Medication-Assisted Opioid Use Disorder Treatment Pilot Program

Session Law 2016-94, Section 12F.1.(g)

Report to the Joint Legislative Oversight Committee on Health and Human Services

By

North Carolina Department of Health and Human Services

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Introduction

Session Law 2016-95, Section 12F.1, enacted in July 2016 and updated through technical amendment, via Session Law 2017-212, Sec. 3.1, which eliminated the definition of randomized control group members and references to the same, required the Department of Health and Human Services (Department) to utilize funding from the Substance Abuse Prevention and Treatment Block Grant to develop and oversee the administration of a three-year pilot program to be conducted by designated Federally Qualified Healthcare Centers (FQHCs) to address North Carolina's growing opioid addiction and overdose crisis. As written, the Pilot Program was to center on: (1) patients who were clinically appropriate for the extended-release, injectable formulation of the opioid antagonist Vivitrol (XR-naltrexone) and (2) were willing to receive their medication at FQHC settings.

Over the past several years, North Carolina, like most of the nation, has experienced an increase in opioid and heroin use, misuse and overdose. In response, the state has developed strategies and implemented many initiatives to address the problem, including the utilization of federal funds to increase access to medication-assisted treatment and associated clinical services for individuals with an opioid use disorder.

At the time this pilot program was first established, there were less than 60 opioid treatment programs in North Carolina. There are currently 81 providing a full range of FDA-approved medications to approximately 21,000 individuals daily, with current capacity for an additional 5,000. This growth and expansion have largely been fueled by the influx of federal funding to specifically address opioid use disorder among uninsured and under-insured individuals.

Background

In accordance with the legislation, eligibility to participate was prioritized for those FQHCs that had been awarded Health Resources & Services Administration (HRSA) expansion dollars for substance use disorder treatment. In August 2016, surveys were sent by the NC Community Health Center Association to seven FQHCs to identify level of interest. Phone conferences were completed with six FQHCs, as one did not respond to the survey. Four FQHCs were selected using criteria established in HB 1030. Additional information was obtained from each of the four sites through emails and phone conferencing. Based on the responses received, the FQHCs meeting the initial criteria for the pilot program were:

- Blue Ridge Community Health Services,
- High Country Community Health in Boone,
- Lincoln Community Health Center in Durham, and
- Metropolitan Community Health in Washington.

Surveys were solicited from the above four sites for additional information and meetings were held to discuss the project. Pilot sites identified current and/or planned sites for opioid use disorder (OUD) treatment, agreements with other behavioral health providers, current capacity, primary referral sources and a description of billing practices for behavioral health services. The

pilot sites also identified concerns with having clinical patients randomized and the amount of staff time needed to manage a randomized control trial (these meetings were conducted prior to the technical revision). Department staff also held conversations with Alkermes regarding training and education for sites to assure participation and a higher degree of comfortability with the project.

Following these meetings, direct contracts in the amount of $166,666 per site per year were executed with the three FQHCs that agreed to participate: High Country Community Health, Lincoln Community Health Center, and Metropolitan Community Health. Contracts were executed annually for state fiscal years 18-19 and 19-20. Funding in these contracts was budgeted to cover the cost of medication (XR-naltrexone), provider fees, clinical and counseling services and necessary labs, such as urine drug analyses. Division staff-maintained contact and offered technical assistance prior to execution of the contracts, as well as throughout the duration of the contract periods with the goals of identifying and mitigating any barriers or obstacles that negatively impacted recruitment and participation.

Additionally, the Department partnered with Vaya Health in the selection of an evaluator and development of a methodology for the collection of information on program participants and overall evaluation of the initiative. The Treatment Research Institute Center on Addictions, Research and Evaluation Group, Public Health Management Corporation (PHMC), an independent, nonprofit research and development organization, submitted a proposal and was selected for such.

Results and Findings

Immediately following this document is the final report prepared by PHMC. This report details outcomes from a mixed-methods evaluation of this initiative conducted within three participating FQHCs across North Carolina. The primary goals of the evaluation were to examine the effectiveness of XR-naltrexone in increasing rates of participants' opioid abstinence through 18-months post-evaluation entry; understand staff and provider opinions and perceptions of OUD and its treatment via buprenorphine and XR-naltrexone; and to explore the economic costs of establishing XR-naltrexone treatment programs in this context.

Despite concerted efforts over a period of two years, only five participants were enrolled. One FQHC was unable to enroll any participants. Reasons cited for low participation included the required need for detoxification prior to induction, heightened risk of overdose if participants discontinued the medication and costs for continued use of XR-naltrexone after the pilot ended. Providers, staff and patients reported more familiarity and comfortability with buprenorphine products, and the need for additional education and training on XR-naltrexone.

Suggestions from FQHCs to increase utilization of Vivitrol included enlarging participating agencies to include detoxification facilities and other levels of care, increasing access to and affordability of the medication providing additional education for FQHC staff on the medication, increasing public awareness and assisting participants with travel costs. Overall staff perceptions towards the utilization of Vivitrol did not drastically change, as buprenorphine products were seen as the safest and most effective treatment approach for individuals with opioid use disorder.

In conclusion, despite efforts to educate and provide technical and financial support, staff were largely unable to recruit and engage participants in this pilot. However, each individual seeking recovery from opioid use disorder should be afforded adequate and timely information and resources in order to make well-informed decisions about his or her health care and medication options. While utilization may be low, XR-naltrexone should be available as an option for individuals desiring and meeting medical criteria for this type of medication. Recovery is best operationalized through environments that offer a full array of treatment options, including medications, recovery supports and address barriers to care, as well as social determinants such as housing and food security, transportation, childcare and employment.

Evaluation of Extended-Release Naltrexone in Selected North Carolina Federally Qualified Healthcare Centers

Final Report

Prepared by
Treatment Research Institute Center on Addictions
Research & Evaluation Group
Public Health Management Corporation

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Study Team Members

The Treatment Research Institute Center on Addictions at Public Health Management Corporation wishes to acknowledge the staff who contributed across the span of this evaluation:

Adam Brooks, Ph.D. – Principal Investigator

Karen Dugosh, Ph.D. – Principal Investigator

Elena Bresani, M.S. – Project Manager

Brook Burkley, M.S.W. – Senior Project Manager

David Gastfriend, M.D. – Medication Assisted Treatment Consultant

Salini Inaganti, M.P.H. – Project Manager

Jessica Lipkin, M.P.H. – Research Assistant

Sean Murphy, Ph.D. – Health Economist Consultant

Anand Petigara, M.S.W. – Project Manager

Chloe Sierka – Research Assistant

Anna Todaro, M.P.H. – Project Manager

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Executive Summary

The United States is currently experiencing an epidemic of opioid use disorder (OUD), and the state of North Carolina has been especially affected. It is estimated that there are 61.5 opioid prescriptions for every 100 people in North Carolina, which is higher than the national average of 51.4 opioid prescriptions per 100 (National Institute on Drug Abuse [NIDA], 2020a). In 2018, approximately 79% of overdose deaths in North Carolina involved opioids. The opioid epidemic also imparts severe financial consequences; in 2015, opioid overdose deaths cost North Carolina over $1 billion (North Carolina Department of Health and Human Services [NC DHHS] Prescription Drug Abuse Advisory Committee, 2017).

As a part of a larger strategy established to address the opioid epidemic, members of the North Carolina general assembly passed legislation on July 14, 2016 that allocated $500,000 in funding from the federal Substance Abuse Prevention and Treatment Block Grant to develop a medication-assisted treatment (MAT) pilot program that aimed to evaluate the effectiveness of providing psychosocial treatment and extended release naltrexone (XR-naltrexone, i.e., Vivitrol®), a non-narcotic non-addictive injectable opioid antagonist that is FDA-approved for the prevention of opioid relapse, within the context of a Federally Qualified Healthcare Center (FQHC).

This report details outcomes from a mixed-methods evaluation of this State-funded initiative conducted within three participating FQHCs across North Carolina. The primary goals of the evaluation were to examine the effectiveness of XR-naltrexone in increasing rates of participants' opioid abstinence through 18-months post-evaluation entry; understand staff and provider opinions and perceptions of OUD and its treatment via buprenorphine and XR-naltrexone; and to explore the economic costs of establishing XR-naltrexone treatment programs in this context.

Evaluation Participant Outcomes

- Although 367 patients with OUD presented across the three FQHCs during the evaluation period from March 2019 through June 2020, only five participants were enrolled in the evaluation. Participants came from two of the three participating FQHCs as one of the study sites enrolled no participants into the evaluation. This small sample size limited our ability to conduct a comprehensive outcomes analysis. For this reason, outcomes were examined descriptively.
- Two evaluation participants were compliant with their treatment (i.e., received a monthly injection) for at least six months. The remaining participants (n = 3) received three or fewer injections before discontinuing XR-naltrexone treatment at the FQHC.
- Three of the five participants provided drug-positive urines while they were actively engaged in treatment, and one participant provided an opioid-positive urine at the appointment prior to dropping out of treatment.
- Based on both clinic and self-report, three of the five patients engaged in adjunctive psychosocial treatment (i.e., outpatient treatment, therapist visits to address alcohol and drug issues) in the six month period following induction. All four participants who completed the six-month follow-up assessment reported engaging in self-/mutual-help groups during this same time.
- Finally, the two participants who were actively engaged in treatment at the six-month follow-up point demonstrated increases in of quality of life relative to baseline than those who were not engaged in treatment.

FQHC Provider and Staff Outcomes

Key Informant Interviews

- FQHC providers and staff reported several benefits of XR-naltrexone in relation to other forms of MAT. They generally liked that XR-naltrexone cannot be diverted and the convenience of clients only having to take the medication once per month. They also noted that it is a viable option for both opioid and alcohol use disorder.

- Stakeholders cited a number of concerns about XR-naltrexone with the most frequently mentioned barrier to XR-naltrexone treatment being the detoxification process required prior to induction. They were also concerned about the heighted risk of overdose among patients who discontinue the medication. Finally, stakeholders reported that XR-naltrexone was cost prohibitive and shared concerns about its affordability to patients after the grant ended.
- Overall, providers and staff were much more familiar with buprenorphine and they reported that this was the case for patients as well. Buprenorphine was often the prescribers' preferred treatment method, and lack of prescriber buy-in for XR-naltrexone was cited as a leading barrier to implementation. Finally, they reported that patients generally preferred buprenorphine as a treatment as they were unwilling or unable to complete the detoxification process.
- Stakeholders cited education and training as instrumental for program success. Many felt that additional education and training is necessary in order to increase their level of comfort in providing XR-naltrexone treatment and in presenting it as a treatment option for patients. It was suggested that pharmaceutical manufacturers of XR-naltrexone should play a more active and engaged role in educating and training the public and healthcare professionals.
- Stakeholders mentioned difficulties in establishing/maintaining strong relationships with various community partners (e.g., local correctional facilities, treatment courts, detoxification facilities) that could potentially provide referrals to the FQHC.
- Suggestions for increasing the success of the pilot program included involving a system of agencies including detoxification facilities in the pilot rather than only FQHCs; expanding the application of XR-naltrexone within the pilot to include patients with alcohol use disorder; and expanding the pilot program to include other medications such as buprenorphine.
- Stakeholders provided a number of suggestions for the state that they believed could facilitate the success of initiatives like the XR-naltrexone pilot program in the future. Suggestions included increasing access to and affordability of the medication (by reducing or covering its cost or through Medicaid expansion), creating more educational opportunities for FQHC staff and providers on XR-naltrexone, increasing public

awareness of XR-naltrexone, offsetting patient costs to travel to treatment, and increasing oversight/involvement from agency leadership.

Staff Survey

- Based on a three-wave provider and staff survey administered pre-, during, and post-program implementation, staff members had somewhat positive attitudes about working with people who use drugs and somewhat positive attitudes for people who use drugs.
- Providers and staff reported having limited knowledge on the effectiveness of XR-naltrexone in reducing relapse and helping patients to improve their lives across all three waves of data collection. Overall, buprenorphine was seen as the most effective treatment approach for OUD and detoxification with drug-free counseling as the least effective.

Cost Analysis

- The small sample size of the current evaluation (five participants from two of the three participating sites) limited our ability to conduct a formal cost-benefit analysis. To provide some indicator of the costs of implementing the program, we examined the pilot start-up and ongoing operational costs for the FQHC with the largest number of XR-naltrexone patients and most complete cost-reported data.
- Start-up costs involved on-site training; ongoing operational costs were associated with client screening for XR-naltrexone suitability, XR-naltrexone induction, subsequent injection appointments, and urinalysis at the induction and monthly appointments. The cost of XR-naltrexone itself was not included in calculations, as it was covered through pilot funding and costs of the medication may vary for different types of facilities and patients.
- The start-up costs and ongoing operational costs for the three evaluation participants at the site totaled $3,467.58. This total reflects the added costs incurred by the FQHC specific to the XR-naltrexone pilot program, and were incurred in addition to the FQHC's standard operation costs.

Recommendations

Using information gathered through this mixed methods evaluation, the evaluation team has developed a number of recommendations for the state legislature should they choose to continue or expand the pilot program including and to other programs that are developing XR-naltrexone programs:

Provide Ongoing Education and Training for MAT Providers and Staff

Providers and staff could benefit from ongoing and comprehensive trainings on XR-naltrexone, including empirical support for its effectiveness, information about potential risks, side effects, and guidance on how to discuss the medication as a treatment options to patients.

Identify Internal Champions to Promote Buy-in

Across the pilot sites, providers and staff generally did not consistently embrace XR-naltrexone as a viable treatment option for patients with OUD. To promote broader adoption of this treatment option, sites could benefit from identifying a champion who can promote the acceptability and effectiveness of XR-naltrexone.

Increase Access to and Utilization of On-site Behavioral Health Support

Existing guidelines suggest that medications for OUD should be provided in concert with ongoing psychosocial services to increase retention and improve outcomes. Clinics should work to increase the number of behavioral health services available to MAT patients and identify ways to more fully engage patients in these services.

Develop Strategies to Increase Patient Knowledge

Patients have limited knowledge about XR-naltrexone for treating OUD and, for this reason, are less likely to embrace it as a treatment option. It is recommended that FQHCs develop strategies to educate patients about the medication including its safety and effectiveness.

Establish Robust Community Partnerships and Strengthen Systems of Care

It is recommended that sites identify and establish working relationships with community agencies that could consistently refer patients who would be appropriate for XR-naltrexone

treatment. Establishing these networks of care can serve to ensure patients are not lost during transitional periods (e.g., discharge from detoxification center, completion of residential SUD treatment, release from prison).

Increase Utilization of Ambulatory Detoxification

Sites should find ways to promote the use ambulatory detoxification procedure to increase the uptake of XR-naltrexone by patients who are deemed appropriate. This could involve providing ongoing peer-based trainings and other educational opportunities.

Provide Ongoing Adjunctive Services

Clinics should establish ways (e.g., peer support, case management) to close gaps for patients who may require additional social services to support their abstinence (e.g., housing, transportation, health insurance, vocational training, employment, social security income), and ensure that programming is tailored to the specific needs of individuals with OUD.

Introduction

The United States is currently experiencing an unprecedented opioid epidemic. According to recent reports from the Centers for Disease Control and Prevention (CDC), the number of opioid overdose deaths has risen fivefold from 2000 to 2017, from approximately three deaths per 100,000 people to approximately 15 deaths per 100,000. By 2015, other synthetic opioids surpassed natural and semi-synthetic prescription opioids and heroin as the cause of opioid overdose death (CDC/National Centers for Health Statistics [NCHS], 2018). This stark increase was initially fueled by misuse of potent prescription opioid medications for pain relief beginning in the late 1990's (U.S. Food and Drug Administration [FDA], 2020). In 2018 alone, 9.9 million Americans reported using prescription opioids (POs) non-medically (Substance Abuse and Mental Health Administration [SAMHSA], 2019).

Opioids are used for pain management and relief but are highly addictive. When opioids are misused, a powerful withdrawal syndrome is elicited, necessitating increasing amounts of opioids for the individual to simply feel "normal." Consequently, PO misuse can easily develop into an opioid use disorder (OUD; National Institute on Drug Abuse [NIDA], 2020b). Due to decreased availability or high costs, the addicted individual may transition from prescribed opioids to cheaper illicit opioids, such as heroin, which increases the risk of overdose (NIDA, 2018). In response to the burgeoning opioid crisis, from 2001 onward, several governmental agencies such as the FDA, SAMHSA, NIDA, and CDC have partnered to increase warnings on medication packaging and patient materials, revise provider prescription guidelines, and increase accountability among pharmaceutical manufactures through mandatory Risk Evaluation and Mitigation Strategies. These agencies have also funded key research towards better understanding environments that facilitate opioid misuse and abuse, and methods to combat it at the patient, provider, and healthcare system levels (FDA, 2020).

The state of North Carolina has been especially affected by the opioid epidemic. It is estimated that there are 61.5 opioid prescriptions for every 100 people in North Carolina, which is higher than the national average of 51.4 opioid prescriptions per 100 (NIDA, 2020a). In 2018, approximately 79% of overdose deaths in North Carolina involved opioids; synthetic opioids

were most often implicated in these deaths, followed by heroin and prescribed opioids. Although the opioid overdose death rate declined by 4.1% from 2017 to 2018, the rate remains higher than 20 years ago (NIDA, 2020a). In addition to taking the lives of North Carolinians, the opioid epidemic also imparts severe financial consequences; in 2015, opioid overdose deaths cost North Carolina over $1 billion (North Carolina Department of Health and Human Services [NC DHHS] Prescription Drug Abuse Advisory Committee, 2017).

Medication-assisted treatment (MAT) is the gold standard in treatment for OUD (American Society of Addiction Medicine, 2013a). MAT involves combining efficacious medications for OUD with counseling and/or behavioral therapy. MAT can incorporate agonist replacement therapies like methadone and buprenorphine (which fit the same receptors in the brain as opioids and mimic their effects in the brain) or antagonist medications such as extended release naltrexone (which fit the same receptors in the brain as opioids and produce a blockade that prevents opioids from eliciting a response in the brain) (SAMHSA, 2020). Despite the effectiveness of MAT, access to these medications is often limited, particularly among uninsured and under-insured individuals. Beyond issues related to cost, lack of access to MAT can be due to complex and lengthy authorization and approval processes, lack of accessibility to required counseling services, and stipulations that other treatments must be shown to fail before allowing the use of certain medications (American Society of Addiction Medicine, 2013b).

Evaluation Overview

As a part of a larger strategy established to address the opioid epidemic, members of the North Carolina general assembly passed legislation on July 14, 2016 that allocated funding from the federal Substance Abuse Prevention and Treatment Block Grant to develop a MAT pilot program that aimed to evaluate the effectiveness of providing psychosocial treatment and extended release naltrexone (XR-naltrexone), a non-narcotic non-addictive injectable opioid antagonist that is FDA-approved for the prevention of opioid relapse, within the context of a Federally Qualified Healthcare Center (FQHC). The Treatment Research Institute Center on Addictions at Public Health Management Corporation ("evaluation team"), was selected to conduct this evaluation according to the parameters of the legislation, working in tandem with NC DHHS.

The original legislation called for a randomized controlled trial (RCT) to evaluate the effectiveness of providing XR-naltrexone relative to standard care in the FQHC setting. After discussions with the proposed sites, however, it became clear that a RCT was not feasible given the amount of money appropriated in the legislation, and the dearth of sites agreeing to participate in the pilot to fulfill the legislative requirement. In response, the general assembly of North Carolina convened in a special session to revise the opioid legislation. The revised legislation removed the mandate to conduct a RCT, and instead called for an evaluation of the delivery of the XR-naltrexone treatment by participating FQHCs. The revised legislation was enacted on April 4, 2017.

Four FQHCs in North Carolina originally expressed interest in participating in the evaluation. Following a thorough vetting process conducted by the NC DHHS to assess candidate suitability – including staffing capacity, patient load, OUD screening methods, standards of care for OUD patients, and ability to comply with evaluation logistics – three FQHCs ultimately were selected and agreed to participate in the evaluation: High Country Community Health in Boone, Metropolitan Community Health Services, Inc. (Agape Health Services) in Washington, and Lincoln Community Health Center in Durham (see Figure 1).

Figure 1. Map of FQHCs participating in the evaluation of extended-release naltrexone

This evaluation used a mixed methods (qualitative and quantitative) approach with several data collection instruments over a longitudinal time period. The primary goals of the evaluation were to understand staff and provider opinions and perceptions of OUD and its treatment via buprenorphine and XR-naltrexone; to examine the effectiveness of XR-naltrexone in increasing rates of participants' opioid abstinence through 18-months post-study entry; and to evaluate the incremental economic costs and benefits of XR-naltrexone treatment. Evaluation outcomes and associated measures are outlined in Table 1.

Table 1. Evaluation outcomes and associated measures.

Outcome	Measure	Points in Time[1]
Urinalysis Results	Clinical Record/EHR	Baseline, Months 1, 2, 3, 6, 12, and 18
Self-reported Substance Use (prior 30 days)	RecoveryTrack	Baseline, Months 1, 2, 3, 6, 12, and 18
Healthcare Utilization (SUD treatment, ED utilization, hospitalizations) and Self-Help Participation	RecoveryTrack, NSMOS	Throughout the 18-month period; Baseline, Months 1, 2, 3, 6, 12, and 18
Health-Related Quality-of-Life	SF-12	Baseline, Months 1, 2, 3, 6, 12, and 18

[1] The observation period for each participant varies due to the rolling nature of admissions; no evaluation participant reached the 18 month follow-up time period.

Methods

Evaluation Start-up and Implementation

The evaluation team prepared to implement the process and outcomes evaluation of XR-naltrexone in selected North Carolina FQHCs in 2017. Standard operating procedures for patient screening, participant enrollment, and data collection compliance were established by the evaluation team and confirmed with the participating FQHCs. Between September and December 2018, FQHCs were provided with patient education materials on XR-naltrexone; an online training on XR-naltrexone induction; and a recorded training from FEI Systems on Web Infrastructure for Treatment Services (WITS). The evaluation team conducted a comprehensive training with the FQHCs on evaluation procedures and expectations for each site's participation, outlining the evaluation timeline, patient enrollment criteria, documentation, urinalysis, and payment procedures.

The ASAM CONTINUUM Triage (CO-Triage), a brief level of care assessment, was integrated into FQHC standard operating procedures for evaluation participants. The evaluation team worked closely with the three sites to facilitate their purchase of the ASAM CO-Triage software from FEI Systems (the software vendor), and provided online training resources on ASAM CO-Triage and implementing the software into FQHC current clinical procedures. Virtual trainings with the three participating FQHCs on the use of ASAM CO-Triage, led by Dr. David Gastfriend, took place during November and December 2018. The evaluation team also engaged in troubleshooting ASAM CO-Triage with site clinicians throughout the evaluation.

In November 2018, Dr. David Gastfriend led a webinar training on XR-naltrexone induction and ambulatory opioid detoxification procedures with the treatment providers at all sites, addressing existing and ongoing questions and concerns about prescribing XR-naltrexone to clients. FQHCs were also connected with a sales representative from Alkermes, a manufacturer of XR-naltrexone; sites scheduled XR-naltrexone administration training directly with Alkermes.

FQHCs commenced patient recruitment in January 2019. To address subsequent FQHC provider concerns about the appropriateness of XR-naltrexone treatment for their patients who are high risk/high need as well as provide practical suggestions to help increase XR-naltrexone utilization, the evaluation team scheduled physician-peer trainings for each of the sites. Dr. Raymond Pomm, a psychiatrist specializing in addictions who has successfully provided XR-naltrexone treatment to FQHC patients and has served as medical director of two addiction centers in Florida, conducted hour-long webinar trainings with each site. The trainings provided important information to providers related to high risk/high need patients, delivering this treatment in a safe and effective manner, and best practices for establishing patient referral pathways. The peer-mentor training took place in June 2019 for High Country and Metropolitan, and in September 2019 for Lincoln.

To maintain transparent communication of ongoing progress, biweekly meetings were held between the evaluation team and representatives from NC DHHS. During these meetings, the evaluation team reported ongoing enrollment numbers for each site, provided administrative and project-related updates, and discussed any pertinent action items. Weekly meetings were also held internally within the evaluation team.

Data Collection | FQHC Providers and Staff

Both qualitative and quantitative data were collected from FQHC providers and staff through key informant interviews and an anonymous online survey conducted at pilot program outset, one year into implementation, and pilot closure.

Key Informant Interviews

To obtain richer and more granular perspectives from providers and staff on the process of planning for and implementing XR-naltrexone treatment for OUD at each FQHC, key informant interviews were conducted by the evaluation team. The purpose of these interviews was to assess, at multiple points during the pilot, positive and negative staff perceptions about XR-naltrexone treatment for OUD, perceived/actual patient perceptions about XR-naltrexone, factors that hinder or facilitate pilot implementation, additional needed supports, and implementation

concerns. Other questions specific to activities at that particular time period were also included, such as FQHC experience with providing XR-naltrexone versus buprenorphine, differential treatment success of XR-naltrexone versus buprenorphine, patient treatment preferences and interest or resistance to XR-naltrexone, any changes to staff and patient perceptions about XR-naltrexone throughout the pilot, how the pilot program could be improved upon, and specific supports the state could provide to facilitate the success of similar future initiatives. Interviews with key providers and staff at each FQHC took place in March 2018, October and November 2019, and June 2020, with interview length ranging from 20 to 35 minutes each.

A standardized moderator's guide was developed by the evaluation team to guide the interviews. Interviews were conducted via telephonic conference call, audio-recorded with the participants' verbal consent, and transcribed for qualitative analysis through coding. Transcripts were de-identified to ensure respondent confidentiality. For the first round of interviews, transcripts were reviewed for key concepts that were organized into themes. For the qualitative analysis of the second and third round of interviews, both deductive and inductive approaches were applied. The moderator guides were utilized to develop codebooks for the second and third interviews, with any additional codes identified inductively during analysis also added to the codebook. Following coding completion, any codes that were unused were documented in the codebook. Concepts in each interview were organized into themes. Please refer to Appendix A for the moderator guides for all three key informant interviews.

Staff Survey

The staff survey was designed to better understand FQHC stakeholders' attitudes and opinions about OUD and available treatments, as well as identify any overall changes over time. The survey was built using SurveyGizmo, an online secure survey platform, and was administered in 2018, 2019, and 2020. The survey link was sent via email by the evaluation team to the primary contact at each of the three participating FQHCs; these contacts were instructed to share the link with all physicians, physician assistants, nurses, behavioral health counselors, and other staff involved in the XR-naltrexone pilot program. Participation was voluntary, with response confidentiality maintained by the evaluation team. For each of the three surveys, respondents were entered into a drawing to win a $50 Amazon electronic gift card if they completed the

survey by the deadline and provided consent to be included in the drawing. Each survey was open for approximately two weeks, with several reminder emails sent by the evaluation team to FQHC primary contacts until survey closure.

The survey incorporated targeted questions designed specifically for the evaluation along with several psychometrically-validated instruments. The survey included the following data elements:

Demographic information. Demographic data included gender, race, ethnicity, age, professional role, and prior experience providing buprenorphine (Suboxone) and XR-naltrexone treatment to patients with OUD. Descriptive statistics were calculated for each item.

Drugs and Drug Users' Problems Perceptions Questionnaire (DDPPQ). The DDPPQ is a well-validated 20-item measure of care providers' attitudes toward and preparedness for working with individuals who have substance use disorders (SUDs). Respondents indicated their agreement with each item using a seven-point Likert scale (1 = strongly agree, 4 = neutral, 7 = strongly disagree). The DDPPQ measures aspects of role adequacy, motivation, role support, work satisfaction, task-specific self-esteem, and role legitimacy. Total scale scores were calculated by reverse-scoring negatively-worded items and averaging item responses. Scale scores could range from 1 to 7 with *lower scores* indicating *more positive attitudes* towards individuals who use drugs and *greater preparedness* to work with individuals in this population (Watson, Maclaren, & Kerr, 2007).

Medical Condition Regard Scale (MCRS). The MCRS was developed as a non-condition specific measure of the extent to which providers find patients with a given medical condition to be enjoyable to work with, treatable, and a good use of medical resources. For the purposes of the evaluation, the 11-item instrument was tailored to assess provider attitudes about individuals who use drugs. Respondents indicated their agreement with each item using a six-point Likert scale (1 = strongly disagree to 6 = strongly agree). Total scale scores were calculated by reverse-scoring negatively-worded items and averaging responses to the items. Scores could range from 1 to 6 with *higher scores*

reflecting *higher regard* for individuals who use drugs (Gilchrist et al., 2011; van Boekel, Brouwers, van Weeghel, & Garretsen, 2014).

MAT-related questions. Additional items captured respondents' perceptions about the effectiveness of different types of MAT in both reducing relapse and improving the lives of those with OUD. Respondents rated their perceptions of the effectiveness of four different treatment approaches (i.e., methadone, buprenorphine, XR-naltrexone, and detoxification with drug-free counseling) in (1) reducing relapse and (2) improving the lives of OUD patients using five-point Likert scales (1 = totally ineffective to 5 = completely effective). Respondents were also provided with the option to report "I Don't Know" if a treatment technique fell outside the scope of their knowledge or role. Descriptive statistics were calculated for each item across the three waves of data collection.

Pilot program and COVID-19 questions. As the third and final staff survey took place after the onset of the COVID-19 pandemic, eight additional items were included in the third staff survey to understand the impact of COVID-19 on FQHC clients and service provision. Respondents rated the impact of COVID-19 on each of the eight activities using a five-point scale (1 = decreased greatly, 3 = stayed the same, 5 = increased greatly). Respondents were also provided with the option to report "I Don't Know/Not Applicable" if a responsibility fell outside the scope of their knowledge or role. A free-response question also provided respondents with an opportunity to share additional ways COVID-19 impacted MAT protocols and service delivery at their site. A second free-response question asked how the pilot program could be improved upon in the future. Descriptive statistics were calculated for each item. Responses to free-response questions were reviewed and summarized.

With the exception of the pilot program feedback and COVID-19 questions, the same items were repeated at each of the three survey administrations to obtain a longitudinal perspective of staff attitudes and opinions towards OUD and available treatments. However, because the surveys were anonymous to prevent socially desirable responding, surveys could not be matched to each individual across the three survey administrations. Descriptive statistics were calculated for items reflecting respondent characteristics, total scale scores for the MCRS and DDPPQ, each MAT-

related effectiveness question, and item responses to the third survey's supplemental COVID-19 questions. Scale scores for the MCRS and DDPPQ were compared descriptively across each administration to identify differences in the snapshot of respondent attitudes at each wave as the sample sizes precluded formal statistical analysis. Please refer to Appendix B for an example of the staff survey (Wave 3).

Data Collection | Evaluation Participants

Patient-level data for the outcomes evaluation were collected from both participants and clinic staff. Participant assessments used were selected because they are directly relevant to the outcomes evaluation, and have been demonstrated in prior research to be significantly predictive of outcomes; consideration of participant burden also played a significant role in assessment selection. All of the instruments were computerized for direct entry into laptop computers. Prior to all assessments, participants were clearly informed that they were free to refuse to answer any question they did not wish to answer, and that they could discontinue participation in an assessment any time without consequence to their OUD treatment or any other care sought from the FQHC. In addition, clinical data for each patient were provided to the evaluation team by a designated FQHC staff member using the Clinician Survey. These clinical data included XR-naltrexone injection dates, urinalysis results, and FQHCs visit dates.

Participant Eligibility, Recruitment, and Enrollment

At each of the three participating FQHCs, patients who were identified as eligible and a good candidate for XR-naltrexone treatment by the care team met with a Behavioral Health Counselor to discuss XR-naltrexone as a treatment option. The final decision to engage in XR-naltrexone treatment was made by the patient with guidance from the care team.

The following inclusion criteria were identified to determine participant eligibility for enrollment into the evaluation:

- Is a patient of the FQHC and seeking treatment for OUD
- Has an OUD diagnosis and may benefit from treatment for drug use
- Is 18 years of age or older

- Is not currently pregnant
- Does not have liver-related illnesses
- Has decided to pursue XR-naltrexone treatment
- Is accepted by a FQHC medical provider for XR-naltrexone treatment
- Is able to understand and consent to the evaluation (e.g., not currently intoxicated, normal cognitive functioning), and is not acutely suicidal or psychotic

Exclusion criteria included patients for whom FDA labeling provided a contraindication or notable warning regarding the use of XR-naltrexone (e.g., acute hepatitis, expected continuing or ongoing opioid dependence or use, pregnancy, etc.).

Individuals who were interested in XR-naltrexone treatment and met the evaluation inclusion criteria were informed of the evaluation and asked if they were interested in participating. Interested individuals were guided through a standardized written informed consent process led by an FQHC staff member, and assured that all information collected in the evaluation would be kept strictly confidential and in no way would affect the status of their treatment at the FQHC. The FQHC staff member informed interested patients that the evaluation was separate from receiving FQHC healthcare services, and participation was completely voluntary. Patients were not required to complete evaluation assessments in order to receive XR-naltrexone treatment from the site; however, enrollment in the evaluation was a prerequisite for the cost of their XR-naltrexone medication to be covered by the grant. The consent also emphasized the patient's right to refuse to answer any question or withdraw from the evaluation at any time without any negative consequences. Members of the evaluation team would still attempt to contact the patient at each assessment timeframe even if the patient did not return to the FQHC to complete the assessments, and also to remind the patient to continue to submit urine samples. Additionally, HIPAA authorization was obtained as the evaluation team collected protected health information (PHI) as part of the evaluation. Patients were informed that FQHC staff would be in contact with the evaluation team to provide updates on the patient's treatment progress. However, data collected by the evaluation team through the assessments would not be shared with any FQHC staff or providers, nor with any party outside of the evaluation team. Patients were also informed that their XR-naltrexone medication would be covered by funds provided for the evaluation.

Following the consent process, patients were enrolled in the evaluation. A Behavioral Health Counselor administered the ASAM CO-Triage to determine the optimal level of care for the patient, which was also provided to the evaluation team. This standardized referral assessment can be completed in ten minutes, and facilitates identifying needs that require immediate attention, including withdrawal management or ancillary services.

Once enrolled, and while the patient was still at the FQHC, a staff member would provide the patient with a private room where they connected with a member of the evaluation team via phone to complete the baseline assessment. If the patient was unavailable to conduct the baseline assessment during the same appointment as their enrollment, a member of the evaluation team rescheduled the baseline for a more convenient time. Baseline data collection took approximately 30 minutes. Assessments completed by the patient at baseline (and repeated at months 1, 2, 3, 6, and 12 of treatment) consisted of the Non-Study Medical and Other Services (NSMOS), RecoveryTrack™, and Short Form-12 (SF-12). A urine sample was also collected from evaluation participants by FQHC staff as a component of standard FQHC procedures, and tested for THC, cocaine, opiates, amphetamines, PCP, methamphetamine, benzodiazepines, and barbiturates. The urine sample was provided using standard processes to detect tampering or dilution. Additional information about these assessments is provided in the following "Participant Assessments" section of this report. For a depiction of XR-naltrexone evaluation participant enrollment, please refer to the flow chart in Appendix C.

After completing the baseline assessment with a member of the evaluation team, XR-naltrexone evaluation participants would complete any necessary detoxification services if applicable, and continue to receive other services at the participating FQHC. When it was determined appropriate by an FQHC provider (i.e., after the patient was successful detoxified from opioids), the patient would begin to receive scheduled XR-naltrexone injections in addition to their other clinically appropriate treatment services. Only those who completed detoxification were inducted to XR-naltrexone. Patients were also informed they would be scheduled to complete follow-up assessments with a member of the evaluation team at months 1, 2, 3, 6, and 12.

A member of the evaluation team called enrolled evaluation participants monthly to maintain their engagement in the evaluation. When these monthly calls coincided with assessment time frames, the evaluation team member reminded the client to visit the FQHC to provide their urine sample and receive their travel reimbursement.

Participant Assessments

Assessments completed by the patient at baseline and months 1, 2, 3, 6, and 12 of treatment consisted of the NSMOS, RecoveryTrack™, and SF-12. These self-report assessments were administered via phone by a member of the evaluation team, who set up appointments with each evaluation participant at the specified time periods. When possible, the phone appointment was scheduled to coincide with the participant's appointment at the FQHC. Evaluation participants were contacted to complete the follow-up assessments regardless of whether they were still engaged in treatment at the FQHC.

Non-Study Medical Outcomes Survey (NSMOS). The NSMOS (Chambers et al., 2016) records the number of additional services outside of XR-naltrexone treatment that patients received across seven domains: medical, employment, alcohol, drugs, legal, family, and psychological/emotional. The NSMOS takes approximately five to ten minutes to complete. For the current evaluation, the 1, 2, and 3 month follow-up assessments reflected services received in the past 30 days; the 6 and 12 month follow-up assessments included additional items reflecting services received in the past six months.

Short Form-12 (SF-12). The SF-12 (Ware, Kosinski, & Keller, 1996) is a 12-item validated measure of current functional status for both physical health and mental health. It has been normed on a variety of international populations and was used to detect baseline functional deficits and change in health function over time. A weighted sum of the 12 items was calculated to determine clients' physical and mental health composite scale scores. The scale ranges from 0 to 100, with 0 being the least healthy and 100 being the healthiest.

RecoveryTrack. RecoveryTrack (Cacciola et al., 2015) is a 19 item monitoring instrument that is used to examine progress during SUD treatment. The instrument contains items

reflecting self-reported drug use and engagement in self-help groups during the past 30 days, which are both secondary outcomes in the current evaluation.

Urine samples were also collected from evaluation participants by FQHC staff at follow-up appointments scheduled for months 1, 2, 3, 6, and 12. The specimens were provided using standard procedures to detect tampering or dilution, and were tested for THC, cocaine, opiates, amphetamines, PCP, methamphetamine, benzodiazepines, and barbiturates. If applicable, the FQHC would provide the evaluation team with a list of any excusable substances for each evaluation participant at the time of the urine screen. If a urine sample was provided at the corresponding assessment time point, the evaluation participant was provided a $30 transportation stipend to cover their travel to the FQHC in the form of a VISA gift card. Evaluation participants were asked to provide a urine sample at the specified assessment time points even if they were no longer receiving XR-naltrexone treatment at the FQHC. Each week, a member of the evaluation team securely emailed the point of contact at the FQHC with the participants who were eligible to provide a urine sample and receive the $30 travel reimbursement. Gift cards were mailed to and confirmed by FQHCs at the outset of the evaluation. Disbursed travel reimbursements were tracked via receipts and a tracking spreadsheet completed by the FQHC staff; completed receipts were mailed via certified mail to the evaluation team on a monthly basis. All gift cards were stored at the FQHC in a locked filing cabinet or other secure container.

Weekly Calls with Sites

Each week, a member of the evaluation team held a scheduled call with a designated staff member at each of the FQHCs to gather information about the status of evaluation-enrolled patients (e.g., if a XR-naltrexone injection appointment had been scheduled or cancelled/rescheduled) and identify upcoming appointments during which the evaluation team could also schedule phone assessment administration. To facilitate data collection, the designated contact at each FQHC was required to have access to detailed patient data, including information on detoxification, substance use treatment, FQHC visits, and urine drug screen results. During the calls, the number of new patients presenting to the FQHC with OUD were also obtained, and questions or concerns that FQHC staff had during pilot program implementation were

documented. Calls were approximately five to ten minutes in length. Questions or concerns were escalated to NC DHHS as needed and appropriate.

Clinician Survey

At the corresponding assessment time period for each evaluation participant (baseline and months 1, 2, 3, 6, and 12), specific information was collected from the lead clinician at the FQHC. Depending upon the clinician's preference, information was input directly through an online survey, or provided via phone to a member of the evaluation team. If the information was provided via phone, the evaluation team member sent a secure email listing the evaluation participants that would be discussed during the call and the questions that would be asked. The designated contact was encouraged to review the questions for each patient before the call to ensure they could answer each question. At baseline, the clinician survey recorded ASAM CO-Triage recommended level of care, information about detoxification if the evaluation participant required such services, and urinary drug screen data from the participant's intake appointment. At months 1, 2, 3, 6, and 12, the clinician survey recorded all of the participant's visits to the health center since their last evaluation/MAT assessment (including XR-naltrexone injections) and participant urinary drug screen data since their last evaluation/MAT assessment. These clinic-level data were provided for clients who were still actively engaged with the FQHC.

Data Collection | Cost Analysis

A cost-benefit analysis cannot be conducted due to the limited and insufficient sample size. Costs were still explored by providing a series of questions about the costs involved in the start-up and ongoing operation of the pilot program to each FQHC. In order to obtain the most accurate information for responses to cost questions, FQHCs were encouraged to obtain the input of managers and staff across the site, rather than from one individual. FQHCs were instructed to note "Not Applicable" if any of the questions did not apply to their setting. Costs for pilot start-up and ongoing operation were calculated for the FQHC that had the largest number of XR-naltrexone patients and provided the most complete self-reported data. When annual personnel salaries were provided by the site, hourly wages were calculated by assuming 52 work weeks of 40 hours each; when annual salary ranges were provided, the midpoint of the range was used for

derivations of hourly wage. If information on staff and provider hourly rates or annual salaries were not obtainable, FQHCs were encouraged to include staff/provider job titles. These titles were then used to obtain average associated wages from the U.S. Bureau of Labor Statistics' (U.S. BLS) Wage Data by Area and Occupation, which provides average hourly and annual wages for both employment categories and specific occupation titles. The most recent data calculates salary estimates as of May 2019 (U.S. BLS, 2020). Any average wage obtained from U.S. BLS data for the cost analysis was for the state of North Carolina specifically. When an exact title match was not possible, wage for an equivalent role was used. The FQHC confirmed the approximate portion of time used in the analysis for each staff member involved in the induction and monthly injection appointments. The cost of urinalysis per sample was also obtained from the FQHC.

Evaluation Results: FQHC Provider and Staff Outcomes

Key Informant Interviews

First Interview

The first key informant interview with FQHC providers and staff took place in March 2018, prior to pilot program implementation at the sites.

Benefits of the Use of XR-Naltrexone and Implementation Facilitators

FQHCs reported several benefits of XR-naltrexone treatment in relation to other types of MAT. Two FQHCs mentioned the convenience of the client only having to take the medication once per month, as opposed to taking it daily or being required to come to the FQHC for weekly medication management appointments. One FQHC reported that XR-naltrexone has a low diversion potential as it is an injection rather than a pill or sublingual film. Two FQHCs also noted that it is a viable option for several different patient populations, including both opioid and alcohol use disorder patients and drug court clients. One staff member mentioned that XR-naltrexone is a safeguard during the month between drug court clients' status hearings because,

"Once [XR-naltrexone] is in there it's in there…so there's less risk for opiate use during that month." In discussing factors that would facilitate the implementation of the XR-naltrexone program in the FQHCs, two sites reported that they did receive training from drug representatives for the use of XR-naltrexone with alcohol use disorder patients. Additionally, one site mentioned that they already have integrated behavioral health in the organization which enhances their ability to provide MAT on-site.

Negatives of the Use of XR-Naltrexone and Implementation Barriers

FQHCs did report some challenges with the use of XR-naltrexone. All three FQHCs mentioned that providing detoxification services prior to administration of the first dose would be an obstacle. Staff members felt that one challenge to the detoxification process would be ensuring that a solid protocol was in place. One staff member stated, "I think one of the big concerns I have is just making sure we have a strong process in place…to make sure they…don't have opioids in their system when they come in…. so that we aren't sending our patients into immediate withdrawal." Additionally, two FQHCs reported that they were concerned about the potential for the patient to overdose if they decided to use opioids again after having gone through detoxification. FQHC staff members also identified several barriers to implementation specific to their sites. All three FQHCs had concerns about the lack of knowledge about XR-naltrexone among both patients and providers, and a lack of formal provider training. One site also mentioned that XR-naltrexone was not currently in their formulary. Furthermore, FQHCs reported barriers for their patients. All three FQHCs cited cost as a significant challenge to engaging their patients in this type of MAT, especially after state funds are no longer available to cover the costs of treatment. One staff member stated, "A number of our patients are uninsured and they can't afford it…it's not even an option for them financially." Additionally, two FQHCs said that a monthly injection disincentivizes patients from attending their counseling appointments. With other forms of MAT that are taken daily or monthly, clients are incentivized to attend their behavioral health appointments because they will also receive their medication at that time.

Second Interview

The second key informant interview with FQHC providers and staff took place in October and November 2019, approximately half way through the evaluation period and in the midst of pilot program implementation.

XR-Naltrexone versus Other OUD Treatment Medications

At all three sites, patients were more aware of and knowledgeable about buprenorphine (e.g., Subutex and Suboxone) than XR-naltrexone as a treatment option prior to meeting with the provider to discuss treatment options and develop a treatment plan. Often, patients specifically requested buprenorphine at their appointment. They may have been introduced to buprenorphine by friends or family members currently using the medication, had prior success using buprenorphine, sought to continue existing buprenorphine treatment at the more cost-effective FQHC, preferred the "protective factors" of buprenorphine, or presented at the FQHC with buprenorphine in their system that they had procured themselves. In group therapy settings with other patients, buprenorphine treatment was often their providers' preferred treatment method and a common denominator among attendees. Patients often assumed XR-naltrexone was a newly-released medication. As one staff member explained:

> "I think what does a lot of the work for us, we of course talk to patients about risk benefits and side effects with Suboxone treatment, and proper storage and the expectations that we have of them, and that they should have of us. But I think that for a lot of the people that come to us, the fact that they already know what it's going to do, in terms of them having taken whatever amount of Suboxone that they've taken from the street or borrowed from a friend, seems to do a lot of the work in terms of getting that person on board."

When comparing buprenorphine with XR-naltrexone, an identified benefit of buprenorphine was that patients were able to manage their symptoms on their journey to recovery. Further, buprenorphine is familiar to patients; it is taken daily just like many other medications, and do not require injections. Conversely, XR-naltrexone was identified as an "excellent alternative" as it is not a controlled substance, which alleviates some patient anxieties around managing a controlled substance as part of their OUD treatment. While a triggering barrier for some patients, receiving a monthly XR-naltrexone injection prevents risks of OUD medication being stolen, misused, or diverted. One staff member commented:

> "I think for some individuals Suboxone can escalate some issues that they already had related to their addiction … when those situations happen … it's actually not, doesn't seem to be reducing harm. That person is not in a motivational stage where they're able to use the Suboxone therapeutically. So those type of barriers, a person doesn't have to navigate with [XR-naltrexone]. So I'd say that's the biggest difference."

An injection also removes from patients the responsibility of daily medication management and decision-making to remain compliant with the prescribed dosage, which can be stressful for some individuals:

> "…patients who are on Vivitrol and the fact that they're not making that decision every day to take a medication, is very helpful for someone that is experiencing that ambivalence that is so common in early recovery, that they've got that shot, and they're experiencing that relief, and those cravings are well-managed, without them having to decide each day, 'Do I wanna *[sic]* take this?'"

Monthly injection appointments can be positive for patients' work and personal schedules, and were noted as helpful to staff in providing education and support to guide a patient towards their next injection appointment. The patient for whom XR-naltrexone would be the most well-suited medication was identified as one who had made a "conscious decision" to stop using mood-altering substances and is "genuinely committed" to not getting high.

The importance of patient agency in evaluating several possible treatment options was highlighted by one site, which expressed concern over institutional-level influence exerted deliberately or unintentionally upon patients to persuade them towards a particular treatment:

> "I think for some of the populations that we're working with, they are very vulnerable, it's easy for power dynamics to come into play and I would hate for MAT to be another way that they are exploited in a sense that what somebody sees is what is best for them is forced upon them. .. So I would hope that the right to self-determination with treatment services is maintained."

Implementation Facilitators

Provider Awareness and Buy-in

Clinician familiarity with XR-naltrexone supported the education of recently hired clinicians about XR-naltrexone as a treatment option, and site interest in expanding inductions was communicated with new providers. One provider in particular was described as a key support:

> "Our medical prescriber, he's amazing. So, he's more of a teaching type. And so, when we talk about [XR-naltrexone] and we introduce it to a patient or to each other, he's very

> patient with us and helps us to understand the whole mechanism … of how it works and how it helps the patient with not having the cravings and withdrawals, and not also having the withdraws from the medication … once they discontinue use. So, when a patient comes in … if they haven't had any use, we automatically are evaluating them for [XR-naltrexone] and buprenorphine but we're introducing both to them. And then sometimes our medical prescriber will automatically say, "I think this is a Vivitrol candidate," and so that's the way we go."

Further, new providers were receptive to reviewing provided literature on XR-naltrexone in order to broach the option and educate patients. Site 3 also ensured staff were familiar with XR-naltrexone, its function, and its administration. Education and training were valued as a way to be responsive to patients, especially with patients' widespread access to health information through the internet.

Site 2 noted their collaborative environment where integrated teams facilitated communication among behavioral health, medical, and pharmacy was "instrumental" to their implementation. An example of this was a nurse who provided XR-naltrexone injections attending patient care meetings and helping other teams ensure preparations were complete before a patient's injection appointment. Site 2's partnerships with other entities were key to expanding treatment accessibility.

Communications

If a patient was already going to undergo detoxification, one site noted that framing treatment with XR-naltrexone as the beginning of a new stage ("Let's get you to a different spot … that you don't have to deal with that again.") increased initial receptivity to the medication. Both staff and providers play a central role in educating patients about XR-naltrexone, including clarifying information from patients' own research. Traditional methods such as informational pamphlets may need to be revisited, as they are provided to patients but suspected as unread due to the questions patients raise that are addressed in the pamphlet.

Cost

At Site 3, patient assistance and the pilot program's coverage of injection costs improved patient receptivity to the medication.

Other Facilitators

A holistic approach to supporting patients with multiple social needs was suggested for sustaining patient engagement with treatment. Site 3 felt well-supported in administering the monthly injection given their existing medical and counseling resources. Monthly injection appointments, versus the weekly appointments required for other medications, can be helpful for certain patient schedules. When feasible and appropriate, involving members of the patient's support system in decision-making and appointment attendance was suggested to assist with patient willingness to begin XR-naltrexone and remain compliant with treatment.

Implementation Barriers

Lack of Knowledge and Buy-in

Lack of familiarity with and knowledge about XR-naltrexone, both internally among FQHC prescribers and externally among the public, was identified as a significant barrier to implementation. At one site with a newly-established MAT program, XR-naltrexone was novel, as most patients were familiar with maintenance therapy via buprenorphine. While some patients were completely unaware or inexperienced with XR-naltrexone, others stated there was not enough research supporting use of the medication. Staff also perceived patient hesitancy with "change and something new." A member at Site 2 elaborated:

> "It's like trying to sell a medication nobody's ever heard of for some other chronic health condition. Unless you get on the TV and advertise it and people don't know what it is, they don't want it. I serve a particularly vulnerable patient population … those folks don't want you to try any medication on them. [chuckle] They … never heard of it. It's sketchy-sounding."

With regard to providers, Site 3 noted that educational vectors such as academic detailing and waiver trainings include a lot of content on buprenorphine, which increases provider knowledge for that treatment option. Further, providers often automatically equivocated the concept of injected medication with buprenorphine. Even if a provider had heard of XR-naltrexone, two sites noted lack of buy-in with prescribing XR-naltrexone as a leading barrier to implementation, whether the dissonance be due to anxiety around administering the medication, unfamiliarity of using XR-naltrexone to treat OUD, ideological differences such as a preference for harm reduction approaches, or uncertainty about how to discuss multiple treatment options with patients. Lack of familiarity with XR-naltrexone among FQHC staff was a similar barrier; Site 3

explained the unfamiliarity translated to discomfort when conversing with patients about XR-naltrexone.

One site stated that because they were a primary care setting and not an addiction treatment facility, provision of care was not characterized by providers presenting a range of treatments to patients. Rather, care at their site involved a provider recommending to the patient the course of treatment that they believed would lead to the patient's best outcomes. A staff member reflected that an on-site champion for XR-naltrexone treatment, preferably a physician champion, would have been central for success by facilitating expanded conversations about treatment options:

> "They're not used to laying out a range of options. And so, my primary care doctor believes that buprenorphine is the medication for everyone. … I don't think that it was presented as a viable range of options for every patient that walked in the door. ... I will 100% guarantee you that that conversation was not had. … So you have to find a prescriber that is willing to invest in this medication … that is not the personnel that we had in place when we signed up for this project."

Providers and staff also cited concerns about the potential for increased risk of overdose among XR-naltrexone patients.

Cost

Outside of the XR-naltrexone provided under the pilot program funding, Site 3 noted cost as a prohibitive barrier to use of the medication. Site 2 shared they were attempting to have the medication added to the formulary through patient assistance. In addition to the overall cost of the medication, participants expressed concerns about how uninsured patients would be impacted after losing the financial incentive of no-cost XR-naltrexone once the pilot program ended and how patients would pay for subsequent doses.

Medication Requirements

The requirement that patients must be detoxified from opioids prior to beginning XR-naltrexone treatment was one of the primary barriers reported by all three FQHCs; detoxification remained a barrier even if the patient was open to XR-naltrexone treatment and/or if the patient had completed opioid detoxification successfully in the past. If a patient was still using opioids or already taking an alternate medication (e.g., buprenorphine), it was difficult to have them

consider going through the detoxification process in order to initiate XR-naltrexone. Anecdotally, even when a patient bought into XR-naltrexone treatment ("I had a patient that I thought was perfect for [XR-naltrexone] recently, and they did too"), completing detoxification was an insurmountable barrier – not just because of an aversion to it, but also due to lack of access to a facility given family and work responsibilities. Two FQHCs noted that the injection administration of the medication was a deterrent for some patients, to the point of being a trigger.

Patient Barriers

Multiple staff reported difficulty with ensuring patients return to the FQHC in between monthly injection appointments. If a patient was feeling improvements from being on XR-naltrexone, there was similar difficulty in encouraging continuation with the medication:

> "They're feeling good for that month, so it's kind of difficult … to motivate them to come back for that next injection, and even afterwards. I've had patients tell me, "I'm feeling good. I think I'm just gonna *[sic]* stop," and I'm having to educate them on the importance of continuing with services, or at least speaking with a provider prior to ending services, because at the time, they are feeling good, and they don't see a need to continue it."

Other patient concerns relayed by staff included frequent apprehension that the medication would "wear off' over the course of the month and potentially interact with other medications (e.g., pain management following surgery), health conditions (e.g., contraindications of Hepatitis C liver issues), or other substances such as alcohol. Staff also noted barriers of patient disinterest when other medications (i.e., amphetamines/benzodiazepines) are not prescribed alongside XR-naltrexone, patient familiarity with or current use of other therapies (e.g., buprenorphine), and patient loss to follow-up after the first injection. The inability to divert the medication was also brought up by staff as a deterrent to adoption.

One site noted that patients may be receiving XR-naltrexone due to court order. When the order is lifted, or the individual satisfies the conditions of their release, patients often do not return to the FQHC for treatment.

Site 2 shared that patients' social stressors affected their ability to connect and remain in services. Insecure employment, housing, and transportation were cited as examples of major barriers to patients continuing with treatment, especially for frequent appointments.

Other Barriers

Mirroring apprehensions surrounding the affordability of XR-naltrexone after the pilot program, similar concerns were expressed about XR-naltrexone induction within a few months of pilot close-out: “At this point in time, people aren't willing to even consider it, because they know it's gonna *[sic]* end, and none of the people that believe in [XR-naltrexone] believes that it's gonna *[sic]* cure people in three or four months, not in my community. So we don't wanna *[sic]* start something, something else that we can't finish.”

Organizationally, hours of FQHC operation being inconvenient for patient schedules (even if special provisions were made for extended hours), competing work priorities for staff time, the newness of MAT programming, and staff turnover creating a gap in institutionalized knowledge about the pilot project were also cited as implementation barriers.

Additional Supports

Several additional needed supports referenced by interview participants echoed some of the identified implementation barriers. Supplying providers with support and education on XR-naltrexone was suggested to improve medication familiarity and comfort with use. As one staff member at Site 3 elaborated:

> *“*...When I say [XR-naltrexone], [providers say] "Oh we don't do that," ... But that's opioid treatment as well, but they only know that to be used for alcohol use. So, I think educating and providing support to the ones that are actually doing the prescribing, that is huge. We have four, five providers in our facility now in addition to … the [provider] that's already doing it, and each one of them are terrified of using [XR-naltrexone], and they can actually administer that now without a waiver, and they don't wanna *[sic]* do it. They're afraid.”

Prescriber buy-in was identified by Site 2 as instrumental for success: “The project happens because of the person that writes the prescription writes the prescription. They're the ones that make the decisions, not the patient, not the behavioral staff, but the people that have a prescription pad. And if you don't have them sold, you're not gonna *[sic]* have a prescription written.”

Site 2 expressed the need for pharmaceutical manufacturers to play a more engaged role in increasing awareness of XR-naltrexone treatment (“I just think nobody knows about this

medication"). One staff member noted their desire to implement XR-naltrexone at their clinic in order to serve patients with alcohol use disorder, and their disappointment in the restriction of pilot funds for OUD treatment alone. Two different staff members at Site 2 both noted additional financial supports were needed to make XR-naltrexone a more affordable treatment option for patients in general, whether through free injections for a specific number of visits, or assistance with co-pays. As another method of raising awareness, Site 1 suggested that personal accounts and testimonies from XR-naltrexone patients would be "powerful."

Sites 1 and 2 noted personnel and facilities as additional supports that would improve pilot program success. Site 1 stated that larger clinic capacity would permit an increase in the volume of patients seen that meet the criteria for opioid treatment; Site 2 emphasized the importance of an integrated staff, and the key role nurses specifically play in their breadth of involvement in patient care:

> "In a setting like this, everyone is wearing many hats, and they're being pulled in different directions … but a nurse is a vital person to have, a vital professional to have, especially in terms of flexibility of what they can do. But having a nurse available, who has the time and space to meet with the team around [XR-naltrexone] patients, not just to see the person, but to actually attend any meetings that we may need related to care, would be very helpful. … I think if we had multiple patients then, we would most certainly need that support consistently."

Partnership Development

Lack of a foundational understanding of substance use treatment within certain entities, such as local correctional facilities, stymies referral opportunities. Relationship building with other entities, such as area hospitals and detoxification facilities, facilitates a more continuous coordination of care with the FQHC:

> "We have an excellent relationship with some of our area hospitals and detox facilities. We have patients that will get their first injection while in treatment at the detox facility and then they'll come to us for after care, so, we already know when they're coming out, when to expect their next injection so we go ahead and work with it. Or when we send them to the detox, they'll come back to us with [XR-naltrexone]. So, that has been really good."

While an investment of time, coordinating in-person interactions with partner site contacts at their location – even if just for 30 minutes – was more impactful in establishing a connection. As one staff member shared, "Physically going is huge, them actually seeing who's providing the

service because they hear of so many agencies but they don't know which ones are accurate, which ones are still providing the service, which ones can serve patients regardless of their ability to pay." In-person meetings also provided the opportunity for FQHCs to network and answer questions from partner staff and/or prospective patients during interim time periods, such as transitioning from incarceration, where individuals may become lost to follow-up. One staff member relayed how months of unreturned emails and calls were resolved by learning that the key contact's email was outdated. In addition to individual-level meetings, participating in community collaborations was another method of increasing civic awareness of XR-naltrexone treatment provided by the FQHC.

For supports that would strengthen partnerships and establish pipelines for patients who could benefit from XR-naltrexone, Site 2 noted that peer support services would be useful in providing linkages between settings, such as from a hospital to primary care or from incarceration to a hospital, an intensive outpatient program, or other MAT treatment facility. Site 2's community has worked to increase MAT accessibility for patients, and the importance of collaborative institutional networks that are able to initiate or continue a patient's MAT after a hospital stay, detoxification, or incarceration were discussed ("We know that we cannot treat this with just one place … we need these partnerships in order to make [treatment] more accessible to more individuals"). Without continuity of MAT service, there are concerns for a higher risk of overdose.

Examples of successful relationships were shared by FQHC staff. One involved a nearby criminal justice system, which transformed from not permitting the FQHC's incarcerated patients to have their buprenorphine prescription to actively inducting individuals to Suboxone while incarcerated. While the site is interested in furthering progress by encouraging detoxification and introducing XR-naltrexone to incarcerated individuals, a desire was expressed for manufacturers of XR-naltrexone to participate in partnership development, as they are a vital stakeholder. A second example of success was engaging with a substance use treatment facility to broach conversations about introducing XR-naltrexone to patients before they leave the facility so that patients are not starting buprenorphine as they prepare to leave detoxification.

Barriers to partnership development included lack of referrals from initially interested parties, nonresponse to FQHC outreach, being located in a rural area, and staff turnover at partner locations (e.g., due to inconsistent funding, such as time-bound grants).

In-process partnerships at the time of the interview included working with local courts, commissioners, correctional facilities, and detention centers to establish FQHC referrals for the mandated population so that medication can be administered prior to their release and avoid "having overdoses once they get back into the community thinking they can use … [at] the same rate they were before." Other growing relationships were with community mental health providers and intensive outpatient programs.

Third Interview

The third key informant interview with FQHC providers and staff took place in June 2020, during pilot program closure.

Changes in Perceptions of XR-Naltrexone Treatment

Only one site noted a positive change in staff perception about the use of XR-naltrexone for OUD treatment due to increased awareness and knowledge about the medication and its benefits, which facilitated equipping individuals to make decisions about their own treatment through patient education. New site hires during the pilot program were educated on XR-naltrexone by leadership (Behavioral Health Director and MAT Director) and a pharmaceutical sales representative. Although the pilot program exposed staff to XR-naltrexone, the other two sites were unable to quantify any changes in staff perceptions, and attributed this to their patients not meeting the criteria for safe receipt of the XR-naltrexone injection and overall low pilot program patient enrollment. Site 2 reflected that the pilot experience did demonstrate to staff that XR-naltrexone could be an alternative to other more commonly-used medications, but staff exposure to the medication was still not robust. Site 1 noted that their resources and capacity were limited in supporting patients through withdrawal and bringing them to a level where they would meet the criteria for induction, both given their current staffing mix and the lack of behavioral,

inpatient, and outpatient facilities in their geographic location. XR-naltrexone may have been more successful if used for patients with alcohol use disorder at their clinic.

As was experienced during the lifecycle of the pilot program, initial patient curiosity towards XR-naltrexone waned when patients learned they needed to logistically and behaviorally complete detoxification in order to be inducted. Two sites noted that potential XR-naltrexone patients were already a small subset of the population being seen for OUD.

Treatment Barriers

Both staff and patient concerns about the use of XR-naltrexone were sustained through the close of the pilot program. At one site, a provider believed that buprenorphine and methadone are first-line options and XR-naltrexone is a second-line option for OUD treatment due to the requirements for induction, the importance of not interrupting treatment, and the potential heightened risk of subsequent overdose if injections are missed and the patient relapses. The provider noted that these discussions with patients required a level of nuance for which non-medical providers (e.g., behavioral health staff), may not have appropriate training to help assess the risks and benefits of XR-naltrexone given a particular patient's context, and advocated for more training to facilitate counseling. A parallel sentiment was also echoed at Site 3, where access would be improved if FQHC clinical providers outside of those in the behavioral health/MAT program knew that, unlike buprenorphine, they do not need a waiver to prescribe XR-naltrexone and provide the first injection. The site shared how this misperception resulted in unnecessary referrals and avoidable delays for a patient to get their first injection.

At one site, conversations about XR-naltrexone likely did not occur if the patient was unaware of XR-naltrexone, as one prescriber had an existing predilection toward other options such as buprenorphine; the inducted patients were those who requested XR-naltrexone specifically at their appointment. Similarly, if a patient was already interested in or familiar with a particular medication, they often still opted for it, even if XR-naltrexone and several other medication options were presented at the appointment. An overall lack of success stories with XR-naltrexone was believed to further undermine patient interest in the medication. Pain management following

surgery or an accident and the fact that one injection administration lasted for 30 days in one's body remained concerns among patients.

Required detoxification prior to induction was a persistent barrier for patients at multiple sites. A member from Site 1 shared:

> "Buprenorphine works better. It's just less dangerous for these folks. I do have some very stable patients, but … a lot of them do not wait to go through withdrawal, they don't have time in their lives to take a break, even to go to any kind of detox, inpatient, outpatient. And the inpatient that we do have is very far away for a lot of folks, and [it's] a big barrier that they can't just drop their lives, they're stable on the buprenorphine. It's maintenance therapy, basically, it's just like the [XR-naltrexone] would be, but it's way less dangerous, way less commitment, I guess you could say, to going through withdrawal and disrupting their lives."

Site 3 also noted that patients who are currently using agonist medications such as buprenorphine are reluctant or unwilling to discontinue using them in order to be inducted to XR-naltrexone. Thus, introducing XR-naltrexone earlier in the process, such as during detoxification/prior to seeking care at the FQHC, may increase success.

Similarly, precise follow-up timeframes for subsequent XR-naltrexone injections proved to be a recurring issue. Site 2 noted that a lapse in treatment would require repeating the detoxification and induction cycle if the individual had returned to using – and for some patients, late appointments and relapse were a monthly occurrence. To strengthen sustainability of XR-naltrexone use, a provider suggested providing patient support during the "daunting" required abstinence period prior to induction, such as completing detoxification at a facility that houses and/or monitors patients through withdrawal and provides the initial injection, and then establishing a treatment plan for remaining on XR-naltrexone that involved a treatment agreement to continue care through the FQHC. Further, patient support through daily check-ins to ensure timely attendance at follow-up injection appointments and sustained abstention from substance use was highly recommended by a provider both for current outpatient detoxification patients, and those who had completed detoxification and had progressed to the monthly XR-naltrexone injections.

Costs at the patient- and facility-levels created barriers to treatment. While staff noted it was advantageous to provide XR-naltrexone at no cost to patients under the pilot program, future sustainability of patient use is compromised by cost of the medication, which was prohibitive whether or not the individual was insured. For some patients, however, covered medication cost as part of the pilot project did not persuade them to become inducted due to other factors such as lack of knowledge and/or required detoxification. At the facility-level, one FQHC shared that general funding has been cut for uninsured patients at their site and that some partner facilities do not serve the uninsured. One site referenced insufficient budgets for behavioral health care, and concerns about full staff caseloads affecting patient safety.

Needed Supports

Ongoing training and education were identified as needed supports given FQHC staff turnover and a lack of institutionalized knowledge to serve as a resource for new hires. Streamlining bureaucratic processes for obtaining XR-naltrexone was suggested to facilitate faster access and reduce burden on staff time. Consistent contact with XR-naltrexone sales representatives, which lapsed for several months for FQHCs during the pilot program, was also noted as desired operational support.

Task-sharing was also suggested; for example, a provider was responsible for coordinating with the pharmacy, preparing the injection, and providing it to patients when a nursing position was not filled. Task-sharing also has cost implications, given the differential hourly rates of staff who are qualified to prepare and administer the injection.

As OUD does not exist in a vacuum, addressing community-wide deficits in closing gaps for patients who require additional social services that are outside of FQHC scope to support their abstinence (e.g., housing, transportation, insurance, vocational training, halfway houses) was also noted as a needed support. This concept also includes increasing accessibility to existing resources, such as reducing costs for these services, as well as tailoring services to the specific needs of individuals with OUD.

Improving Upon Pilot Program

One FQHC stated that the pilot program may have been more successful if participating sites also included a system of agencies, such as detoxification and behavioral health facilities, rather than singular FQHCs. It was suggested that program involvement be expanded to all types of providers beyond the behavioral health clinical team, including nurse practitioners and pharmacy personnel, and include approaches for integrating and interweaving the program throughout the health center.

It was noted that the use of XR-naltrexone could also have been improved by the pharmaceutical manufacturers directly engaging with FQHCs to educate providers and staff about the use and benefits of the medication, rather than working through the legislation as an intermediary and having the onus of sustaining awareness and education on internal staff.

If similar programs are pursued in the future, considerations should be made to expand the application of XR-naltrexone within the pilot program. One staff member noted that they wanted to use XR-naltrexone for their FQHC's alcohol use disorder patients, but was unable to due to the parameters of the pilot program. It was also recommended that future investments in SUD programming involve medication options that are more accessible and have the ability to affect more people, such as buprenorphine.

One site noted that it plans to continue engaging patients in XR-naltrexone treatment, even after the end of the pilot program.

Future State-Provided Supports

Improving medication access by reducing or covering its cost (whether XR-naltrexone specifically or expanding Medicaid to increase medication access in general for OUD patients), arranging and/or providing educational opportunities for FQHC staff and providers on XR-naltrexone, increasing public awareness of XR-naltrexone, offsetting patient costs to travel to treatment (i.e., the gift card to reimburse patients for travel to the FQHC to provide a urine sample), and increasing oversight/involvement from agency leadership were noted as types of

support the state could provide to facilitate the success of initiatives like the XR-naltrexone pilot program in the future.

There were conflicting opinions on the use of state funds for XR-naltrexone versus more prevalent OUD medications. As a staff member from one site noted:

> "If the state believed that this was something that they wanted to be behind, it looked as though they were looking for data to tell them whether or not this is something that they should support financially. But, if they are convinced that this is a good medication, which it is, they should just fund it. ... I think the state should fund it because it is an effective medication. And if there was no cost barrier for this medication, then I think people would be more likely to utilize it successfully. So, if the state funds treatment through their human services departments, they should just fund it."

At the same site, a provider shared a conflicting opinion:

> "I was a little bit frustrated that the state felt like the best way to spend their money was to fund [XR-naltrexone] treatment ... I just wondered why that decision was made, whereas I think there's tons of patients in the state who are interested in treatment for their addiction with Suboxone or methadone, and [the patients] can't afford it, they don't have access to it. ... I would love to see the state maybe recognize that Suboxone treatment can have stronger evidence, they can help a wider range of patients, and that more patients are interested in that, and that [it's] valid, and that they should be wanting to fund that."

Overall, the provider was pleased that the FQHC was able to offer XR-naltrexone as one of a suite of medication options patients could choose based on their circumstances and history. While the pilot program experience demonstrated to the provider that some patients prefer XR-naltrexone and do well, they believed increasing patient access to other medications should be prioritized.

Staff Survey

Respondent Characteristics

Wave 1. In total, 37 health center staff members participated in the first wave of the staff survey, administered in 2018 before program implementation. There were eight (21.6%) from Site 1, 25 (67.6%) from Site 2, and four (10.8%) from Site 3.

Wave 2. In total, 47 health center staff members participated in the second wave of the staff survey, administered in 2019 during implementation. There were 14 (29.8%) from Site 1, 26 (55.3%) from Site 2, and seven (14.9%) from Site 3.

Wave 3. In total, 18 health center staff members participated in the third wave of the staff survey, administered in 2020 at pilot program closure. There were two (11.1%) from Site 1, 10 (55.6%) from Site 2, and six (33.3%) from Site 3.

Respondent characteristics for Waves 1, 2, and 3 are detailed in Table 2 below.

Table 2. Survey respondent characteristics.

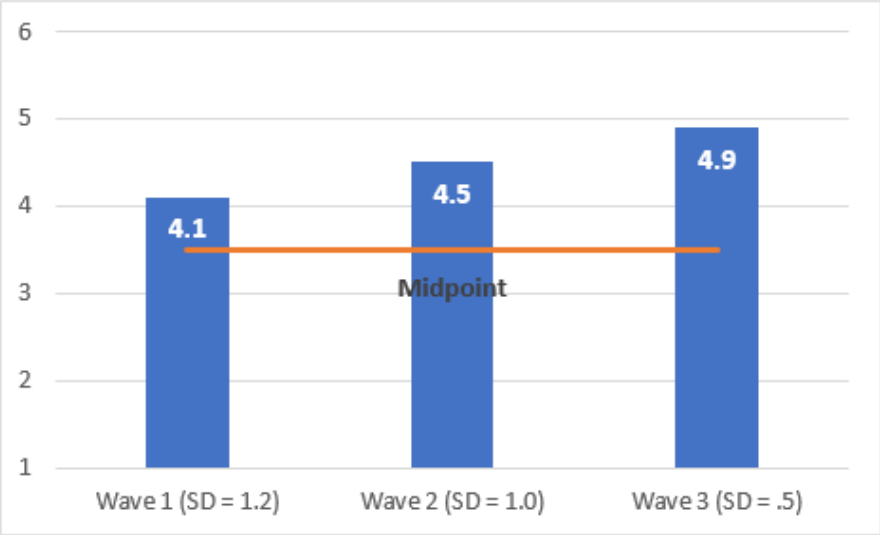
		Wave 1 (2018) ***n* = 37**	**Wave 2 (2019)** ***n* = 47**	**Wave 3 (2020)** ***n* = 18**
Variable		M/N (SD/%)	M/N (SD/%)	M/N (SD/%)
Age		44.5 (12.3)	39.7 (13.7)	40.5 (12.0)
Gender	Male	4 (10.8%)	9 (19.1%)	2 (11.1%)
	Female	33 (89.2%)	38 (80.9%)	16 (88.9%)
Race	White	23 (62.2%)	35 (74.4%)	13 (72.2%)
	Black/African American	12 (32.4%)	10 (21.3%)	5 (27.8%)
	Asian/Pacific Islander	1 (2.7%)	1 (2.1%)	0 (0%)
Ethnicity	Hispanic/Latino	1 (2.7%)	3 (6.4%)	1 (5.6%)
	Not Hispanic/Latino	36 (97.3%)	44 (93.6%)	17 (94.4%)
Position	Behavioral Health Counselor (BHC)	11 (29.7%)	15 (31.9%)	10 (55.6%)
	Physician	6 (16.2%)	7 (14.9%)	2 (11.1%)
	Physician Assistant	5 (13.5%)	3 (6.4%)	1 (5.6%)
	Nurse	4 (10.8%)	3 (6.4%)	2 (11.1%)
	Nurse Practitioner	2 (5.4%)	3 (6.4%)	0 (0%)
	Nurse's Aid	1 (2.7%)	1 (2.1%)	1 (5.6%)
	Crisis Worker	1 (2.7%)	0 (0%)	0 (0%)
	Certified Recovery Specialist (CRS)	0 (0%)	1 (2.1%)	0 (0%)
	Other	7 (18.9%)	14 (29.8%)	2 (11.1%)
Years in Position		6.0 (8.9)	2.5 (2.9)	3.3 (3.9)
Buprenorphine experience	Yes	11 (29.7%)	17 (36.2%)	10 (55.6%)
XR-naltrexone experience	Yes	2 (5.4%)	11 (23.4%)	9 (50.0%)

Comparisons of Scores Across the Survey Waves

Regard for People Who Use Drugs

As illustrated in Figure 2, MCRS scale scores were above the midpoint of the scale (midpoint = 3.5) for all three waves, indicating that respondents overall had somewhat positive regard for people who use drugs. Average scale scores were 4.1 (*SD* = 1.2) for Wave 1, 4.5 (*SD* = 1.0) for Wave 2, and 4.9 (*SD* = .5) for Wave 3. Higher scores indicate more positive regard.

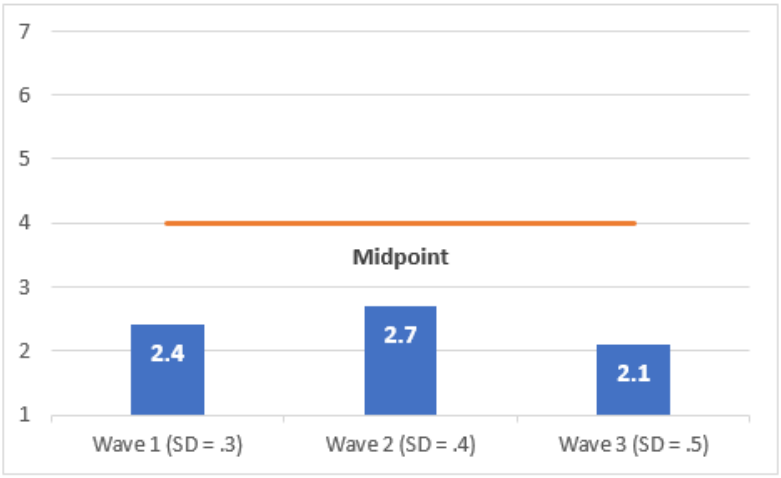
Figure 2. Average MCRS scores in Waves 1, 2, and 3.



Attitudes and Preparedness Regarding Working with People Who Use Drugs

As illustrated in Figure 3, DDPPQ total scale scores fell below the midpoint of the scale (midpoint = 4) across the three waves of data collection, indicating that respondents had somewhat to moderately positive views about working with people who use drugs. Average total scores were 2.4 (*SD* = .3) for Wave 1, 2.7 (*SD* = .4) for Wave 2, and 2.1 (*SD* = .5) for Wave 3. Lower scores indicate more positive regard.

Figure 3. Average DDPPQ scores in Waves 1, 2, and 3.



Effectiveness of Different Treatment Approaches for Patients with OUD

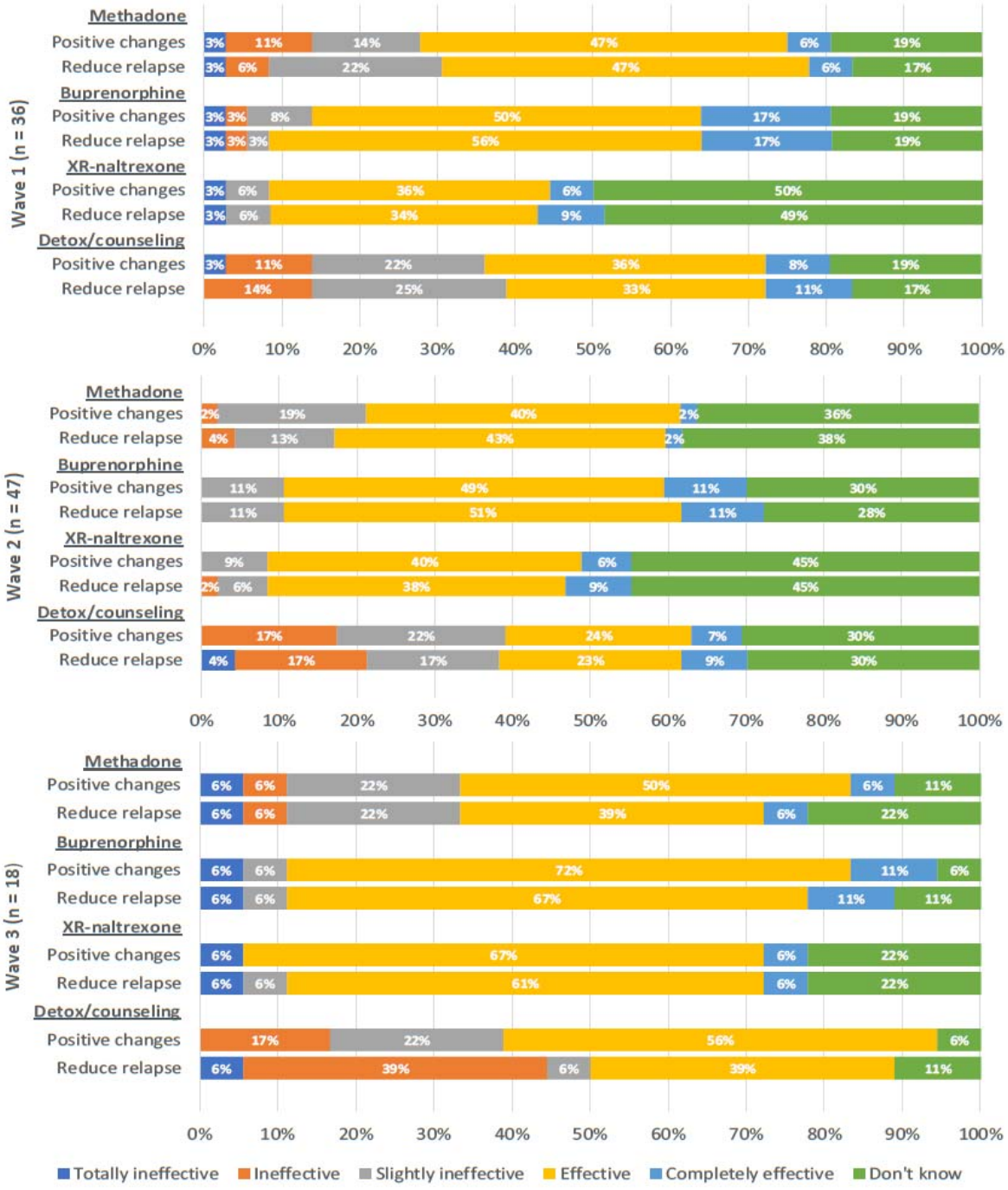
Respondents rated the extent to which they agreed that different treatment medications and approaches (i.e., methadone, buprenorphine, XR-naltrexone, and detoxification with drug-free counseling) were effective in (1) reducing relapse and (2) helping patients to make positive changes in their lives (e.g., gain employment, improve relationships with family and friends, establish permanent housing). Respondent ratings across the three staff survey administrations are illustrated in Figure 4.

Buprenorphine was rated as the most effective treatment approach for reducing relapse and helping patients to make positive changes in their lives across all three waves of data collection. At each wave of data collection, over half of the sample rated it as effective or completely effective across both patient outcomes (range = 60% to 83%). Conversely, providers and staff rated detoxification with drug-free counseling as the least effective approach in reducing relapse and helping patients to make positive changes in their lives. At each wave of data collection, at least almost one-third of respondents rated it as slightly to totally ineffective for each patient outcome (range = 36% to 41%).

Among those respondents who were able to rate the effectiveness of XR-naltrexone, it was perceived as being very effective in reducing the likelihood of relapse and helping patients make

positive changes in their lives. However, XR-naltrexone was associated with the largest number of respondents selecting the "don't know" option across both patient outcomes and all three waves of data collection. Across the three waves of data collection, between 22% and 50% of respondents felt that they could not speak to the effectiveness of the medication.

Figure 4. Perceived effectiveness of different treatment approaches at each staff survey.



Supplemental Pilot Program and COVID-19 Questions

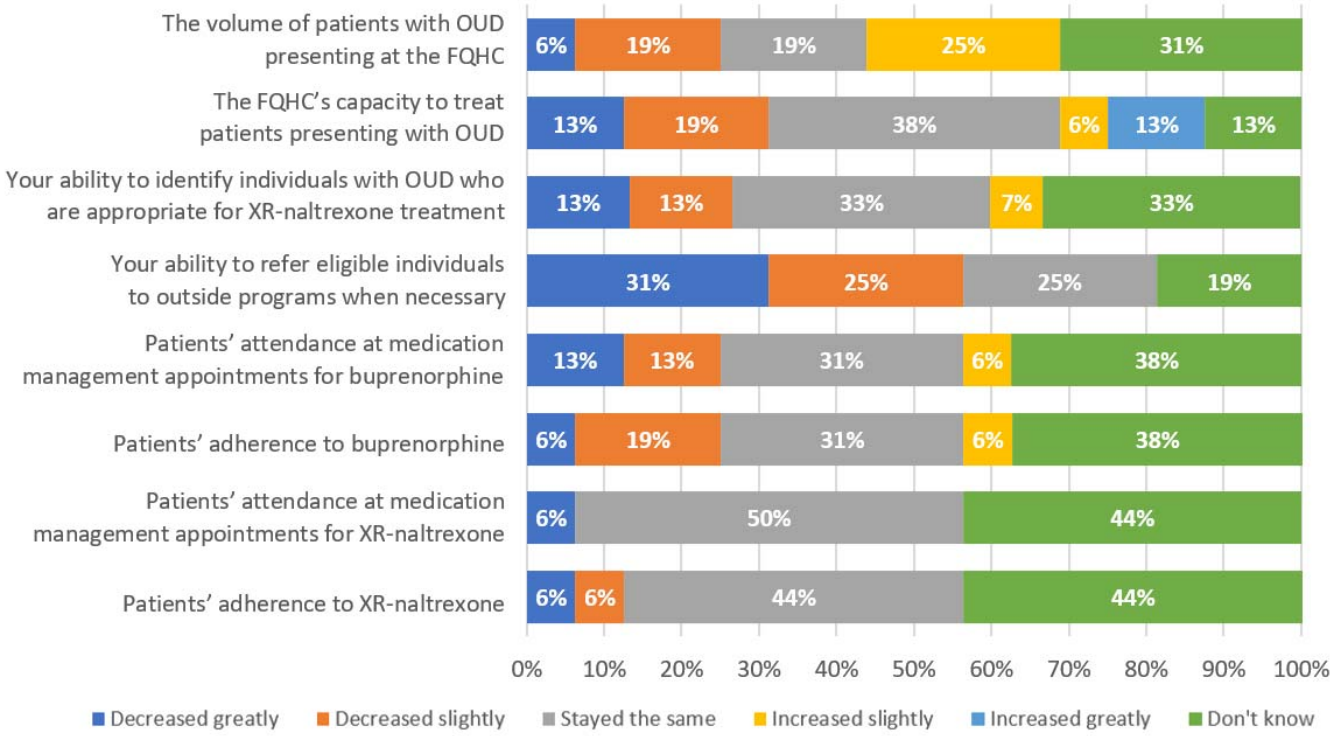
A summary of the impact of COVID-19 on FQHC clients and service provision is provided in Figure 5.

An equal number of respondents reported that the volume of patients with OUD presenting at the FQHC increased (*n* = 4; 36.4%) and decreased (*n* = 4, 36.4%), while three reported that it stayed the same (27.3%). Almost half of respondents reported that the FQHC's capacity to treat patients presenting with OUD remained the same (*n* = 6; 42.9%).

Half of respondents reported that their own ability to identify individuals with OUD who are appropriate for XR-naltrexone stayed the same (*n* = 5), and four reported that it decreased (40%). The majority of respondents reported that their ability to refer eligible individuals to outside programs when necessary, including detoxification services and social service programs decreased (*n* = 9; 69.2%).

Half of respondents reported that patients' attendance at medication management appointments for buprenorphine stayed the same (*n* = 5; 50%), while four reported that attendance decreased (40%). Half of respondents also reported that patients' adherence to buprenorphine stayed the same (*n* = 5; 50%), and four reported that it decreased (40%). The majority of respondents reported that attendance at medication management appointments for XR-naltrexone (*n* = 8; 88.9%) and adherence to XR-naltrexone (*n* = 7; 77.8%) stayed the same. Although it seems that compliance with buprenorphine treatment was more likely to be negatively impacted by COVID-19 than XR-naltrexone treatment, it is important to mention that there was only one active XR-naltrexone patient at one FQHC during the COVID-19 pandemic.

Figure 5. Impact of COVID-19 on FQHC clients and service provision.



The following were provided for the free-response question regarding the other ways that COVID-19 impacted MAT protocols and service delivery for OUD patients at respondents' FQHCs:

- Patients were coming in person to the FQHC less, and getting longer prescriptions
- Patients were only being seen virtually, unless they required an injection; patients had access to sessions by using their telephone or a tablet provided by the FQHC

Respondents who were familiar with the XR-naltrexone pilot program were asked to provide recommendations for how the program could be improved upon in the future. Specific recommendations are reported below. When a concept was raised by more than one respondent, the number of respondents (*n*) is noted.

- Provide more information, education, and marketing to increase patient awareness of the medication and pilot program, and address/reduce patient fears of XR-naltrexone (n = 3)

    - Often, patients request a specific medication after hearing about it from TV commercials
- Expand the program to include XR-naltrexone treatment for alcohol use disorder via a structured program
- Expand the program to include funding for buprenorphine treatment, a more effective medication that is better able to be used by the patients served by the FQHC due to the challenges of needing a period of abstinence prior to XR-naltrexone induction, and the concerns about increased risk of overdose after discontinuation
- Continue to decrease financial barriers toward obtaining the injection
- Improve coordination from detoxification and treatment facilitates to outpatient facilities (including FQHCs) and provide XR-naltrexone as an early option in the inpatient setting, as the transition to XR-naltrexone is difficult for many
- Increase program oversight by state agencies

Evaluation Results: Participant Outcomes

A summary table of the data collected for each evaluation participant across the course of the pilot program can be found in Appendix D.

Patient Flow

Each FQHC provided information to the evaluation team regarding (1) the number of OUD patients who presented at the site during the evaluation period and (2) the numbers of those patients who were inducted onto buprenorphine and onto XR-naltrexone. Site 1 reported 100 new OUD patients with 92 inducted onto buprenorphine and 0 onto XR-naltrexone. Site 2 reported 190 new OUD patients with180 inducted onto buprenorphine and 2 onto XR-naltrexone. Site 3 reported 77 new OUD patients with 65 inducted onto buprenorphine and 4 inducted onto XR-naltrexone (one of whom declined participation in the evaluation).

Participant Characteristics

A total of five individuals participated in the evaluation. As depicted in Table 3, their mean age was 31.1 (*SD* = 9.67) with ages ranging from 28 to 51. Four of the clients were male (80%) and one was female (20%). Four of the five participants were White (80%), and none of the clients were Hispanic or Latino (0%). Four clients reported that their primary drug of choice was heroin (80%) and one reported alcohol (20%). Two clients reported that their secondary drug of choice was other opioids/analgesics (40%), one reported heroin (20%), one reported cocaine (20%), and one reported having no secondary drug of choice (20%). Two clients reported that their tertiary drug of choice was cocaine (40%), one reported cannabis (20%), one reported other opiates/analgesics (20%), and one reported having no tertiary drug of choice (20%). Three patients were referred by inpatient treatment (60%), one referred themselves (20%), and one was referred by an FQHC staff member (20%). All participants had completed the detoxification process prior to their initial meeting with the MAT provider.

Table 3. Participant demographics and baseline status variables.

Variable		Mean or *n*	SD/%
Age		31.1	9.67
Gender	Male	4	80.0%
	Female	1	20.0%
Race	White	4	80.0%
	Other	1	20.0%
Ethnicity	Hispanic/Latino	0	0.0%
	Not Hispanic/Latino	5	100%
Primary Drug of Choice	Heroin	4	80.0%
	Alcohol	1	20.0%
Secondary Drug of Choice	Heroin	1	20.0%
	Cocaine	1	20.0%
	Other opioids/analgesics	2	40.0%
	None	1	20.0%
Tertiary Drug of Choice	Cocaine	2	40.0%
	Cannabis	1	20.0%
	Other opioids/analgesics	1	20.0%
	None	1	20.0%
Referral Source	Inpatient treatment	3	60.0%
	Self	1	20.0%
	FQHC staff member	1	20.0%

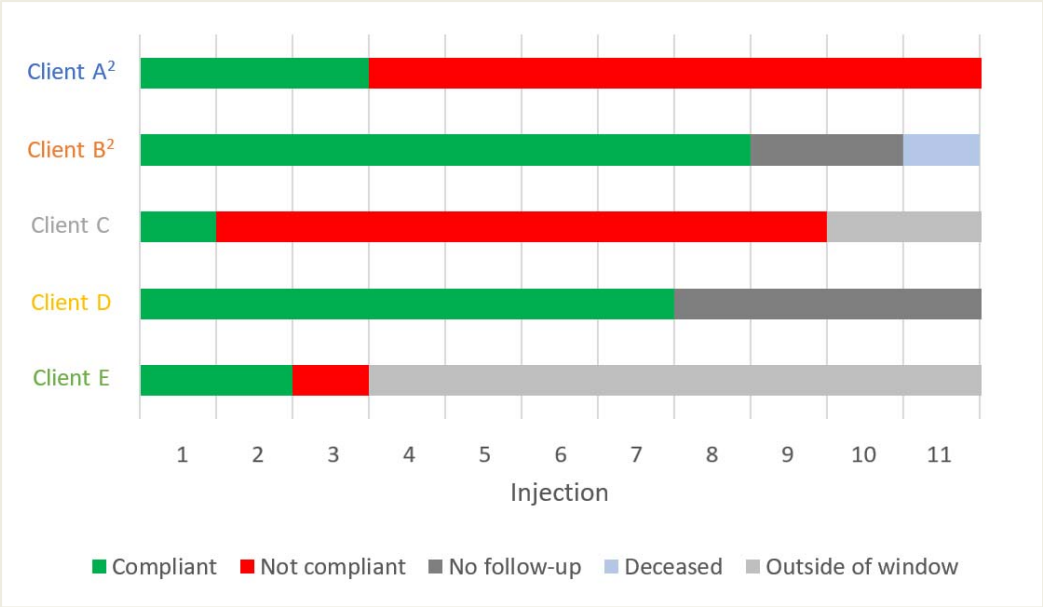
ASAM CO-Triage

The ASAM CO-Triage was administered at the baseline appointment for three out of five participants. For one of the missing assessments, the FQHC experienced technical difficulties with the software; for another, they had staffing limitations that prevented them from administering the assessment. The ASAM CO-Triage was intended to be administered prior to detoxification; however, none of the patients required detoxification at intake (three participants were referred directly from residential treatment and two had participated in treatment prior to induction). Therefore, the ASAM CO-Triage had limited clinical utility. For the three participants that completed the ASAM CO-Triage, two were recommended residential/inpatient services and one was recommended outpatient services, and all received outpatient services. The two participants for whom residential/inpatient services were recommended received outpatient services as one was referred from inpatient treatment, and the other had received inpatient treatment within the six months preceding XR-naltrexone induction.

XR-Naltrexone Compliance and Engagement

Figure 6 below presents participant-level XR-naltrexone compliance information. Based on data provided by clinic staff, two evaluation participants were compliant with their treatment (i.e., received a monthly injection) for more than six months (range = 7-8). The remaining participants (n = 3) received three or fewer injections before discontinuing XR-naltrexone treatment at the FQHC (range = 1-3).

Figure 6. XR-naltrexone compliance, 12 month period post-evaluation enrollment.[1,3]



[1] The observation period for each participant varies due to the rolling nature of admissions. Participants who had not yet reached that monthly timepoint at the time of final data collection (i.e., June 30, 2020) are indicated as "outside of window" throughout the report.

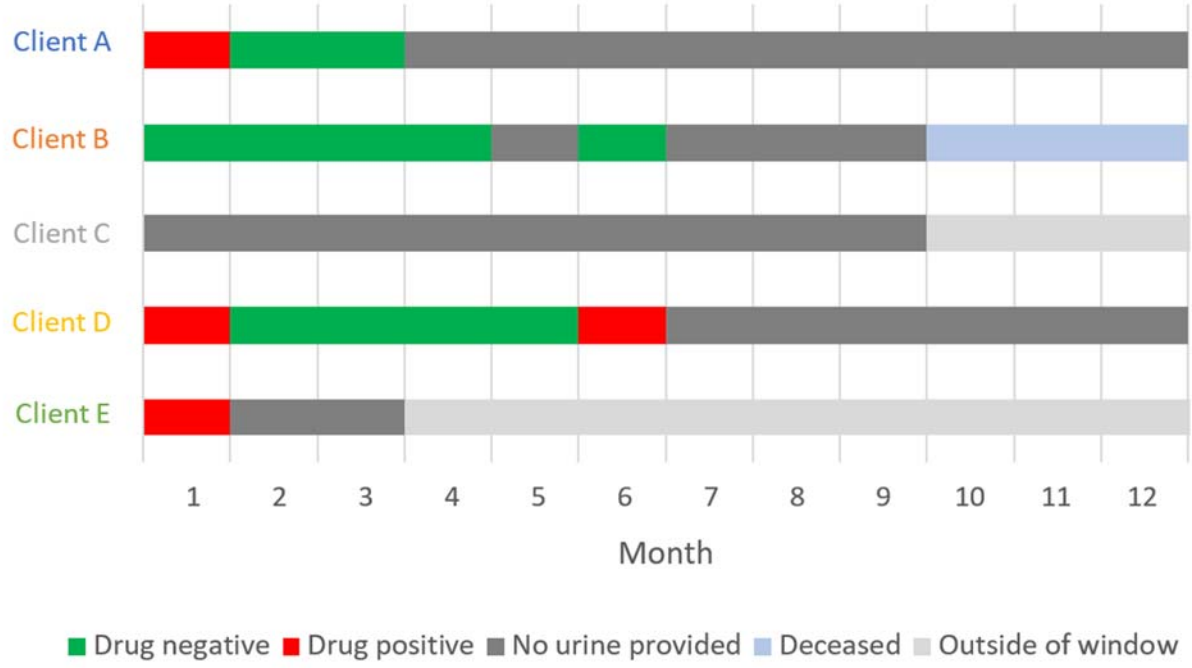
[2] Clients A and B participated in concurrent outpatient substance use treatment.

[3] In May 2020, Client B passed away due to existing chronic health conditions (COPD, obstructive sleep apnea, Hepatitis C, hypertension), which were likely exacerbated by drug use. The client did not pass away due to an overdose.

Urinalysis-Confirmed Abstinence

Urinalysis data were only available for clients while they were fully engaged in XR-naltrexone treatment. Although participants could be remunerated for transportation costs for presenting at the clinic to provide an evaluation urine sample after they had discontinued treatment, no participants chose to do so. Figure 7 presents the results of the monthly urinalysis tests for each of the five evaluation participants following receipt of their first injection. As can be seen, three participants provided at least one drug-positive urine sample while they were engaged in XR-naltrexone treatment. These three participants provided an initial urine at the time of induction that was drug positive for non-opioid drugs. Furthermore, only one of these screens reflected an opioid-positive result; this sample was provided prior to the participant dropping out of treatment.

Figure 7. Urinalysis results for the 12-month period following induction.[1]

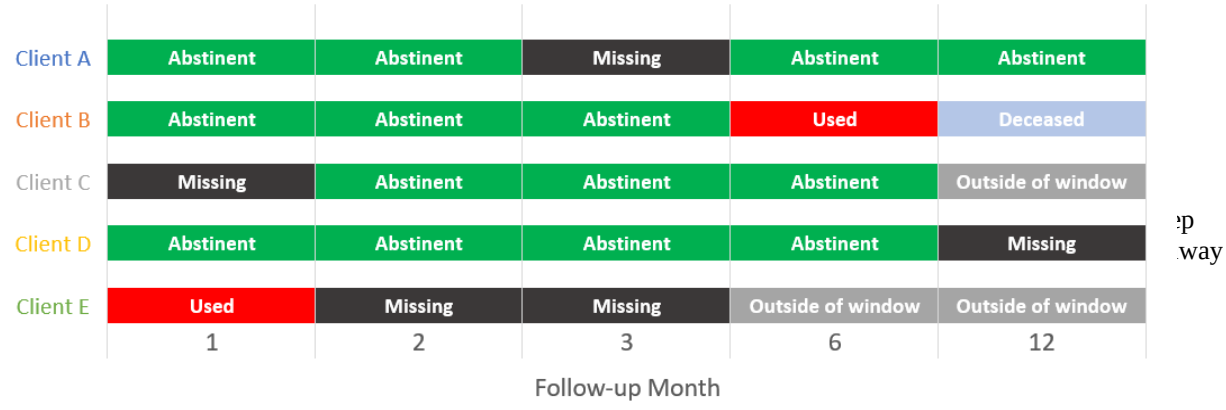


[1] In May 2020, Client B passed away due to existing chronic health conditions (COPD, obstructive sleep apnea, Hepatitis C, hypertension), which were likely exacerbated by drug use. The client did not pass away due to an overdose.

Self-Reported Drug Use (Prior 30 Days)

At each follow-up assessment (i.e., 1, 2, 3, 6, and 12 months post-baseline), participants reported the number of days they used illicit substances in the past 30 days. As seen in Figure 8 below, two participants reported any drug use in the past 30 days at the time of the follow-up assessments.

Figure 8. Evaluation participant self-reported drug use (prior 30 days) at each follow-up point.[1]



Psychosocial Treatment Engagement

According to both the clinic report and client assessments (i.e., NSMOS), two of the five participants were engaged in outpatient (OP) psychosocial treatment while they were receiving XR-naltrexone treatment. Participants engaging in OP treatment received eight and three injections, respectively. In addition, three patients reported meeting with a therapist to discuss drug and alcohol issues during the six-month period.

Other Health Service Utilization

Information pertaining to patient health service utilization for the six month period following evaluation entry was collected through the six-month follow-up assessment (NSMOS; $n = 4$). Three of the four clients who completed the assessment reported no emergency department (ED) visits or hospitalizations. The remaining client reported one ED visit and two hospitalizations during this time period. No clients reported overnight stays for detoxification services.

Engagement in Self-/Mutual-Help Groups

All four participants who completed the six-month follow-up assessment reported engaging in self-/mutual-help groups in the six-month period following the baseline assessment. Level of engagement in self-help varied substantially across the four participants (range = 5-180) with clients reporting an average of 105 sessions attended ($SD = 75$).

Quality of Life (SF-12)

Clients' average physical and mental health composite scores increased overall from baseline to six months post-intake (Figure 9). At baseline, the average physical health composite score was 44.6 ($SD = 11.9$), and 46.7 ($SD = 11.4$) six months post-intake. The average mental health composite score was 46.0 ($SD = 7.7$) at baseline, and 52.3 ($SD = 2.8$) six months post-intake.

At six months post-intake, two of the four clients were still actively engaged in treatment. Their average physical and mental health composite scores increased from baseline to six months post-intake. At baseline, their average physical health composite score was 38.4 ($SD = 15.5$) and 44.0 ($SD = 18.0$) six months post-intake. Their average mental health composite score was 43.9 ($SD = 0.6$) at baseline, and 50.0 ($SD = 0.9$) six months post-intake. In contrast, the average physical

health composite score of the two clients that had discontinued treatment decreased, and their average mental health composite score increased by less than 1.5 points. At baseline, their average physical health composite score was 54.5 (*SD* = 2.0) and 49.5 (*SD* = 5.7) six months post-intake. Their average mental health composite score was 53.2 (*SD* = 3.8) at baseline, and 54.6 (*SD* = 0.9) six months post-intake.

Figure 9. Evaluation particpants' physical and mental health composite scores from baseline to six months post-intake.[1]

[1]Clients B and D were compliant at six months post-intake. Clients A and C were not compliant.

Referrals to Other Providers

Finally, sites were asked to provide information about any referrals made to outside agencies/providers for evaluation participants. Among the two sites that enrolled participants, only one participant received referrals to an outside provider. This participant received six referrals over the course of their treatment. Two referrals were for X-rays and four were to medical specialists.

Evaluation Results: Cost Analysis

As only five individuals across two of the three participating FQHCs were enrolled during the lifecycle of the pilot program, a cost-benefit analysis could not be conducted due to the limited and insufficient sample size. In order to provide some indictor of the costs of implementing a

XR-naltrexone program in and FQHC setting, the evaluation team calculated the cost for pilot start-up and ongoing operation for the FQHC with the largest number of XR-naltrexone patients and the most complete cost-related data. This exploration of cost can inform planning efforts should the pilot program be expanded elsewhere in North Carolina or replicated in an alternate location. Tables of full cost calculations are located in Appendix E. The cost of XR-naltrexone itself was not included in calculations, as it was covered through pilot funding and costs of the medication may vary for different types of facilities and patients.

Start-up costs involved on-site training, which was conducted internally by a Physician with specialization in addiction and the site's Behavioral Health Director. In total, 19 employees were trained across five trainings of one hour each. The total cost of the trainings was $1,170.88 ($729.10 for trainers; $441.78 in trainee time). If the pilot program is replicated, training length, frequency, and facilitator will depend upon facility resources. The number and type of trainees will depend upon site decision making around staff roles and responsibilities.

Ongoing operational costs included client screening for XR-naltrexone suitability, induction, and subsequent injection appointments. Client screening for XR-naltrexone suitability was performed by three staff members: a Licensed Clinical Mental Health Counselor (LCMHC), a Medical Assistant/Lab Technician, and a Peer Support Specialist. On a weekly basis, staff usually spent 1-3 hours screening for XR-naltrexone suitability. The weekly cost of screenings totaled $34.22.

At induction, the initial XR-naltrexone induction appointment involved a Pharmacist, Medical Assistant, LCMHC, Peer Support Specialist, and a Physician. The length of an induction appointment was 1.5 hours. The FQHC confirmed the approximate portion of time for each staff member involved in the induction appointment (included in Appendix E). Three clients were inducted at the FQHC (Clients A, B, and C), during which each provided a urine sample (unit cost of urinalysis provided by FQHC). Per patient, the cost of an induction appointment was $61.99. For all three patients, induction appointments cost $185.97 total.

Subsequent monthly XR-naltrexone injection appointments involved the same staff as the induction appointment: Pharmacist, Medical Assistant, LCMHC, Peer Support Specialist, and

Physician. The length of a monthly injection appointment was 0.75 hours (45 minutes). The FQHC confirmed the approximate portion of time for each staff member involved in a subsequent monthly injection appointment (included in Appendix E). In addition to their induction injection, Client A received two monthly injections and Client B received seven monthly injections, during which each also provided a urine sample (unit cost of urinalysis provided by FQHC). Client C only received the initial induction injection. Per patient, the cost of a monthly injection appointment was $36.81. For Clients A and B, monthly injection appointments cost $331.29 total.

As summarized in Table 4, the start-up cost of internal trainings and the ongoing/operation costs of client screening, induction, monthly injections, and urinalysis for the three evaluation participants at the FQHC totaled $3,467.58. This total reflects the added costs incurred by the FQHC specific to the XR-naltrexone pilot program, and were incurred in addition to the FQHC's standard operation costs.

Table 4. Summary of site cost analysis.

Start-up Costs			
Training			
Trainers			$729.10
Trainees			$441.78
Subtotal			$1,170.88

	Cost	Unit	Total
Operational Costs			
Screening	$34.22 (total staff time, per week)	52 weeks[1]	$1,779.44
Induction	$56.39 (total staff time, per client)	3 clients	$169.17
Urinalysis	$5.60 per sample[2]	3 urine samples	$16.80
Monthly Injection	$31.21 (staff time per client per month)	Client A[3]	$62.42
		Client B[4]	$218.47
Urinalysis	$5.60 per sample[2]	9 urine samples (Client A and B)	$50.40
Subtotal			$2,296.70
			$3,467.58

[1] 52 weeks used in calculations as Client A was retained in the evaluation for one year

[2] Unit cost of urinalysis ($5.60) provided by FQHC

[3] Client A received two monthly injections in addition to their initial induction injection

[4] Client B received seven monthly injections in addition to their initial induction injection

Note 1: Client C only received the initial induction injection

Note 2: The cost of XR-naltrexone itself is not included in calculations, as it was covered through pilot funding, and costs may vary substantially

Discussion and Recommendations

Although participating FQHCs reported a significant number of clients seeking treatment for OUD during the evaluation period (*n* = 367 across the three sites), the pilot program was largely unsuccessful in increasing the use of XR-naltrexone in FQHC settings as only 1% of OUD patients were inducted onto the medication during the given time frame. In fact, the large majority of OUD patients from the three sites (92%) received MAT using buprenorphine. Approximately half of participants who received XR-naltrexone were still active in treatment at the six-month follow-up point (i.e., received six or more injections) which is consistent with engagement rate observed in other studies of the medication (Lee et al., 2018). Three of the five participants provided drug-positive urines while they were actively engaged in treatment, and one participant provided an opioid-positive urine at the appointment prior to dropping out of treatment. Based on both clinic and self-report, only two of the five patients were actively engaged in adjunctive psychosocial treatment. Finally, the two participants who were actively engaged in treatment at the six-month follow-up point demonstrated increases in quality of life relative to baseline than those who were not engaged in treatment.

A cost-benefit analysis could not be conducted due to the insufficient sample size. Costs for pilot start-up and ongoing operation were calculated for the FQHC that had the largest number of XR-naltrexone patients and provided the most complete cost-related data. Start-up costs involved on-site training; ongoing operational costs were associated with client screening for XR-naltrexone suitability, XR-naltrexone induction, subsequent injection appointments, and urinalysis at the induction and monthly appointments. The cost of XR-naltrexone itself was not included in calculations, as it was covered through pilot funding and costs of the medication may vary for different types of facilities and patients. The start-up costs and ongoing operational costs for the three evaluation participants at the FQHC totaled $3,467.58. This total reflects the added costs incurred by the FQHC specific to the XR-naltrexone pilot program, and were incurred in addition to the FQHC's standard operation costs.

Overall, staff members had somewhat positive attitudes about people who use drugs and working with people who use drugs. Staff rated buprenorphine as the most effective treatment technique

for reducing relapse and helping OUD patients make positive changes in their lives. Staff rated detoxification with drug-free counseling as the least effective treatment technique for reducing relapse and helping OUD patients make positive changes in their lives, which is congruent with the high rate of MAT prescription among OUD patients at all three FQHCs.

Through the key informant interviews, providers and staff offered important information about why the pilot program may have not been successful in increasing adoption of XR-naltrexone at the three sites. The major barriers that were identified through the key informant interviews include a lack of patient knowledge about XR-naltrexone and its biochemical properties (e.g., interactions, contraindications, long-acting formulation), lack of provider knowledge and buy-in regarding XR-naltrexone, difficulties associated with the detoxification process, cost of the medication outside of the pilot program, and other patient factors that may impede their ability to follow through with requirements (e.g., issues related to childcare, employment schedule, transportation).

Using information gathered through this mixed methods evaluation, the evaluation team has developed a number of recommendations for the state legislature should they choose to continue or expand the pilot program. In addition, these recommendations may be useful to states who are considering adopting similar initiatives and FQHCs who are considering development of an XR-naltrexone program. These recommendations are summarized in the sections that follow.

Provide Ongoing Education and Training for MAT Providers and Staff

Despite the trainings provided throughout the evaluation period, providers and staff across the pilot sites had knowledge gaps about the medication and its safety and efficacy. In addition, they expressed uncertainty about how to present the medication as a treatment option, particularly to patients who were currently engaged in agonist-based MAT. Providers and staff could benefit from ongoing and comprehensive trainings on XR-naltrexone, including empirical support for its effectiveness as well as side effects and contraindications associated with the medication. Several providers expressed concerns about the detoxification process and overdose risk, both of which could be addressed to some extent through additional training. It is important that these trainings be ongoing given the rates of turnover that are observed in these settings.

Identify Internal Champions to Promote Buy-in

Across the pilot sites, providers and staff generally did not consistently embrace XR-naltrexone as a viable treatment option for patients with OUD. To promote broader adoption of this treatment option, sites could benefit from identifying a champion who can promote the acceptability and effectiveness of XR-naltrexone. Having a champion who can model how to effectively provide this type of treatment (e.g., presenting XR-naltrexone as a treatment option, navigating the detoxification process, building patient motivation to remain engaged in treatment) could serve to educate providers and staff by example and, in turn, promote their buy-in of this medication as an effective treatment option. Sites specifically emphasized the importance of having a physician/prescriber as a champion for maximum impact.

Increase Access to and Utilization of On-site Behavioral Health Support

Existing guidelines suggest that medications for OUD should be provided in concert with ongoing psychosocial services and systematic reviews (e.g., Dugosh et al., 2016) have indicated that psychosocial treatment has been shown to increase retention in various forms of MAT. In the current evaluation, not all participants were engaged in adjunctive psychosocial services. In addition, only one of the three sites indicated that they provided peer support to patients who were receiving MAT. Clinics should work to increase the number of behavioral health services available to MAT patients and identify ways to more fully engage patients in these services.

Develop Strategies to Increase Patient Knowledge

Patients have limited knowledge about XR-naltrexone for treating OUD and, for this reason, are less likely to embrace it as a treatment option. It is recommended that FQHCs develop strategies to educate patients about the medication including its safety and effectiveness. For example, materials such as videos and pamphlets that are provided to individuals who may be appropriate for XR-naltrexone treatment could be modified to be more patient-centered. Including patients in the development and revision process for educational materials, such as through a patient advisory board, is encouraged. Potential adopters of the medication could also be connected to individuals who have successfully engaged in XR-naltrexone treatment for their OUD. Observing these success stories first-hand could help improve patient receptivity towards the medication.

Establish Robust Community Partnerships and Strengthen Systems of Care

Although efforts were made to establish partnerships with community agencies who could serve as referral sites (e.g., residential treatment programs, detoxification centers, reentry programs, drug courts, probation departments), success in establishing these partnerships was limited across the study sites, which likely contributed to the small number of patients in the evaluation sample. It is recommended that sites identify and establish working relationships with community agencies that could consistently refer patients who would be appropriate for XR-naltrexone treatment, or could induct the patient onto the medication prior to connecting the patient with the FQHC (e.g., a detoxification center provides first injection and refers patient to FQHC for subsequent injections). Establishing these types of partnerships could serve to not only build the FQHCs' capacity, but also help to ensure the continuity of care for individuals who are transitioning from different care settings. Establishing these networks of care can serve to ensure patients are not lost during transitional periods (e.g., discharge from detoxification center, completion of residential SUD treatment, release from prison).

Increase Utilization of Ambulatory Detoxification

Although providers were trained on an ambulatory detoxification protocol at the beginning of the evaluation period, this procedure was not utilized by providers at any of the sites. Sites should find ways to promote the use of this procedure to increase the uptake of XR-naltrexone by patients who are deemed appropriate. This could involve providing ongoing peer-based trainings and other educational opportunities.

Provide Ongoing Adjunctive Services

Patients with OUD often experience social stressors that can negatively impact their ability to connect to and remain engaged in treatment. It is important to close gaps for patients who may require additional social services to support their abstinence (e.g., housing, transportation, health insurance, vocational training, employment, social security income), and ensure that programming is tailored to the specific needs of individuals with OUD. Having on-site case managers who regularly check-in with patients to connect them with services and discuss and address barriers that may negatively impact their treatment attendance/adherence can provide much needed supports to assist individuals in their recovery.

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Appendices

Appendix A: FQHC Key Informant Interview Moderator's Guides

First Interview

NORTH CAROLINA EVALUATION OF THE IMPLEMENTATION OF VIVITROL IN FQHCs
Pre-Implementation Key Informant Interview

INTRODUCTION
Read aloud: Thank you for agreeing to talk with me today.

The purpose of this interview is to document your views on the implementation of Vivitrol at your treatment site in the coming months.

As you may already know, this project will be evaluating the use of Vivitrol in three FQHCs in the state of North Carolina.

I am a researcher with Public Health Management Corporation, and one of my roles on this project is to document the *process* of planning for, and implementing Vivitrol at your health center. We will be conducting interviews at the three FQHCs where the study will take place: Metropolitan Community Health, Lincoln Community Health, and High Country Community Health.

Information gathered during interviews with key clinic staff, such as the interview we are having today, will be used to help the our team to identify ways to address as many barriers as possible prior to the start-up of the project, and to make the project feel like one that is valuable both to the clinicians and patients at your clinic.

We will gather information before, during, and even after the project is completed so that we are able to describe the successes and challenges that occur along the way. We will do this by talking with staff, as well as patients who participate in the project.

I'd like to get started with the interview now, but before I begin, do you have any questions?

TAPING
I would like to tape record our conversation. I will use this tape to review our conversation and to summarize key themes or points that arise. Our conversation will be private. Only members of the research team at Treatment Research Institute and at PHMC will have access to these recordings. You also will never be identified personally in discussing the findings from the

interviews or in any written reports that may be generated from the interviews conducted at the three clinics.

QUESTIONS/FOLLOW-UP
If you have any questions after our interview or think of anything you would like to add to our discussion today, I will give you my contact information so that you can contact me.

1. What positive perceptions does your FQHC have about the use of Vivitrol?

2. What negative perceptions does your FQHC have about the use of Vivitrol?

3. What are some of the **organizational** and **staff**-related factors that may **increase** the likelihood of success of the Vivitrol program?

4. What are some of the **organizational** and **staff**-related factors that may **decrease** the likelihood of success of the Vivitrol program?

5. What are some of the **patient**-related factors that may **increase** the likelihood of success of the Vivitrol program?

6. What are some of the **patient**-related factors that may **decrease** the likelihood of success of the Vivitrol program?

7. What supports do you anticipate that your program may need to be successful?

8. Are there any other concerns that you have about implementation of the program?

Second Interview

NORTH CAROLINA EVALUATION OF THE IMPLEMENTATION OF VIVITROL IN FQHCs
Post-Implementation Key Informant Interview

INTRODUCTION

Read aloud: Thank you for agreeing to talk with me today.

The purpose of this interview is to follow-up with you about your experience in providing Vivitrol treatment at your site.

I am a researcher with Public Health Management Corporation, and one of my roles in this project is to document the *process* of planning for and implementing Vivitrol at your health center. We are conducting interviews at the three FQHCs where the study is taking place: Metropolitan Community Health, Lincoln Community Health, and High Country Community Health. This is the second of three interviews that will be conducted at each site.

Information gathered through interviews with key clinic providers and staff will be used to help our team to identify the barriers and facilitators that each program has encountered in providing Vivitrol treatment to patients with opioid use disorders. We will use this information along with other data that we have collected through the evaluation period to describe the successes and challenges that have occurred along the way and to provide recommendations for best practices.

I'd like to get started with the interview now, but before I begin, do you have any questions?

TAPING

I would like to tape-record our conversation today. I will use this tape to review our conversation and to summarize key themes or points that arise. Our conversation will be private. Only members of our research team at PHMC will have access to these recordings. You also will never be identified personally in discussing the findings from the interviews or in any written reports that may be generated from the interviews conducted at the three clinics.

QUESTIONS/FOLLOW-UP

If you have any questions after our interview or think of anything you would like to add to our discussion today, I will give you my contact information so that you can contact me.

1. What positive perceptions do members of your FQHC staff have about the use of Vivitrol treatment for people who have opioid use disorders?
    a. *Follow-up*: What about your patients? What are some of their positive perceptions about Vivitrol as a treatment option?
        i. *Additional prompts*: Thoughts on a monthly injection? Thoughts on needing detoxification first?

2. What negative perceptions do members of your FQHC staff have about the use of Vivitrol for people who have opioid use disorders?
    a. *Follow-up*: When presenting Vivitrol as a treatment option, what are some concerns you from patients? What are you hearing from them? How does this contrast with buprenorphine?
        i. *Additional prompts (if answers aren't freely shared)*: Thoughts on a monthly injection? Thoughts on needing detoxification first? Concerns of relapse/overdose? Etc.

3. What are some of the factors that have **facilitated** the implementation of the Vivitrol program?
    a. *Follow-up*: Could you speak more about some organizational factors? Staff-related factors? Time? Training/Education? Leadership/Staff buy-in? etc.

4. What are some of the factors that have been **barriers** to the implementation of the Vivitrol program? And by the implementation, I mean getting the program up and running and sustaining it through recruitment and follow-up.
    a. *Follow-up*: Could you speak more about some organizational factors? Staff-related factors? Time? Training/Education? Leadership/Staff buy-in? etc.

5. When thinking about the patients receiving Vivitrol treatment, what factors have made this option more successful for them than compared with bupe, or other treatment options?
    a. *Follow*-up: What are the big differences you're seeing patients who are on Vivitrol vs. buprenorphine?

6. What factors do believe are most important when determining which treatment (Vivitrol or buprenorphine) is the best choice for a given patient?
    a. *Follow-up*: For patients resistant to Vivitrol treatment, or have a preference for bupe, what are some of their concerns they've expressed about Vivitrol?
    b. *Follow-up*: How can staff improve the communication/conversations they are having with patients, to educate them on Vivitrol as a treatment option?
        i. *Examples*: more informative literature/media to explain the pros/cons? Better training? Patient testimonials? Peer educator?
    c. *Follow-up*: How are patients getting educated on bupe prior to entering treatment? Do you think similar tactics could be used for Vivitrol?

7. Are there additional supports needed for your program to be successful?
    a. *Follow-up*: How can your FQHC build and/or strengthen partnerships with organizations/facilities (e.g. detoxification/rehab) that have patients who could benefit from the Vivitrol program?

b. *Follow*-up: For those pipelines that are already in place, what are some strategies that could help make it easier for patients to get through the referral process and connecting to this Vivitrol program?

8. Are there any other concerns that you have about the implementation of the program?

9. Overall, how has your experience with Vivitrol compared with that of buprenorphine?

10. Are there any other comments?

Third Interview

NORTH CAROLINA EVALUATION OF THE IMPLEMENTATION OF VIVITROL IN FQHCs
Pilot Closeout Key Informant Interview

INTRODUCTION

Read aloud: Thank you for agreeing to talk with me today.

The purpose of this interview is to learn about your experience providing Vivitrol treatment at your site as the pilot program draws to a close.

I am a researcher with Public Health Management Corporation, and one of my roles in this project is to document the process of planning for and implementing Vivitrol at your health center. As you know, we are conducting interviews at the three FQHCs where the study is taking place. This is the third and final interview that will be conducted at each site. Our conversation should take approximately 45 minutes.

Information gathered through these interviews with key clinic providers and staff will be used to help our team identify the barriers and facilitators that each program has encountered in providing Vivitrol treatment to patients with opioid use disorders. We will also use these insights, along with other data that we have collected through the evaluation period, to provide recommendations for best practices that can inform future programs.

I'd like to get started with the interview now, but before I begin, do you have any questions?

TAPING

First, I would like to ask for your permission to tape-record our conversation today so that I can review our conversation and summarize key themes or points that arise. Our conversation will be private, and only members of our research team at PHMC will have access to these recordings. Also, you also will never be identified during any discussions of findings from the interviews, or in any written reports that may be generated from the interviews conducted at the three clinics. May I tape record our conversation?

QUESTIONS/FOLLOW-UP

If you have any questions after our interview or think of anything you would like to add to our discussion today, please don't hesitate to contact me. I will provide my contact information at the end of our conversation.

1. To what extent did staff perceptions about the use of extended-release naltrexone (Vivitrol) treatment for people with Opioid Use Disorder change during the pilot program at your site?

   a. *Probe*: Did perceptions change positively or negatively during the pilot program? In what ways?
      i. *Examples*: Vivitrol effectiveness, ease of use, perceived risk of relapse/overdose, injection delivery, or cost

2. To what extent did perceptions about Vivitrol change among patients with Opioid Use Disorder (OUD) during the pilot program? *(Internal note: patients refers to anyone with OUD, not just Vivitrol patients)*
   a. *Probe:* Did perceptions change positively or negatively during the pilot program? In what ways?

3. According to the data we obtained during the evaluation, as of March 30th, [FQHC] had XX OUD patients, of which XX were prescribed buprenorphine and XX were prescribed Vivitrol. Can you speak to the difference in uptake of Vivitrol treatment at your clinic relative to buprenorphine?
   a. *Probe:* What factors would have increased patient enrollment at your site?
      i. *Examples*: Clinical or staff champions? Partnerships with other facilities (e.g., detoxification/rehab)? Referral processes connecting patients to a Vivitrol program?

4. What resources or supports would your staff need to make Vivitrol a more viable option for patients with OUD at your clinic?

5. How could staff be better equipped to have conversations with patients about Vivitrol treatment?
   a. *Examples:* More informative literature/media to explain the pros/cons? Better training? Patient testimonials? Peer educator?

6. If this Vivitrol treatment pilot program was to be replicated at other sites, what do you think should change? What should be kept the same?
   a. *Probe:* Overall, how could this pilot program be improved upon?

7. What types of support could the state provide to facilitate the success of initiatives like this in the future?
   a. *Examples:* Financial support? Patient peer support? Educational campaigns? Networking/collaboration among referral and treatment sites?

8. Before we close, is there anything else you'd like to share?

CLOSING

Thank you so much for your time in sharing your experience providing Vivitrol at your site. We appreciate your informative insights and have learned a great deal from you today. If you have any further comments or questions, please do not hesitate to contact me.

Appendix B: FQHC Staff Survey, Wave 3

NC Vivitrol Evaluation - Staff Survey 3

Thank you for agreeing to participate in this survey. The survey is being conducted by researchers at the Public Health Management Corporation (PHMC) as part of an evaluation of the use of extended-release naltrexone (Vivitrol®) in selected Federally Qualified Healthcare Centers (FQHC) in the state of North Carolina. The survey will be used to gauge staff and stakeholder's thoughts and opinions about opioid use disorder (OUD) and its treatment.

The survey will be completed by individuals in various roles in the FQHC including physicians, physician assistants, nurses, nurse practitioners, and other clinical staff.

If you complete the survey by Friday, June 19th, you will be entered to win a $50 Amazon eGift card. To enter to win an eGift card, you must provide us with your email address through the link at the end of this survey.

Participation in this survey is voluntary and your responses will be kept confidential. The information collected will only be used to help inform evaluation results and recommendations.

1) What is your gender?

( ) Male

( ) Female

( ) Other

( ) Choose not to answer

2) What is your race?

( ) White

( ) Black or African American

( ) Native American or American Indian

( ) Asian/Pacific Islander

( ) Other - Please specify: _____*

3) Are you Hispanic or Latino?
( ) Yes

( ) No

4) How old are you?
_____ years

5) Which health center do you work for?
( ) Agape Community Health Center

( ) High Country Community Health Center

( ) Lincoln Community Health Center

6) What type of healthcare provider are you?
( ) Physician

( ) Physician Assistant

( ) Nurse

( ) Nurse Practitioner

( ) Nurse's Aid

( ) Behavioral Health Counselor (BHC)

( ) Certified Recovery Specialist (CRS)

( ) Crisis Worker

( ) Other - Please specify: _____*

7) How long have you been in this position?

Years	Months

8) Do you have experience providing buprenorphine (e.g. Suboxone ®, Sublocade™)-based treatment to patients with opioid use disorder?

( ) Yes

( ) No

9) Do you have experience providing extended-release naltrexone (Vivitrol®)-based treatment to patients with opioid use disorder?

( ) Yes

( ) No

10) Based on your knowledge and personal experience, how effective is each of the following treatment techniques in reducing relapse **in patients with opioid use disorder? Please select the appropriate response option.**

	Totally ineffective	**Ineffective**	**Slightly ineffective**	**Effective**	**Completely effective**	**Don't know**
Methadone	( )	( )	( )	( )	( )	( )
Buprenorphine (Suboxone ®, Sublocade™)	( )	( )	( )	( )	( )	( )
Extended-release naltrexone (Vivitrol®)	( )	( )	( )	( )	( )	( )
Detoxification with drug-free counseling	( )	( )	( )	( )	( )	( )

11) Based on your knowledge and personal experience, how effective is each of the following treatment techniques in helping patients with opioid use disorder make positive changes in their lives (e.g. gain employment, fulfill familial and social obligations)? Please select the appropriate response option.

	Totally ineffective	**Ineffective**	**Slightly ineffective**	**Effective**	**Completely effective**	**Don't know**
Methadone	( )	( )	( )	( )	( )	( )
Buprenorphine (Suboxone ®, Sublocade™)	( )	( )	( )	( )	( )	( )

Extended-release naltrexone (Vivitrol®)	( )	( )	( )	( )	( )	( )
Detoxification with drug-free counseling	( )	( )	( )	( )	( )	( )

12) Please indicate how much you agree or disagree with each of the following statements about working with people who have substance use disorders (SUD).

	Strongly disagree 1	**2**	**3**	**4**	**5**	**6**	**Strongly agree 7**
I feel I have a working knowledge of drugs and drug-related problems.	( )	( )	( )	( )	( )	( )	( )
I feel I know enough about the causes of drug problems to carry out my role when working with people who use drugs.	( )	( )	( )	( )	( )	( )	( )
I feel I know enough about the physical effects of drug use to carry out my role when working with people who use drugs.	( )	( )	( )	( )	( )	( )	( )
I feel I know enough about the psychological effects of drugs to carry out my role when working with people who use drugs.	( )	( )	( )	( )	( )	( )	( )
I feel I know enough about the factors which put people at risk of developing drug problems to carry out my	( )	( )	( )	( )	( )	( )	( )

role when working with people who use drugs.							
I feel I know how to counsel people who use drugs over the long term.	( )	( )	( )	( )	( )	( )	( )
I feel I can appropriately advise my patients/clients about drugs and their effects.	( )	( )	( )	( )	( )	( )	( )
If I felt the need when working with people who use drugs, I could easily find someone with whom I could discuss any personal difficulties that I might encounter.	( )	( )	( )	( )	( )	( )	( )
If I felt the need when working with people who use drugs, I could easily find someone who would help me clarify my professional responsibilities.	( )	( )	( )	( )	( )	( )	( )
If I felt the need I could easily find someone who would be able to help me formulate the best approach to a drug user.	( )	( )	( )	( )	( )	( )	( )
I feel I am able to work with people who use drugs as well as other client groups.	( )	( )	( )	( )	( )	( )	( )
In general, one can get satisfaction from working with people who use drugs.	( )	( )	( )	( )	( )	( )	( )
In general, it is rewarding to work with people who use drugs.	( )	( )	( )	( )	( )	( )	( )

In general, I feel I can understand people who use drugs.	( )	( )	( )	( )	( )	( )	( )
I feel that there is little I can do to help people who use drugs.	( )	( )	( )	( )	( )	( )	( )
All in all, I am inclined to feel I am a failure with people who use drugs.	( )	( )	( )	( )	( )	( )	( )
In general, I have less respect for people who use drugs than for most other patients/clients I work with.	( )	( )	( )	( )	( )	( )	( )
I feel uncomfortable when working with people who use drugs.	( )	( )	( )	( )	( )	( )	( )
I feel I have the right to ask patients questions about their drug use when necessary.	( )	( )	( )	( )	( )	( )	( )
I feel that I have the right to ask a patient for any information that is relevant to their drug problems.	( )	( )	( )	( )	( )	( )	( )

13) Please indicate how much you agree or disagree with each of the following statements about working with people who have opioid use disorders (OUD).

	Strongly disagree 1	**2**	**3**	**4**	**5**	**Strongly agree 6**
Working with patients with opioid use disorder is satisfying.	( )	( )	( )	( )	( )	( )

Insurance plans should cover patients with opioid use disorder to the same degree they cover patients with other conditions.	( )	( )	( )	( )	( )	( )
There is little I can do to help patients with opioid use disorder.	( )	( )	( )	( )	( )	( )
I feel especially compassionate toward patients with opioid use disorder.	( )	( )	( )	( )	( )	( )
Patients with opioid use disorder irritate me.	( )	( )	( )	( )	( )	( )
I wouldn't mind getting up on call nights to care for patients with opioid use disorder.	( )	( )	( )	( )	( )	( )
Treating patients with opioid use disorder is a waste of medical dollars.	( )	( )	( )	( )	( )	( )
Patients with opioid use disorder are particularly difficult for me to work with.	( )	( )	( )	( )	( )	( )
I can usually find something to help patients with opioid use disorder feel better.	( )	( )	( )	( )	( )	( )
I enjoy giving extra time to patients with opioid use disorder.	( )	( )	( )	( )	( )	( )
I prefer not to work with patients with opioid use disorder.	( )	( )	( )	( )	( )	( )

14) The North Carolina state legislature implemented a pilot program at your FQHC to increase the use of extended release naltrexone (Vivitrol®) to treat people with opioid use disorders (OUD). If you are familiar with this program, how do you think it could be improved upon in the future?

_____

_____

_____

_____

15) We would like to learn more about any effects the COVID-19 pandemic may have upon your clients and service provision at your FQHC. If any question does not apply to you or you are unable to provide an answer, please select "Not applicable/I don't know."

	Decreased greatly	**Decreased slightly**	**Stayed the same**	**Increased slightly**	**Increased greatly**	**Not applicable/I don't know**
The volume of patients with opioid use disorder (OUD) presenting at the FQHC	( )	( )	( )	( )	( )	( )
The FQHC's capacity to treat patients presenting with OUD	( )	( )	( )	( )	( )	( )
Your ability to identify individuals with OUD who are appropriate for Vivitrol treatment	( )	( )	( )	( )	( )	( )
Your ability to refer	( )	( )	( )	( )	( )	( )

eligible individuals to outside programs when necessary, including detoxification services and social service programs						
Patients' attendance at medication management appointments for buprenorphine (i.e., Suboxone®)	( )	( )	( )	( )	( )	( )
Patients' adherence to buprenorphine (i.e., Suboxone®)	( )	( )	( )	( )	( )	( )
Patients' attendance at medication management appointments for extended-release naltrexone (i.e., Vivitrol®)	( )	( )	( )	( )	( )	( )
Patients' adherence to extended-release naltrexone	( )	( )	( )	( )	( )	( )

(i.e., Vivitrol®)						

16) Are there any other ways COVID-19 has impacted medication assisted treatment protocols and service delivery for OUD patients at your FQHC? If so, please describe:

_____

_____

_____

_____

17) Do you wish to enter your email address into the drawing for a $50 Amazon eGift card?

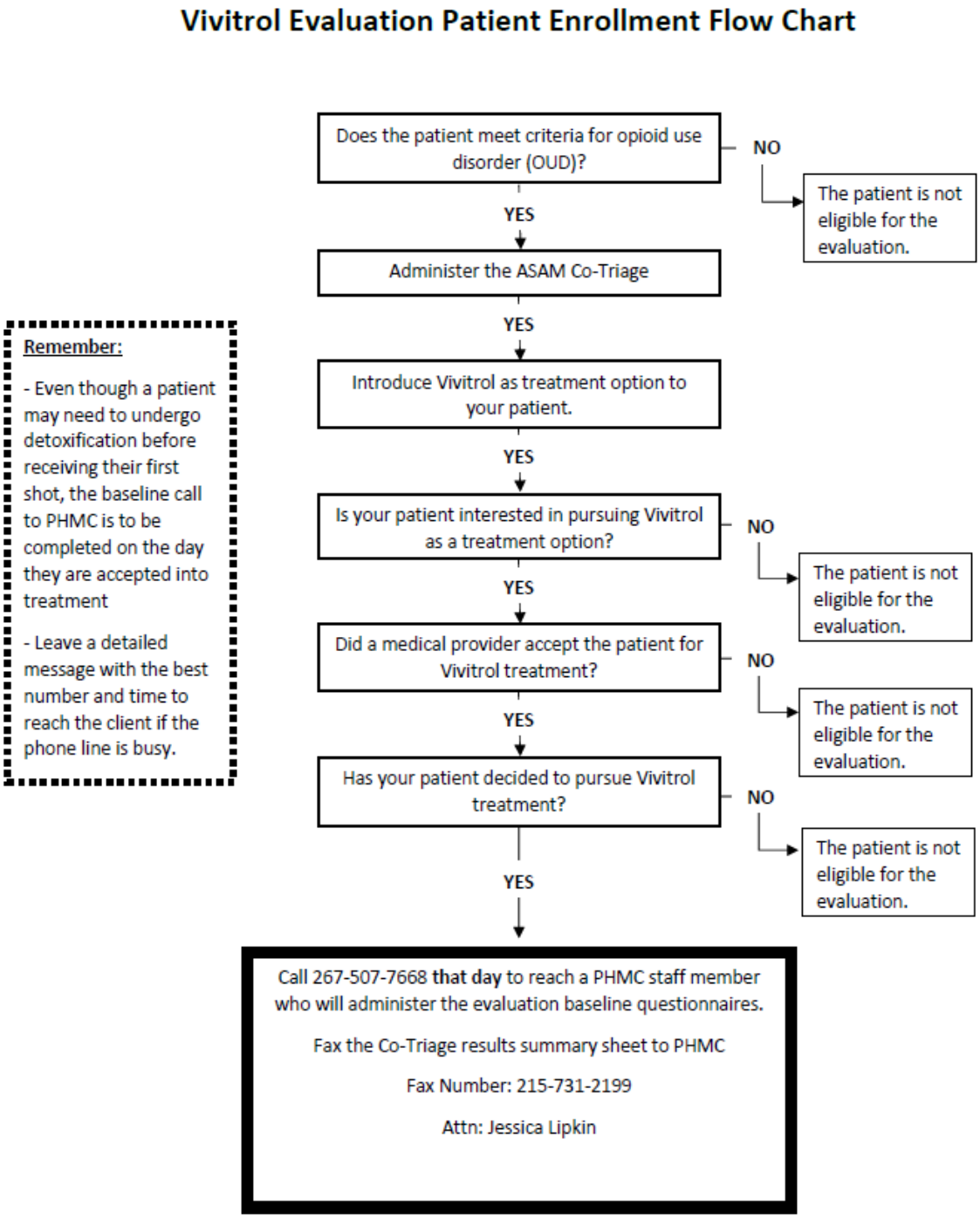
( ) Yes

( ) No

Thank You!

Thank you for taking our survey. Your response is very important to us.

Appendix C: Evaluation Participant Enrollment Flow Chart



Appendix D: Data Collected for Each Evaluation Participant across the Pilot Program

Assessment	Client A	Client B	Client C	Client D	Client E
Co-Triage	Complete	Not complete	Complete	Complete	Not complete
Baseline	Complete	Complete	Complete	Complete	Complete
1-month follow-up	Complete	Complete	NR	Complete	Complete
2-month follow-up	Complete	Complete	NR; Complete	Complete	NR
3-month follow-up	NR	Complete	NR; Complete	Complete	X
6-month follow-up	NR; Complete	Complete	NR; Complete	Complete	X
12-month follow-up	NR; Complete	Deceased	X	NR	X
Clinician Survey – BL	Complete	Complete	Complete	Complete	Complete
Clinician Survey – 1M	Complete	Complete	NR	Complete	Complete
Clinician Survey – 2M	Complete	Complete	NR	Complete	NR
Clinician Survey – 3M	NR	Complete	NR	Complete	X
Clinician Survey – 6M	NR	Complete	NR	Complete	X
Clinician Survey – 12M	NR	Deceased	X	NR	X
Referrals	Complete	Complete	Complete	Complete	Complete

Key

- *Complete* – Assessment collected
- *Not complete* – Assessment not collected
- *NR* – Participant was not retained in treatment, assessment not collected
- *NR; Complete* – Participant was not retained in treatment, but the evaluation team was able to reach the participant and perform the assessment
- *X* – Assessment due after June 30, 2020
- *Deceased* – Participant passed away prior to follow-up point

Appendix E: Site Cost Analysis

Start-up Costs: Training

	Hourly Rate	Number of Trainings	Length of Training (ea.)	Total
Trainers				
Physician	$89.08[1]	5	1 hour	$445.40
Behavioral Health Director	$56.74[2]	5	1 hour	$283.70
				$729.10

	Number of Trainees	Hourly Rate	Trainings Participated[3]	Length of Training (ea.)	Total
Trainees					
Licensed Clinical Mental Health Counselor Associate (LCMHC-A)	2	$24.16[4]	1	1 hour	$48.32
Family Nurse Practitioner (FNP)	2	$58.41[4]	1	1 hour	$116.82
PharmD	1	$66.83[5]	1	1 hour	$66.83
Pharmacy Technician	2	$15.00[6]	1	1 hour	$30.00
Peer Support Specialist	3	$15.00[5]	1	1 hour	$45.00
Patient Access Representative	5	$12.00[6]	1	1 hour	$60.00
Compliance Specialist	1	$29.81[5]	1	1 hour	$29.81
Medical Assistant	3	$15.00[6]	1	1 hour	$45.00
					$441.78

[1] U.S. BLS dataset mean hourly wage for physicians in North Carolina

[2] Functional equivalent for Behavioral Health Director in U.S. BLS dataset is "Medical and Health Services Managers," for which mean hourly wage in North Carolina was used ($56.74)

[3] While five trainings took place at Site 3, it is assumed that each trainee only participated in one training

[4] Annual salary range provided by FQHC; hourly rate calculated by using midpoint of salary range, then assuming 52 work weeks of 40 hours each

[5] Annual salary provided by FQHC; hourly rate calculated by assuming 52 work weeks of 40 hours each

[6] Hourly salary provided by FQHC; if hourly range was provided, midpoint was used

Operational Costs: Screening (Staff Time)

	Hourly Rate	Average Hourly Rate	Weekly Time Commitment	Total (per week)
Licensed Clinical Mental Health Counselor (LCMHC)	$23.32[1]	$17.11	2 hours[3]	$34.22
Medical Assistant/Lab Technician	$13.00[2]			
Peer Support Specialist	$15.00[1]			
				$34.22

[1] Annual salary provided by FQHC; hourly rate calculated by assuming 52 work weeks of 40 hours each

[2] Hourly salary provided by FQHC

[3] Midpoint of 1-3 hours (2 hours) was used in calculations

Operational Costs: Induction (Staff Time)

	Hourly Rate	Approximate Portion of Induction Appointment[1] (minutes / hours)	Total (per patient)
Pharmacist	$66.83[2]	(10 minutes / 0.167 hours)[4]	$11.16
Medical Assistant	$13.00[3]	(20 minutes / 0.333 hours)	$4.33
Licensed Clinical Mental Health Counselor (LCMHC)	$23.32[2]	(20 minutes / 0.333 hours)	$7.77
Peer Support Specialist	$15.00[2]	(20 minutes / 0.333 hours)	$5.00
Physician	$56.25[2]	(30 minutes / 0.500 hours)	$28.13
			$56.39

[1] Per FQHC, length of induction appointment was 1.5 hours; the FQHC also confirmed the approximate portion of time for each staff member involved in an induction appointment

[2] Annual salary provided by FQHC; hourly rate calculated by assuming 52 work weeks of 40 hours each

[3] Hourly salary provided by FQHC

[4] Pharmacist is assumed to prepare XR-naltrexone before actual patient appointment (i.e., not during 1.5 hour appointment)

Operational Costs: Monthly Injections (Staff Time)

	Hourly Rate	Approximate Portion of Injection Appointment[1] (minutes / hours)	Total (per patient per month)
Pharmacist	$66.83[2]	(10 minutes / 0.167 hours)[4]	$11.16
Medical Assistant	$13.00[3]	(5 minutes / 0.083 hours)	$1.08
Licensed Clinical Mental Health Counselor (LCMHC)	$23.32[2]	(15 minutes / 0.250 hours)	$5.83
Peer Support Specialist	$15.00[2]	(15 minutes / 0.250 hours)	$3.75
Physician	$56.25[2]	(10 minutes / 0.167 hours)	$9.39
			$31.21

[1] Per FQHC, length of monthly injection appointments was 0.75 hours (45 minutes); the FQHC also confirmed the approximate portion of time for each staff member involved in a monthly injection appointment

[2] Annual salary provided by FQHC; hourly rate calculated by assuming 52 work weeks of 40 hours each

[3] Hourly salary provided by FQHC

[4] Pharmacist is assumed to prepare XR-naltrexone before actual patient appointment (i.e., not during 0.75 hour appointment)