone Maintenance Outpatient Treatment Program, We have reviewed the documents submitted for the above mentioned project. The project does not meet the regulatory definition of research involving subjects as noted here:

[ ]

[X]Not Research

The activity does not meet regulatory definition of research at 45 CFR.102(d)

§46.102 Definitions for purposes of this policy.

- *Certification* means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

-*Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

- *Department or agency head* means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

- *Federal department or agency* refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.*, the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

-(1) *Human subject* means a living individual about whom an investigator (whether professional or (2) Identifiable private information.

Therefore, the project is not required to be reviewed by OTP Institutional Review Board (IRB**). This** determination is based on the information provided. If the scope or intervention of the project changes in a manner that could impact this review, please resubmit for a new determination. Also you are responsible for keeping a copy of this determination letter in your project file as it may be necessary to demonstrate that your project was properly reviewed.

Sincerely

THE EVALUATION OF NP-MD SHARED CARE MODEL IN OTP

Appendix O. NP RECRUITMENT/ORIENTATION TIMELINE

Addition of Nurse Practitioners in Shared Care Role in Opioid Treatment													
2017		Apr	May	June	July	Aug	Sept	Oct	Nov	Dec			
Recruitment													
Application													
Interview & Shadowing													
Acceptance & Credentailing													
OTP Orientation													
Review of OASAS P&P													
Physical Examination													
Medication Management													
IDC Admin Detox First Take Home Fair Hearing													

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