

**Reflections on an urban federally qualified health center's (FQHC) medication-assisted treatment
(MAT) program**

A. Mikael Clothier

School of Nursing

Oregon Health and Science University

Dr. Jonathon Soffer

March 4, 2022

Abstract

Introduction: The prevalence of individuals with opioid use disorder (OUD) and OUD-related unintentional overdose deaths has risen over the last three decades, leading OUD to be classified as a national epidemic. Medication-assisted treatment (MAT) is an evidence-based treatment model for OUD, whose widespread adoption could lead to a decline in OUD-associated comorbidities, infectious diseases, and reduction of trauma, suicide, and overdose deaths. The 2016 Comprehensive Addiction and Recovery Act (CARA) took an assertive stance on the need to combat OUD and offered advanced practice registered nurses and physician assistants eligibility to prescribe medications for OUD.

Methods: The Richmond Family Medicine Clinic (Richmond clinic) at Oregon Health and Science University offers a well-established OUD treatment program with patient-centered goals. An historical chart review was to evaluate the impact of CARA on patient access to Richmond clinic MAT program.

Results: Due to unforeseen barriers, most historical data was not acquired and analysis became a mixed methods discussion of Richmond clinic's MAT program. While the short-term impacts of CARA on the MAT program and patient access to MAT treatment was inconsistent, five year qualitative and quantitative data demonstrated an expansion of the MAT program and increased access to MAT treatment since CARA.

Discussion: The aim to access historical charts was met with unanticipated and significant opportunity costs. There were other environmental and situational project limitations, which led to a difficulty in establishing any causal relationship between CARA and changes in Richmond clinic's MAT program. However, the project identified major balancing measures including unmet tracking needs (record-keeping) within the MAT program and the inefficiencies in MAT team processes. The subsequent discussion of data storage system complexities related to an organization's electronic health records system was an unexpected project benefit.

Table of Contents

Introduction.....4
 Problem Description.....4
 Available Knowledge.....5
 Rationale.....6
 Specific Aims.....7
Methods.....8
 Context.....8
 Interventions.....9
 Study of the Interventions.....10
 Measures.....11
 Analysis.....12
 Ethical Considerations.....12
Results.....12
Discussion.....15
 Summary.....15
 Interpretation.....16
 Limitations.....17
 Conclusions.....19
References.....22
Appendix A: Tables26
Appendix B: Ishikawa (Fishbone) Diagram.....27
Appendix C: Project Timeline.....28
Appendix D: Letter of Support from Richmond clinic.....29
Appendix E: OHSU IRB Letter of Approval30

Introduction

Problem Description

An individual with an opioid use disorder (OUD) demonstrates compulsive and excessive intake of opioid substances with associated signs and symptoms of the disorder, such as increased opioid tolerance, withdrawal effects when abstinent, and impaired social functioning (American Psychiatric Association, 2013). All primary care practitioners (PCPs) should use validated instruments to screen adults regularly for substance misuse (APA, 2013; USPSTF, 2020). An estimated 1.2 % of adults and 0.7% of adolescents in the United States (U.S.) have an OUD, with 1.7 million people using narcotic pharmaceuticals and 526,000 people using heroin, though an estimated additional eight million people misuse opioids at a level under the threshold for an OUD (Klein et al., 2020; SAMHSA, 2020; USPSTF, 2020). OUD is classified as a national epidemic, having dramatically increased in prevalence and OUD-related unintentional overdose deaths over the last three decades (Bohnert et al., 2018; SAMHSA, 2020). The rising prevalence of OUD has been strongly implicated in the concurrent rise of OUD-related comorbidities and hospitalizations, certain infectious diseases, traumas, and suicide, and is responsible for about 60,000 deaths annually in the U.S. (Klein et al., 2020; Lagisetty et al., 2017).

Despite the demonstrated causative relationship between opioid prescribing and the OUD national epidemic, the physical, psychosocial, and emotional harms associated with OUD, and the documented lack of provider confidence and knowledge in screening for, diagnosing, and treating OUD, opioids continue to be frequently prescribed in the U.S. (Volkow & McLellan, 2016). Various medical guidelines and national health strategies have started to target risky opioid prescribing practices, particularly long-term and high-dose opioid prescriptions and co-prescriptions for opioids and benzodiazepines. This guidance has contributed to modest reductions in the prevalence of risky opioid prescriptions and non-fentanyl opioid-related death (Bohnert et al., 2018; OHA, 2020).

Oregon has roughly followed national trends in the overall increasing prevalence of OUD and OUD-associated morbidity, mortality, and hospitalizations since the 1990s (OHA, 2020). State monitoring databanks, however, also demonstrate consistent decreases in opioid prescribing from 2015, when the state had 263 opioid prescription fills per 1,000 residents to 2020, when Oregon had 153 opioid prescription fills per 1,000 residents. Unfortunately, Oregon still experiences accidental deaths due to opioid use, having lost more than 427 people to unintentional opioid overdose deaths in 2020 (many of which involved concurrent use of other substances, such as methamphetamine (OHA, 2021)).

Available Knowledge

While the scope of the OUD problem is large and growing, the medication-assisted treatment (MAT) model for OUD is evidence-based, and its widespread clinical adoption could reduce OUD-associated comorbidities, the spread of certain infectious diseases, and reduction of OUD-related trauma, suicide, and overdose deaths (SAMHSA, 2020). The Food and Drug Administration (FDA) has approved three medically- and cost-effective medications to treat OUD; buprenorphine, naltrexone, and methadone use unique mechanisms to treat physical and psychosocial aspects of the disorder (SAMHSA, 2020). Only one in five people in the U.S. with OUD are receiving MAT, however, leading many government-associated and independent organizations to advocate for expanded access to MAT programs (Klein et al., 2020; SAMHSA, 2020).

Access to MAT has historically been restricted by stringent controls over prescribing rights. While methadone has been restricted to opioid treatment programs (OTPs) since its FDA approval for treating addiction in 1972, The Drug Addiction Treatment Act (DATA) of 2000 paved the way for buprenorphine use for OUD outside of OTPs (SAMSA, 2020). With this legislation, physicians could be granted an X waiver, allowing them to treat patients with OUD with buprenorphine in the outpatient setting. In 2016, the Comprehensive Addiction and Recovery Act (CARA) took a broad and assertive stance on the urgent public health need to combat OUD (Klein et al., 2020; S.524, 2016). CARA greatly expanded federal resources for prevention and treatment of OUD and instituted policies allowing hundreds of thousands of providers, including advanced practice registered nurses (APRNs), to be eligible to acquire an X waiver to prescribe buprenorphine to treat OUD (Klein et al., 2020; S.524, 2016; SAMSA, 2020). In April 2021, the U.S. Department of Health and Human Services sought to increase access to MAT treatment by waiving the extra 8-24 hours (dependent on discipline) of training needed to be granted an X waiver to treat up to 30 patients (DHHS, 2021).

Providers report multiple obstacles to building professional confidence and competence in treating people with OUD with MAT, such as lack of training in screening, diagnosis, and management of OUD, high clinic costs for MAT relative to insurance reimbursement, additional time and energy required to take required and recommended trainings, lack of access to a behavioral or mental health multidisciplinary team, limited access to addiction specialists, lack of available mentors, clinic-specific logistic and staffing issues, and underlying stigmatizing beliefs that MAT for OUD does not work (Charnley, 2021; Korthuis et al., 2017). While national legislation, like that passed in April 2021, seeks to reduce the burden of prescribing MAT for providers, many providers report that they actually feel undertrained to safely prescribe MAT (Charnley, 2021; HHS, 2021).

People using prescribed and illicit opiates also report significant barriers to accessing MAT care, such as difficulty in attending frequent clinic appointments due to lack of transportation, extensive waitlists to access a provider, inappropriately high demands and hurdles to access treatment, stigmatization by health care personnel, legal or court restrictions, and that clinics that offer MAT are disproportionately located in places that are less accessible to people already disadvantaged by their geographical location, socioeconomic class, and race, and ethnicity (Silverstein et al., 2020). The expansion of Medicaid in Oregon with the Affordable Care Act increased access to medical care for large swaths of the uninsured population, resulting in a doubling of patients with OUD enrolled in insurance plans, accessing primary healthcare and psychosocial services, and involved with MAT for OUD (McCarty et al., 2019). CARA was also aimed at reducing barriers for people with OUD in underserved and rural areas by mobilizing non-physician providers as MAT prescribers. APRNs have taken a strong leadership role since this time, and by the end of 2018 (less than two years after the first APRN received their X waiver) APRNs were writing one in five buprenorphine prescriptions for all MAT in Oregon and one in three prescriptions in frontier areas (Klein et al., 2020). These numbers are significantly poignant due to the reality that only 4.3% of physicians were able to prescribe MAT at that time (Klein et al., 2020).

MAT has been repeatedly demonstrated to be more effective than psychosocial or behavioral services alone for the treatment and recovery of patients with OUD (Korthuis et al., 2017). It appears, however, that effectively tackling the OUD pandemic will require diverse inpatient and outpatient treatment models that include four important components: pharmacologic therapy, psychosocial services, integration of care, and education and outreach (Korthuis et al., 2017). A multidisciplinary team approach to care offers a useful framework to optimize each healthcare worker's skillset and provide the highest quality care to patients (Lagisetty et al., 2017). The Richmond Family Medicine Clinic (Richmond clinic) at Oregon Health and Science University (OHSU) offers a well-established OUD treatment program that focuses on the patient-centered goals of harm reduction, opioid use cessation, restoration of health and wellness, improvement in quality of life and function, and reduction in OUD-related comorbidities (Fleishman & Gideonse, 2021). Most providers in this federally qualified health center (FQHC) have an X waiver and the clinic is frequently interviewed by other local healthcare organizations as a model for what OUD treatment can look and feel like in an outpatient clinic (S. Weber, personal communication, May 27, 2021).

Rationale

While there continue to be significant barriers to accessing MAT treatment, CARA signified a turning point in the national rhetoric around OUD, particularly that national legislation had some responsibility in promoting increased access to MAT, that non-physician providers were competent to care for complex patients, and that they had a vital role to play in the battle against OUD (Klein et al., 2020). Since this time, the number of providers and clinics offering MAT services have significantly increased, and many existing programs have become more robust and effective (Klein et al., 2020). The Richmond clinic has followed this national trend by expanding and increasing the effectiveness of its MAT program over this time period. Prior to 2017, the Richmond clinic employed three physicians who independently treated OUD with MAT using buprenorphine. Many Richmond clinic providers report that the number of MAT program members, providers, and patients have increased dramatically since CARA (L. Hallock-Koppelman, personal communication, May 14, 2021). These dramatic subjective changes challenge the presumption that Richmond clinic simply mirrored the national attitude shift towards prioritizing the opioid epidemic and bolstering OUD treatment programs, and instead whether providers of certain designations (like those impacted by CARA) are intrinsically more or less likely to take on complex OUD patients, and use evidence-based MAT to treat them (Klein et al., 2020). The following project seeks to explore this question, as well as to support and direct future actions aimed at decreasing barriers to MAT for patients with OUD.

Specific Aims

1. By December 31, 2021, data will have been compiled from the electronic health record (EHR) used by Richmond clinic (through the OHSU Family Medicine Data Team) from the time period starting one year prior to enactment of CARA (January 1, 2016) to two years after CARA (December 31, 2018).
 - a. Data will have been organized in a monthly format and include:
 - i. total number of providers eligible to offer MAT (had an X waiver)
 - ii. number of providers of each specialty (MD/DO, PA, or APRN) who had an X waiver,
 1. percentage of providers within each specialty who had an X waiver,
 - iii. total number of patients with OUD treated with MAT,
 - iv. average number of MAT patients on each provider's caseload, stratified by provider designation, and

- v. average delay to treatment (time on the waitlist) for patients to be offered MAT.
2. By February 28, 2022, data will have been analyzed to demonstrate the short-term effects of CARA on patient access to MAT at Richmond clinic, and the influence of APRNs on the change in access to MAT will have been identified
3. By March 31, 2022, a report describing the analyzed data will have been finalized.
4. By April 30, 2022, the report findings will have been presented to the MAT team at Richmond clinic. If applicable, associated recommendations will have been offered to Richmond clinic and other community health organizations based on the analysis, with the goal of supporting increased access to MAT services.

Methods

Context

The Richmond clinic is an established primary care FQHC in southeast Portland, Oregon. It is mandated to treat all Portland residents, regardless of age, life stage, insurance status, or ability to pay for services, resulting in a disproportionate number of patients being insured through Medicaid or Medicare (OHSU, 2020). On-site services include testing capabilities (like laboratory draws and X-rays), specialty providers (such as a podiatrist, pharmacists, behavioral health support workers, social workers, and nursing care coordinators), and knowledgeable care for underserved populations (such as LGBTQI patients and those struggling with addiction) (OHSU, 2020).

In June 2021, most eligible providers at Richmond clinic either had their X waiver or were in the process of getting their X-waiver, though not all prescribed MAT regularly (S. Weber, personal communication, May 27, 2021). The MAT team includes the medical director, the MAT program director, two behavioral health support workers, and a registered nurse (RN), who meet weekly to coordinate MAT services for patients with OUD (S. Weber, personal communication, May 27, 2021). MAT program goals include harm reduction, substance use cessation, restoration of health and wellness, quality of life improvement, reduction of morbidities and mortalities related to OUD, and promoting increased access to MAT services (Fleishman & Gideonse 2021). MAT providers at Richmond clinic use primarily buprenorphine or buprenorphine/naloxone medications and are not authorized to prescribe or administer methadone in this population (S. Weber, personal communication, May 27, 2021).

Richmond clinic is well-known in the Portland area for its successful MAT program and frequently hosts other local health organizations who are creating or revamping their own MAT program (S. Weber, personal communication, May 27, 2021).

Interventions

Project interventions began by gathering relevant information from a MAT-practicing APRN at Richmond clinic and by attending multiple Richmond clinic MAT team meetings, beginning in May 2021. Specific areas of inquiry included program history, current principles and processes, team members' perspectives of program changes before and after CARA (specifically focusing on ease of patient access to the program and provider involvement with the program), and a request for identification of potential areas of program improvement. Through this process, specific aims were created to quantitatively define the impact of CARA on the Richmond clinic MAT team and its ability to serve patients with OUD.

The next step of the intervention involved connecting with the Richmond clinic quality improvement (QI) team to discuss the final aims of the project and determine the best avenue through which to collect and analyze data. The QI team was unable to assist with project development or acquiring necessary data, or endorse assistance by the OHSU Family Medicine data team. The QI team also identified that it may be difficult to acquire the necessary data given that Richmond clinic transitioned from one EHR to another in 2018, the year following CARA enactment.

The third action was to pursue data collection through a variety of means. These included asking various members of the MAT team whether they knew about any records related to the MAT program from the years before and after CARA. Local researchers in the area of addiction medicine at OHSU and elsewhere were approached for advice on how to access these needed data sets. When it became apparent that independent access to these records may be unattainable, the same researchers were asked about the existence of current research or quality improvement projects which used this data, with the hope of piggy-backing on it to share data. While there was one research project which could offer the necessary data, it was determined that separating Richmond clinic patients from all other OHSU MAT patients would create a data pool small enough to compromise patient privacy. Discussion with other researchers highlighted the possibility of using data sets that were known to exist to collect periphery information about the Richmond clinic MAT program. The uniform data system (UDS) reports from 2016-2018 were secured in a relatively straightforward fashion by the QI team.

Without a clear way to obtain quantitative data, the project turned towards collecting qualitative interpretations of the history of the MAT program through the pre- and post-CARA years. The fourth attempted intervention was the creation of a provider survey aimed at eliciting the experiences of Richmond clinic providers in working within a clinic that has a well-known, robust MAT program. By analyzing this qualitative data, it was hoped that provider roles and team workings could be pieced together to create a picture of the intricacies of this program. However, not only had providers participated in a MAT program survey in the last two years, but according to the Richmond QI team, a survey would need to be formally endorsed and adopted by the Richmond QI team, which was impossible prior to the project deadline.

In a final attempt to obtain the data sets necessary to carry out the originally planned analysis, the Oregon prescription drug monitoring system (PDMP) was asked about providing medical director access to the Richmond clinic MAT program director, which would allow the director to view records of prescribed Schedule 2-5 medications from Richmond clinic up to three years prior to the inquiry. Due to current staff shortages and heavy workload at the PDMP, they were unable to assist with this request before the end of this project timeline.

Study of the intervention

Originally, the intervention had specific aims, whose analysis could represent pre- and post-CARA functioning of the Richmond clinic MAT team. The changes over this timeline would have been used to discuss the role of providers (by designation) in the current functioning of the MAT program, and to what extent CARA allowed increased access to MAT through recognizing the competence of non-physician providers in working with complex patients with OUD. The impact of the intervention would have been demonstrated not only by an analysis of the types of changes within the MAT program during the pre- and post-CARA years, such as number of MAT patients served, number and percentage of providers involved (by designation), but also by a more focused description of how APRNs have embraced MAT prescribing rights at Richmond clinic and across the U.S.

The review of Richmond clinic's MAT team throughout enactment of CARA considered the possibility that external confounding factors precipitated changes to the MAT team, such as national, organizational, and local attitudes and legislative shifts. National-level confounders included shifts in governmental priorities related to political party changes to executive and legislative branches, widespread enthusiasm for MAT programs in the healthcare community, and CARA occurring soon after the Affordable Care Act increased access to health insurance for underserved populations, like those

with OUD. Organizational-level confounders potentially precipitating MAT program changes may have included changes in organizational (OHSU-wide) or Richmond clinic culture and staff attitudes towards MAT programming, as well as changing MAT-related requirements necessary for Richmond clinic to maintain FQHC designation and funding. Local-level confounders may have included CARA passage closely following the state of Oregon adopting Medicaid expansion and the increasing local prevalence of people with OUD.

The richness of the planned study was stunted by significant barriers, which had not been accounted for during the planning stage. Instead of the previously described approach, the results were ultimately assessed through examination of the processes of and barriers to the intervention, as well as through limited quantitative and qualitative descriptions of the Richmond clinic MAT program.

Measures

Outcome measures originally chosen to assess how CARA may have impacted Richmond clinic MAT program and access to its services (through pre- and post-CARA data points) included:

- total number of providers eligible to offer MAT (had an X waiver)
- number and percentage of providers by designation (MD, DO, PA, APRN) who had an X waiver
- total number of patients with OUD treated with MAT
- average number of MAT patients on each eligible provider's caseload, stratified by provider designation, and
- average delay to treatment (time on the waitlist) for patients to be offered MAT

Process measures included the underlying clinic and patient factors that could have modified the result of outcome measures. Process measures were expected to include:

- total number of providers eligible to obtain an X waiver during each time period
- number of providers (of each designation) at Richmond clinic during each time period
- number of patients desiring MAT treatment during each time period
- number of available openings in provider caseloads at Richmond clinic during each time period
- average amount of time between a patient to be offered MAT and to actually start MAT (i.e., scheduling issues)

Balancing measures included changes that could inadvertently arise due to the process of data collection and analysis. Balancing measures were thought to include:

- uncovering inefficiencies in the MAT program processes
- identifying unmet tracking needs within the electronic health record (EHR)
- disrupting collegial relationships between groups of providers and/or other staff if outcomes demonstrate a disproportionate distribution of MAT patients across clinical specialties.

Analysis

Quantitative data was to be gathered from Richmond clinic's EHR system, where electronic reports would be used to analyze changes in the MAT program over time. The project was able to obtain three UDS reports from the years 2016-2018, which included basic statistics of the MAT program over those years. Owing to the inability to access that data, however, largely qualitative data was informally obtained through private and group conversations about the history of the Richmond clinic MAT program. These conversations occurred individually with those identified in the project processes, such as Richmond clinic MAT team and provider liaison to Richmond clinic.

Ethical Considerations

The Richmond clinic MAT team and QI liaison approved this project, which was deemed exempt by the OHSU Investigational Review Board (IRB). The project planned to access general clinic data through the EHR without identifying or recording any personal identifiers of patients involved in treatment. Ultimately, no specific patient data was acquired, nullifying any risk of patient privacy breaches. Neither the student nor the advisor reports any conflicts of interest.

Results

Data collected from Richmond clinic's UDS reports to Health Resources and Service Administration confirmed a significant increase in number of patients treated by the MAT program from 2016 (pre-CARA) to 2018 (2 years post-CARA implementation) (Table 1). In the first year of implementation, there was a 126% increase in the number of patients with OUD treated with MAT (212 patients treated in 2016 to 480 patients treated in 2017). The following year demonstrated an overall moderate increase from pre-CARA patient volume (58% above 2016 numbers), but a 30% decline from the year prior (2017). For trending purposes, the MAT program treated over 400 patients at any time during the 2021 calendar year (S. Weber, personal correspondence, February 28, 2022), qualitatively

supporting the assumption that the Richmond clinic MAT program has maintained a lasting expansion since CARA.

Interestingly, there was no significant change in the overall number of providers who had an X waiver within two years of CARA enactment, as the waived number of providers decreased by 14.3% in 2017 (despite a 126% increase in number of patients treated), and then increased by 50% from 2017 to 2018 (despite a 30% decrease in number of patients treated). Due to the lack of available EHR data, the original project measures were lost in this analysis, as number of waived providers were not classified by designation (Table 1).

The UDS reports did stratify the overall number of clinic providers by designation and by total full-time equivalent (FTE) (which denotes the number of hours a provider works per week, based on a full-time schedule of 40 hours per week). While this information did not elucidate the role that individuals of each designation played in working with MAT patients specifically, the relative amount of FTE by designation offered a limited glimpse of the clinic culture regarding provider mix. From 2016-2018 PA FTEs remained relatively stable, fluctuating between 1.49 and 1.64, which demonstrated an overall variation of 6 hours per week of PA in-clinic time. During the same time frame, APRN FTEs showed moderate variation, ranging from 8.91 to 9.76, equating to 34 hours per week of APRN in-clinic time. Physician FTEs demonstrated the largest range, fluctuating between 14.93 and 16.5 FTEs, which is 62.8 hours per week of physician in-clinic time (Table 2). With the limited data obtained, it was impossible to ascertain whether individuals of certain provider designations were more or less responsible for the dramatic changes in number of MAT patients treated over the three-year period. While MAT patients were clearly treated by the 14.93 FTEs of physicians in 2016 (as APRNs and PAs were not eligible to obtain an X waiver), the MAT patients counted in 2017 and 2018 could have been treated by a provider of any eligible designation.

While results shown in Table 1 alluded to an overall increase in MAT patients over time, the dearth of process measure data (such as percentage of MAT prescribing by provider designation, amount of local patients with OUD who were interested in MAT, and length of time to be offered MAT treatment) meant that any analysis lacked reliability. For instance, while there was a 126% increase in MAT patients during the first year of CARA, there were actually fewer providers (of unknown designation) offering MAT. This potentially contradicted the hypothesis that 2017 saw an increase in MAT patients as a direct result of APRN and PA providers obtaining new X waivers. During that same time frame, however, the provider mix changed due to a significant physician decrease of 2.1 FTEs/84 hours per week, a small PA decrease of 0.14 FTEs/5.6 hours per week, and an APRN addition of 0.85

FTEs/34 hours per week; this collection of data supported the hypothesis that allowing APRNs and PAs to treat patients with MAT at Richmond clinic significantly increased access to MAT for patients with OUD. Additionally, during this time, APRNs operated about 1.5-2.1 times the number of clinic visits as MDs per year and 0.8-1 times the number of clinic visits as PAs per year, meaning that APRNs and PAs maintained the high visit quantity needed to take on patients needing frequent interactions.

There was also data that suggested that APRNs may have been more likely to obtain an X waiver to treat MAT patients than either physicians or PAs, and that when they had an X waiver, they treated the same number of MAT patients as PAs and 1.4 times the number of MAT patients as physicians. It is important to note, however, that not all documented physicians should have been assumed to have equivalent clinical productivity. For instance, there was often a physician clinical 'preceptor' who did not have their own patients (instead they mentored other providers), and some physicians are residents in training, who may have been expected to have a reduced panel. For these reasons it may have been unfair to completely equate the productivity of a physician resident or preceptor, APRN, PA, or physician non-resident. That being said, residents made up only about a third of physicians at the clinic, and their residency was expected to last a few years at Richmond, during which time it could be assumed that they increased their panel volume.

Data from February 2022 illustrated how the MAT program established itself five years after CARA enactment (Table 2). Providers from three provider designations (MDs, APRNs, and PAs) maintained panels that included patients with OUD on MAT. While MDs treated 57% of MAT patients, they made up 65% of providers able to treat MAT patients. On average, PAs and APRNs who had X waivers treated 20 MAT patients each, which was 43% more than physicians with X waivers, who treated about 14 patients each.

In addition to quantitative data obtained through UDS reports, qualitative data was gathered through conversations with MAT team members and providers at Richmond clinic. Prior to 2016, there were three primary MAT providers at Richmond clinic, who largely operated independently. Patients with OUD who desired MAT would continue to have healthcare managed by their PCP and referred to MAT 'specialist' providers for MAT prescriptions and addiction follow-up. Due to the limited number of MAT providers, patients often waited three to six months before being offered MAT treatment. This length of time between intention and treatment was often cited as a major barrier to patient success, as many patients with OUD endorsed and demonstrated significant difficulty keeping appointments, building clinic relationships, and maintaining an active desire for MAT. Actually, the lifestyle stability afforded by regularly taking (often free) prescribed medications to treat OUD versus the instability

experienced when patients had to constantly find or buy a substance to use is thought to be one of the mechanisms by which MAT works to treat the environmental triggers driving continued OUD (L. Hallock-Koppelman, personal communication, May 14, 2021).

In 2016, the landscape began to shift at Richmond clinic, when two of the main MAT providers collaborated with other Richmond clinic staff in developing a MAT program handbook, which outlined basic processes through which the clinic could run an efficient and supportive MAT program. The handbook and program structure, based on a borrowed skeleton framework from the University of Massachusetts at Worcester addictions team, focused on integrating ancillary supports beyond the prescribing physician to optimize each staff member's skillset, support patient success, and improve program efficiency. From the end of 2016 through 2017, the MAT team grew to include permanent ancillary positions, such as a MAT team RN, MAT team coordinator, MAT team behavioral support worker/s, and MAT team resource specialist. During this time, excitement grew within the national discourse and the enactment of CARA made it possible for APRNs and PAs to become MAT providers. With more providers able to treat OUD with MAT, the Richmond clinic MAT program began to phase out their function as a specialty referral service and instead, MAT became largely integrated into primary care (with their PCP) for patients with OUD.

The additional supports provided by the MAT RN and the MAT behavioral support worker/s resulted in the patients developing better relationships with the behavioral specialists, which is known to be a highly useful component of addictions treatment (SAMHSA, 2020). These supports also reduced pressure on providers to be individually responsible for every aspect of treatment, as RNs and support workers could manage weekly appointments with patients and arrange other psychosocial supports. The new model of MAT care incorporated these positions into the medical care team, instead of periphery to it, and had them perform tasks that were traditionally only performed by providers, such as weekly appointments, consideration of patient treatment stage, patient screenings (such as for housing insecurity), and interventions to support recovery. Working as a team instead of as individuals allowed providers to maintain a larger and more diverse MAT patient panel, resulting in overall increased access to the MAT program for patients needing treatment (SAMHSA, 2020).

These changes in the MAT program have resulted in a dramatically reduced wait time for patients to access MAT, an increased clinic capacity for MAT patients, a reduction in staff stigma around OUD due to increasing staff and clinic familiarity with MAT patients, processes, and treatment plans, and a program that excels at providing person-centered care to some of the most vulnerable residents of Portland.

Discussion

Summary

The original project aimed to perform an historical chart review in order to compare data from before CARA to after CARA implementation of the number of patients treated with MAT, the number of providers (by designation) who were treating MAT patients, and how long patients had to wait to access MAT services, as related to the changing national landscape of addiction medicine. Due to multiple barriers, such as a change in EHR systems, the necessary historical charts were never acquired. The end result of the project included a mix of quantitative data from the years 2016-2018 (the size of the MAT program and provider mix at Richmond clinic), a snapshot of the MAT program in February 2022, and qualitative data exploring staff members recollections of MAT program development over time. The results illustrated expansion and positive development of the Richmond clinic MAT program, with increased patients treated with MAT and increased providers who can treat patients with MAT, from pre- to post- CARA implementation. This project also highlighted key difficulties related to recordkeeping and access to historical records in the age of EHR systems.

Interpretation

In an effort to evaluate the dramatic changes from 2016-2022 in the Richmond clinic MAT program, qualitative and quantitative data was obtained on MAT program size and provider involvement. Since the enactment of CARA, there has been a national attitude shift to combat the opioid epidemic and multiple pieces of legislation to increase access to MAT, both of which seem to have played a role in the expansion of the Richmond clinic MAT program. MAT program staff reported positive feedback from clinic and organizational staff, patients, and the local community in regards to their supportive atmosphere and their success in increasing access to MAT for patients with OUD. Program staff believed this success was a result of increasing the number of MAT providers and creating supportive processes to become an efficient and effective program. Quantitative results also supported the assessment that the MAT program has increased patient access to MAT since CARA, through demonstrating consistently increased numbers of patients treated.

The intention to access historical charts was met with unanticipated and significant opportunity costs, unfortunately, which had not been accounted for during the project planning stage. While it was ascertained fairly early that Richmond clinic had transitioned EHR systems over the studied time period,

it was not fully appreciated that gaining access to relevant historical EHR data would require significant financial resources. Instead of the anticipated analysis of CARA's impact on development of the Richmond clinic's MAT team, the impact of the intervention was instead assessed through exploration of the intervention steps, encountered barriers, and examination of limited quantitative and qualitative data.

Ultimately, the project found a major balancing measure in the unmet tracking needs (record-keeping) of the MAT program. This gap was unanticipated, as the MAT program has been a particular point of pride among providers and staff at Richmond Clinic, and the clinic has been frequently approached by other regional clinics for help setting up their own MAT program. The MAT team has actively monitored data through the EHR for the current month only, and no historical records have been kept besides this. Arguably, keeping records may be redundant and potentially compromise patient privacy, as it is thought that the EHR can store and recall extensive information at any time in a secure way. Unfortunately, Richmond clinic's transition from one EHR to another confounded the ability to access this historical information, which made it difficult to confirm a causal relationship between CARA and the Richmond clinic MAT program expansion or increased access to MAT. This paucity of information also made it difficult to assess the impact that CARA had on APRN and PA scope of practice and the involvement of providers of these designations in MAT programming.

This lack of access to historical records was unexpected, as an EHR is generally assumed to be able to store patient and clinic information easily, quickly, and securely. The awareness of the balancing measure of unmet tracking needs (lack of record-keeping) led to the identification of a different balancing measure, which was inefficiency in the MAT team processes. An effective team must have a process to objectively assess its own history; if the clinical staff, quality improvement team, and organizational review systems cannot access their past through historical records, then the process of continual improvement becomes stymied. These groups cannot review and learn from their mistakes and successes, nor can they assess alleged, presumed, or unknown inconsistencies and inequities within the program in a balanced and least subjective way. Instead, the history of the MAT team can only be evaluated through the memories of those people involved; as the team members change over time and as memories shift and recreate themselves, the MAT team history will be told differently and there will be no objective data by which to guide program improvement.

The process followed throughout these interventions and exploration of the subsequent barriers to data collection provided insight into previously undocumented complexities within the clinic and organization's data collection and storage systems. These insights were unexpected project benefits and

could serve as a warning to other clinics and programs about the potential dangers of relying solely on the EHR to store and assess patient and clinic data, especially if an EHR transition is expected.

Limitations

This project had many limitations due to the very modest data set, as well as the unanswered questions regarding important process measures. Process barriers to obtaining a robust data set included:

- that the terms of Richmond clinic's transition from one EHR to another in mid-2018 did not include ongoing easy and/or free access to patient and clinic data from the prior EHR for OHSU staff or students. The resulting high financial costs required to obtain quantitative data was unacceptable to the nature and capacity of this project.
- an absence of records kept by the MAT team, individual providers, or Richmond clinic itself about program history. This deficiency resulted in the necessity of using verbal historical record as data points, which could not be analyzed as planned to help determine the true effects of CARA on access to MAT for people with OUD.
- the ongoing coronavirus pandemic, as each intervention step took longer than expected due to staffing challenges, communication delays, multiple OHSU departments that were too underpowered to be able to assist students in locating data.
- the legislative barriers meant to protect privacy, which restricted the PDMP from keeping records longer than three years.

One multifaceted barrier to data analysis was the inability to quantify or describe important context-specific details. Because these details remained unknown, it was not clear how they may have impacted the outcomes within the MAT program, and little could be concluded about the effect of CARA on the access to MAT for patients with OUD at Richmond clinic. Some of the process measures unable to be described include:

- the demographics and intricacies of physician residents. As residents often changed part way through the calendar year, each year of UDS data represented two different cohorts of physician residents, which could have represented similar or divergent values around MAT service and dedication to treating patients with OUD with MAT. As well, individual personalities and resident cohorts could have had great impacts on whether patients maintained clinic relationships, which could have then played a role in determining the length of time to offer MAT for other patients.

- information around the local prevalence of people with OUD who desired treatment with MAT during each time frame.

It was originally decided that an historical review using monthly data would provide enough data points to trend changes in the MAT program from pre- to post-CARA implementation. Extensive project modifications were made over time, as it became clear that gaining access to appropriate historical charts may be an insurmountable obstacle. Specific barriers to collection of outcome measures (and some process measures) through chart review were:

- in mid-2018, Richmond clinic transitioned from one EHR system to another. While individual patient data was ported to later charts, data from before 2018, including the ability to run de-identified reports, was not available to anyone working on this project. To access data from the historical EHR for any reason, the original EHR company would need to be financially compensated for their staff to mine the necessary data.
- that the Richmond clinic MAT team did not keep records concerning their program, outside the current month, including basic numbers of providers and patients treated. Individual pieces of information were available through each specific patient's chart in the new EHR system, but there was no streamlined ability to collect reports about MAT program patients or providers; any questions concerning MAT team prescribing, employees, and/or function prior to 2018 could have only been answered through individual and collective memory.
- that the small scale of this project made collecting data from other research studies impossible due to concerns around patient privacy, as it was deemed possible that patients could be identified if data was broken down into clinic-specific information.
- that the Oregon PDMP was unable to keep records for greater than three years, which was not useful for the aims of this project.
- that there was a significant shortage of healthcare staff due to the ongoing Covid 19 pandemic during the time frame when this project was live. The lack of staff made it difficult to obtain the above information in an efficient manner. This shortage also resulted in the OHSU Family Medicine data team being unable to assist in troubleshooting issues that came up with collecting the necessary data to reach the intended outcome measures.

Conclusion

While project results described few details about the expected project aims, available data suggested that the external factors of MAT-positive national discourse and related legislation (CARA), and internal factors of Richmond clinic leadership in and attitudes around MAT program development, supported Richmond clinic in expanding access to its MAT program. Since CARA, the program has increased its capacity to treat patients with OUD with MAT, with a sustained increase in MAT patients of 77% from 2016-2022. It was difficult to concretely identify the impact of each factor on increased program access without more historical data, so a useful follow-up project could occur if access was granted to previous clinic or patient records for the time period of CARA implementation (2016-2018). The available qualitative and quantitative data alluded to the synergistic alignment of (a) an increase in the amount of eligible providers (via CARA), (b) the well-defined, efficient, and supportive MAT program structure, and (c) the strong clinic leadership through MAT champions, which together influenced the growth of Richmond clinic MAT program to almost double its size in less than five years.

As discussed, many of the barriers that inhibited this project from meeting its original aims were related to the inability to access information from a prior EHR system. This obstacle was not anticipated, as it was assumed that OHSU and the legacy EHR would have assured that providers, students, researchers, and OHSU staff would continue to be able to access historical clinic and patient data in a format that allowed for running reports and collecting data sets, without the undue financial burden that it currently requires. The anecdotal experience of having had continued access to a legacy 'read-only' EHR system after EHR transition, as well as the erroneous assumption that healthcare organizations would prioritize maintaining the ability to retrieve historical data for quality improvement purposes, misguided the initial project planning in assuming relative ease of data collection even when it was discovered that Richmond had transitioned EHRs in the middle of the studied time period.

While scholarly literature on EHR systems is considerable and growing, there remains a conspicuous lack of evidence on the complexities of transitioning from one EHR to another, including how to negotiate the ongoing needs to access historical data (Penrod, 2017). Data migration is consistently identified as the most crucial aspect of EHR transition to accomplish well and with careful forethought (Huang et al., 2020; Penrod, 2017). Not only is accurate, complete, and prompt data migration essential for protection of private health information, patient satisfaction, and staff efficiency, but it is critical to all aspects of patient safety (Huang et al., 2020). Depending on the two EHRs involved, it can be challenging to ensure that both structured (discrete) and unstructured (narrative or free text) data is transferred from one EHR to another in a complete, useful, and seamless way, especially if the systems store this information in different formats (Penrod, 2017). Because ensuring complete data

migration during EHR transition is crucially important, may take time, and may be incomplete, however, it is recommended to maintain access to legacy EHR systems (usually in a 'read-only' mode) for an extended time after EHR transition (Huang et al., 2020; Penrod, 2017). For the sake of patient safety and positive program growth, future projects will hopefully identify effective, evidence-based methods to ensure that objective, historical chart data withstands the complexities of EHR transitions.

References

- American Psychiatric Association (APA). (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.). American Psychiatric Association Publishing.
- Bohnert, A. S. B., Guy Jr., G. P., & Losby, J. L. (2018). Opioid prescribing in the United States before and after the Centers for Disease Control and Prevention's 2016 Opioid Guideline. *Annals of Internal Medicine*, 169(6). 367-375. <https://dx.doi.org/10.7326/M18-1243>
- Charnley, C. (2021). Assessment of barriers and facilitators to buprenorphine prescribing among nurse practitioners in rural Oregon [Unpublished doctoral project]. Oregon Health and Science University.
- Daniulaityte, R., Nahhasb, R. W., Silverstein, S., Martins, S., Zaragoza, A., Moellera, A., & Carlson, R. G. (2019). Patterns of non-prescribed buprenorphine and other opioid use among individuals with opioid use disorder: A latent class analysis. *Drug and Alcohol Dependence*, 204. 107574. <https://doi.org/10.1016/j.drugalcdep.2019.107574>
- Fleishman, J., & Gideonse, N. (2016). OHSU Family Medicine MAT Program and clinical quality management plan [Unpublished program manual]. Oregon Health and Science University.
- Huang, C., Koppel, R., McGreevey III, J. D., Craven, C. K., & Schreiber, R. (2020). Transitions from one electronic health record to another: Challenges, pitfalls, and recommendations, *Applied Clinical Informatics*, 11. 742-754. <https://doi.org/10.1055/s-0040-1718538>
- Klein, T. A., Geddes, J., & Hartung, D. (2020). The geographic impact of buprenorphine expansion to nurse practitioner prescribers in Oregon. *The Journal of Rural Health*, 00. 1-8. <https://doi.org/10.1111/jrh.12538>

Korthuis, P. T., McCarty, D., Weimer, M., Bougatsos, C., Blazina, I., Zakher, B., Grusing, S., Devine, B., & Chou, R. (2017). Primary care–based models for the treatment of opioid use disorder: A scoping review. *Annals of Internal Medicine*, 166(4). 268-278. <https://dx.doi.org/10.7326/M16-2149>

Lagisetty, P., Klasa, K., Bush, C., Heisler, M., Chopra, V., & Bohnert, A. (2017) Primary care models for treating opioid use disorders: What actually works? A systematic review. *PLoS ONE*, 12(10). e0186315. <https://doi.org/10.1371/journal.pone.0186315>

Lofwall, M. R., & Walsh S. L. (2014). A review of buprenorphine diversion and misuse: The current evidence base and experiences from around the world. *The Journal of Addiction Medicine*, 8(5). 315–326. <https://dx.doi.org/10.1097/ADM.0000000000000045>

McCarty, D., Gu, Y., McIlveen, J.W., & Lind, B. K. (2019). Medicaid expansion and treatment for opioid use disorders in Oregon: An interrupted time-series analysis. *Addiction Science and Clinical Practice*, 14(31). <https://dx.doi.org/10.1186/s13722-019-0160-6>

OHSU Primary Care Clinic, Richmond: Family Medicine. (2020). Oregon Health and Science University (OHSU). Retrieved June 2nd, 2021, from <https://www.ohsu.edu/primary-care/ohsu-primary-care-clinic-richmond>

Oregon Health and Science University: BHCNISID: 10E00507. (March 21, 2017). Uniform Data Systems (UDS) Reports – 2016: Health Center Profile.

Oregon Health and Science University: BHCNISID: 10E00507. (February 15, 2018). Uniform Data Systems (UDS) Reports – 2017: Health Center Profile.

Oregon Health and Science University: BHCNISID: 10E00507. (February 14, 2019). Uniform Data Systems (UDS) Reports – 2018: Health Center Profile.

Oregon Health Authority (OHA): Public Health Division. (n.d.) Prescribing and overdose data for Oregon. Retrieved July 2, 2021 from <https://www.oregon.gov/oha/ph/PreventionWellness/SubstanceUse/Opioids/Pages/data.aspx>

Oregon Health Authority (OHA), Public Health Division. (2020). Opioid overdose in Oregon: Report to the Legislature. Retrieved on June 25, 2021 from <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/OHA2479.pdf>

Oregon Health Authority: Oregon Essence. (OHA). (2021). Opioid Overdose Public Health Surveillance Update May 17th 2021. Retrieved from https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/monthly_opioid_overdose_related_data_report.pdf

Penrod, L. E. (2017). Clinical informatics in psychiatry: Electronic health record transition considerations. *PM & R*, 9.S13-S18. <http://dx.doi.org/10.1016/j.pmrj.2017.01.009>

S.524 – Comprehensive Addiction and Recovery Act of 2016. (2016, July 22). Congress.gov. Retrieved May 29, 2021. <https://www.congress.gov/bill/114th-congress/senate-bill/524/text>

Silverstein, S. M., Daniulaityte, R., Miller, S. C., Martins, S. S., & Carlson, R. G. (2020). On my own terms: Motivations for self-treating opioid-use disorder with non-prescribed buprenorphine. *Drug and Alcohol Dependence*, 210. 107958. <https://dx.doi.10.1016/j.drugalcdep.2020.107958>

Substance Abuse and Mental Health Services Administration (SAMHSA). (2020). *Medications for opioid use disorder: Treatment Improvement Protocol (TIP) Series 63*. https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-02-01-006_508.pdf

U.S. Department of Health and Human Services (USHHS). (April 27, 2021). HHS releases new buprenorphine practice guidelines, expanding access to treatment for opioid use disorder. *HHS.gov*. <https://www.hhs.gov/about/news/2021/04/27/hhs-releases-new-buprenorphine-practice-guidelines-expanding-access-to-treatment-for-opioid-use-disorder.html>

U.S. Department of Health and Human Services (USDHHS). (April 28, 2021). Practice guidelines for the administration of buprenorphine for treating opioid use disorder. Federal Register, 86(80). 22439-22440. Retrieved on February 12, 2022 from <https://www.federalregister.gov/documents/2021/04/28/2021-08961/practice-guidelines-for-the-administration-of-buprenorphine-for-treating-opioid-use-disorder>

U.S. Preventive Services Task Force (USPSTF). (2020). Final recommendation statement: Unhealthy drug use: Screening. *JAMA*, 323(22). 2301-2309. <https://dx.doi.org/10.1001/jama.2020.8020>

Volkow, N. D., & McLellan, A. T. (2016). Opioid abuse in chronic pain – misconceptions and mitigation strategies. *The New England Journal of Medicine*, 374,(13). 1253-63.

<https://dx.doi.org/10.1056/NEMra1507771>

<https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner>

Appendix A: Tables

Table 1

MAT program information for each calendar year

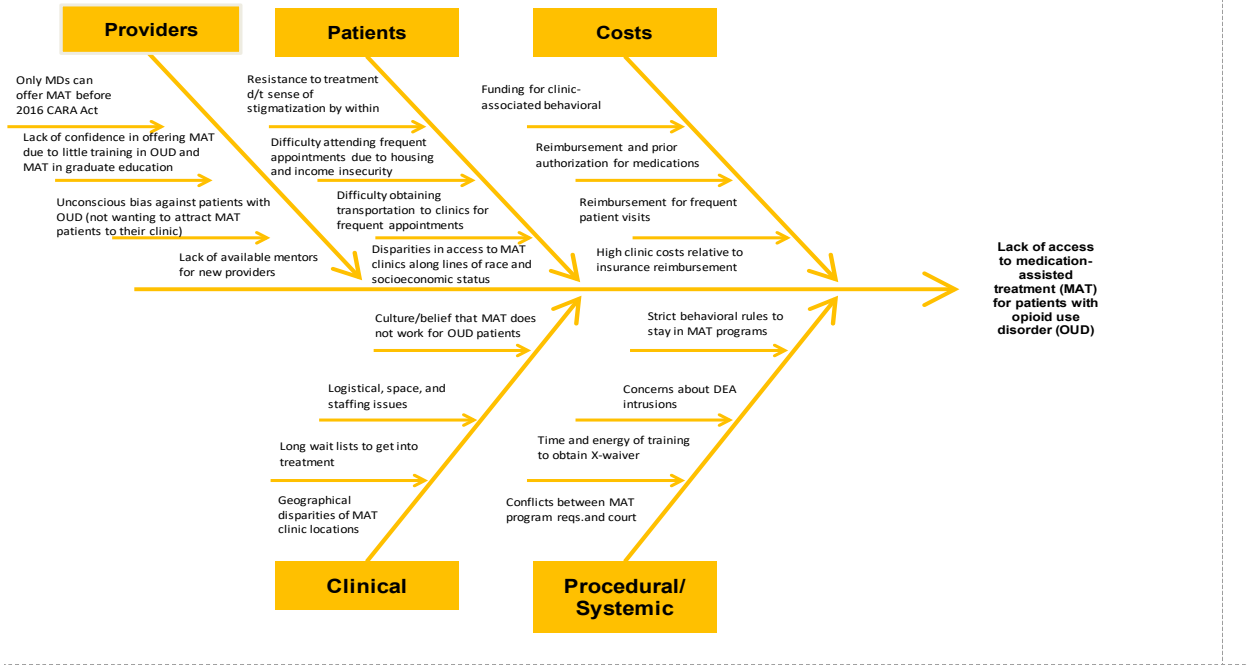
Year	MAT patients	Providers with an X waiver
2016	212	14
2017	480	12
2018	336	18

Table 2

Richmond Clinic provider involvement

	Physicians	APRNs	Physician Assistants	All providers
2016				
Total FTEs	14.93	8.91	1.63	25.47
% of all FTEs	58.6%	35.0%	6.4%	100%
# patient visits per FTE	1,451	2,205	2,692	6,348
2017				
Total FTEs	12.83	9.76	1.49	24.08
% of all FTEs	53.3%	40.5%	6.2%	100%
# patient visits per FTE	1,541	2,360	2,625	6,526
2018				
Total FTEs	16.5	9.27	1.64	27.41
% of all FTEs	60.2%	33.8%	6.0%	100%
# patient visits per FTE	1,201	2,551	2,601	6,353
February 2022				
Total providers	25	7	3	35
Providers with an X waiver	17	7	2	26
% of providers, within designation, who have an X waiver	68%	100%	67%	74%
MAT patients treated	235	140	40	415
Average # of MAT patients per provider, within designation	14	20	20	

Appendix B: Cause and Effect Diagram



Appendix C: Project Timeline

	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Finalize project design and approach (703A)	X	X	X							
Complete IRB determination or approval (703B)			X	X						
Data collection from EHR (703B)				X	X	X				
Final data analysis (703B)							X	X		
Write sections 13-17 of final paper (703B)									X	X
Prepare for project dissemination (703B)										X

Appendix D: Letter of Support from OHSU Richmond clinic

Letter of Support from Clinical Agency

Date 9/9/2021

Dear Mikael Clothier,

This letter confirms that I, Erin Kirk, allow Mikael Clothier (OHSU Doctor of Nursing Practice Student) access to complete his/her DNP Final Project at our clinical site. The project will take place from approximately September 20th, 2021 to April 30, 2022.

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (Laurel Hallock-Koppelman):

- **Project Site(s):** OHSU Richmond Family Medicine Clinic, 3930 SE Division St., Portland OR, 97202
- **Project Plan: Use the following guidance to describe your project in a brief paragraph.**
 - **Identified Clinical Problem:** The prevalence of individuals with opiate use disorder (OUD) and OUD-related unintentional overdose deaths in the U.S. have risen over the last three decades, leading OUD to be classified as a national epidemic. OUD has been strongly implicated in the concurrent rise of related comorbidities and OUD-related hospitalizations, certain infectious diseases, trauma, and suicide, and is responsible for about 60,000 deaths annually in the U.S.
 - **Rationale:** Medication-assisted treatment (MAT) is a proven strategy to treat patients with OUD, which decreases morbidities and mortalities related to OUD. There are significant barriers for patients with OUD to access MAT, including the limited availability of providers who offer these treatments.
 - **Specific Aims:** Historical chart data will be analyzed to demonstrate the short-term effects of the 2016 CARA Act on patient access to MAT at OHSU Richmond clinic, and identify the influence of nurse practitioners (NPs) on the change in access to MAT.
 - **Methods/Interventions/Measures:** This chart review will consider data from one year prior to the 2016 CARA Act (January 1, 2016) to two years after its enactment (December 31, 2018). Data will be formatted by month and include the number of providers of each specialty (MD/DO, PA, or NP) offering MAT, the percentage of total providers within each specialty offering MAT, the number of MAT patients on each provider's caseload, the total number of MAT patients treated, and the approximate delay to MAT treatment [wait list time]. This information will be analyzed to consider the total effects that the 2016 CARA Act had on access to MAT services at OHSU Richmond clinic.
 - **Data Management:** Collected data will include number and percentage of providers at OHSU Richmond clinic and patients in the MAT program. No personally identifiable information will be used. Data and analyses will be stored on OHSU's approved secure storage site and on a personal computer that is password-locked.
 - **Site(s) Support:** OHSU Richmond will allow the student and DNP Project Preceptor to gather information around the history and workings of the MAT program at OHSU Richmond. They will also connect the student and DNP Project Preceptor with the Family Medicine data team to discuss what support may be available to help retrieve clinic data from site files. If the data team is unable to assist with certain components of data collection, OHSU Richmond will allow the student and preceptor to retrieve this data.

During the project implementation and evaluation, Mikael Clothier will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact Mikael Clothier and Jonathon Soffer (DNP Project Chairperson).

Regards,

Laurel Hallock Koppelman DNP
DNP Project Preceptor Job Title
[Signature] 2/8/22
Signature Date Signed

Appendix E: OHSU IRB Letter of Approval



IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

NOT HUMAN RESEARCH

September 15, 2021

Dear Investigator:

On 9/15/2021, the IRB reviewed the following submission:

Title of Study:	Impact of the 2016 CARA Act on medication-assisted treatment (MAT) for opioid use disorder (OUD) in an urban federally qualified health clinic (FQHC)
Investigator:	Jonathan Soffer
IRB ID:	STUDY00023532
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the [HIPAA and Research website](#) and the [Information Privacy and Security website](#) for more information.

Sincerely,

The OHSU IRB Office