2019

BRIEF INTERVENTION AND BUPRENORPHINE INITIATION FOR OPIOID USE DISORDER IN NORTHERN KENTUCKY EMERGENCY DEPARTMENTS

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CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the
requirements for the degree of
Master of Public Health in the
University of Kentucky College of Public Health
Department of Health, Behavior & Society
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April 16, 2019

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Table of Contents

Abstract

The opioid epidemic has had sweeping, devastating effects on the United States. Kentucky has the fifth highest overdose mortality rate in the nation and the Northern Kentucky counties, specifically Kenton and Campbell, have been especially affected. Their opioid overdose mortality rates are the third and fourth highest in the state, respectively. In order to contribute to ongoing Northern Kentucky community efforts to combat the opioid epidemic, St. Elizabeth Healthcare is proposing to implement The Brief Negotiation Interview (BNI) in our emergency departments in order to provide more comprehensive care. The BNI is a motivational interviewing strategy that has been combined with initiation of medication-assisted treatment in order to increase access to addiction treatment. This strategy has been utilized within University research hospitals but will be novel as an implementation strategy in a privately-owned healthcare system. We will utilize the three emergency departments that will serve as implementation locations for this proposal are St. Elizabeth Edgewood, Covington, and Ft. Thomas. Within these EDs, social workers will be the primary interventionists and engage participants in the motivational interview in order to come to a mutual agreement for treatment. If participants present with withdrawal symptoms, they will begin their MAT regimen while still in the ED. This proposal will be evaluated through both a process and outcome evaluation. Primary outcomes of interest are self-efficacy to seek addiction treatment and actual engagement in formal treatment. Secondary outcomes include drug use and overdose mortality over time. Upon completion of the evaluation, results will be disseminated through our membership in health association networks and the program will be implemented within all St. Elizabeth locations. We plan to use existing partnerships and community coalitions throughout the implementation process and plan to develop new partnerships as well. We hope that this intervention can contribute to the larger community efforts to save the most vulnerable within our community.

Target Population & Need

Health Outcome and Need

In 2017, the opioid epidemic was declared a national public health emergency in the United States. Opioids are an addictive class of drug which includes legally prescribed pain relievers such as OxyContin®, Percocet®, and Vicodin®, as well as illegal substances such as heroin and synthetic Fentanyl and Carfentanil. In the late 1990's, these drugs flooded the market following the combination of pharmaceutical company incentivization of opioid prescription practices, a paradigm shift in medical consideration of pain as a vital sign, and an influx of illegal opiates from outside national borders.[1] In 2016, data collected by the Department of Health and Human Services (HHS) showed that 116 people died every day from opioid-related overdoses. A total of 42,249 people died in 2016, but more than 2.1 million were identified as having Opioid Use Disorder, which is defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as "a problematic pattern of opioid use leading to clinically significant impairment or distress.[2]" The high prevalence of opioid use and the consequential health complications, such as heart and lung infections, insomnia, and muscle pain,[3] came with an economic burden of $504 billion.[1] The opioid epidemic is ubiquitous and is unique in that it affects people from all socioeconomic statuses and walks of life.

Kentucky consistently reports some of worst health outcomes among national comparisons, and opioid overdose death is no exception. CDC Drug Overdose Mortality statistics rank Kentucky as having the fifth highest drug overdose death rate in 2016.[4] Deaths per year by opioid overdose have risen steadily over the last two decades, increasing from less than 200 in 1999 to over 1,500 in 2017.[5] Kentucky was one of 23 states to see a significant increase in opioid-related deaths between 2016 and 2017 (**Appendix B: *Figure 1***).[6] In 2007, deaths from accidental poisoning by drug overdose surpassed motor vehicle accidents in the state.[7] This rise in overdoses has also resulted in a surge of drug-related emergency department (ED) visits in Kentucky, with more than 13,000 in 2017.[5] Many epidemiologists conceptualize the epidemic in three waves: heroin, semi-synthetic opioids (i.e. oxycodone), and now

synthetic opioids, specifically fentanyl. Kentucky reports from 2017 showed that 69% of overdose deaths involved fentanyl,[5] a drug with ten times the potency of morphine.

Many of the efforts to combat the opioid crisis within the state of Kentucky are focused on either larger Central Kentucky urban areas, such as Louisville and Lexington, or the rural Appalachian region of Eastern Kentucky. Northern Kentucky counties, meanwhile, have the third largest population in the state and are suffering greatly from this epidemic. A Kentucky Injury Prevention and Research Center (KIPRC) report in 2017 showed a composite risk index for each county in the state based on fatal overdoses, ED visits, overdose hospitalizations, and morphine milligram equivalents (MME) ≥ 100. This report showed all Northern Kentucky counties at the highest possible risk (**Appendix B: *Figure 2***).[5] The Northern Kentucky area lost a resident to drug overdose every 35 hours in 2017.

Target Population

Kenton and Campbell are two of the northernmost counties in Kentucky. Bordered by the Ohio River and the metropolitan area of Cincinnati, Kenton and Campbell counties have similar micropolitan environments. Kenton County encompasses nineteen neighborhoods, the largest of which, Covington, is situated on the Ohio river and is the sixth largest city in the state. Campbell County, similarly, accounts for fifteen neighborhoods and is most populated near the river in the city of Newport. The two counties cover a combined 323 square miles with more than 250,000 residents. They have parallel racial distributions with 91.3% and 93.7% of the population being white, 5.0% and 3.2% being African American, and 3.1% and 1.9% being Hispanic, respectively.[8,9] Both counties tend to fall between the national and state averages on a variety of demographic measures (*Table 1*).

Table 1: **County Health Data for Kenton and Campbell Counties**				
2016[8,9]	Kenton County	Campbell County	Kentucky	US
Population	164,945	92,211	4,436,974	321,418,820

Bachelor's Degree or Higher	28.9%	29.1%	22.3%	29.8%
Unemployment Rate	4.9%	4.6%	4.8%	4.8%
Median Household Income	$52,631	$51,694	$45,178	$55,775
Persons in Poverty	12.8%	14.1%	18.5%	13.5%
Primary Care Providers (per 100,000)	101.7	71.4	80	120.9
Prevalence of Adult Smoking (%; age-adjusted)	24.1%	22.8%	25.9%	15.1%
Total Drug Overdose Hospitalizations	1,551	784	29,683	-
Total Drug Overdose Deaths	296	168	4,931	-

In 2016, Kenton County had a drug overdose fatality rate of 49.7 per 100,000 residents and Campbell had a higher rate of 72.7 overdose deaths per 100,000 residents.[10] Kenton and Campbell ranked 3rd and 4th in the state, respectively, for overdose deaths in 2017.[5] The same report found that Kenton and Campbell ranked highly for emergency department Visit Rate, third and fifth respectively. Although this area only contains 10.3% of the state's population, it accounted for 22.4% of the state's fentanyl overdoses and 21.3% of the state's heroin overdoses last year.[11] Overdose deaths in Kenton and Campbell counties constituted 45% of Kentucky's total in 2016.[12] Outside of overdose mortality, Northern Kentucky has increasing rates of co-occurring risk factors. The area's rates of Hepatitis C are 3.5 times the state average and 11.9 times the rate of the country.[11] Hepatitis B and HIV rates in the area have been stable since 2012, but local official continue to monitor the situation closely.

Individuals with Opioid Use Disorder are the target population of this intervention within these two counties. Emergency departments (EDs) are an ideal intervention site to reach this population. EDs are required, by the Emergency Medical Treatment and Active Labor Act (EMTALA), to provide care for

all patients regardless of insurance status.[13] This means that they are often the only healthcare site of contact with vulnerable populations, such as our target population, who may not have insurance, reliable methods of communication, or stable living arrangements.

Community Resources

Both Kenton and Campbell counties are served by the Northern Kentucky Health Department, who partnered with St. Elizabeth Healthcare, Northern Kentucky University, United Way, the Northern Kentucky Chamber of Commerce, and Skyward to release a Community Health Improvement Plan (CHIP) in 2016 in response to the Community Needs Assessment.[14] These stakeholders utilized the Mobilizing for Action through Planning and Partnerships (MAPP) tool which includes six phases: (1) organize for success, (2) visioning, (3) four assignments, (4) strategic issues, (5) goals and objectives, and (6) action cycle.[14] Through this process, substance use disorders were identified as a priority health outcome for the community. The plan set forward ten goals for the community to reach by 2020, one of which was to decrease the number of people suffering from substance use disorders in Northern Kentucky. Under this goal, the objectives and strategies largely revolve around increasing access to treatment, including medication-assisted treatment (MAT), and developing community partnerships for collaborative care. This proposal seeks to enhance the current efforts by offering new strategies to meet these goals. St. Elizabeth Healthcare System is listed as one of the essential assets for achieving these substance use goals and will be the location of implementation for this proposal. The CHIP gave us a comprehensive picture of current community needs, but St. Elizabeth Healthcare is committed to continued conversation and assessment with our partnering organizations to address new communities needs as they arise.

Along with the CHIP, Northern Kentucky has developed an extensive network of programs and partnerships to contribute to efforts against the opioid epidemic. Both counties have established syringe exchange programs, which include Naloxone distribution, that operate within St. Elizabeth Urgent Care Centers.[15] Naloxone kits are also distributed by Kenton and Campbell Health Centers throughout the

week. The Northern Kentucky Health Department has developed a prescription medication disposal program at dropboxes located throughout both counties. Community coalitions have played a large role in current initiatives, specifically the Northern Kentucky Heroin Response Impact Task Force and the NKY Regional Prevention Alliance. These groups advocate for policy change as well as distribute resources, such as the NKY Hates Heroin Guide, to individuals who suffer from addiction. In addition to Northern Kentucky efforts, individuals living in this area have the advantage of additional access to Cincinnati resources. The immense and collaborative response to the epidemic demonstrates the community's readiness to change and makes it a promising location for implementation of the Brief Negotiation Interview with Emergency Department-Initiated Buprenorphine.

Potential Impact

St. Elizabeth Healthcare has five hospitals, three of which are within Kenton and Campbell counties: Edgewood, Covington, and Ft. Thomas. The Emergency Departments in Covington and Ft. Thomas were both ranked in the top 5 EDs in Kentucky for opioid-related ED visits in 2016.[16] Opioid-related ED visits, including overdoses as well as cases of withdrawal, abscesses, etc., totaled 2,055 for the St. Elizabeth Healthcare System in 2017.[12] Increasing use of St. Elizabeth EDs for overdose efforts in Northern Kentucky leads us to believe that the proposed intervention has the greatest potential to impact the target population in order to combat the opioid epidemic. Recruitment for this intervention is convenience-based by screening individuals who enter the ED for symptoms of opioid use and withdrawal. Thus, the number of individuals who would be offered to participate in the program would be just over 2,000 if ED trends continue. We would expect, however, participation and follow-up to be completed by 600 individuals per year (around 200 per ED), or roughly 30% of opioid-presenting patients. Of the participating patients, 81% are expected to complete the 10-week follow-up when considering retention efforts (laid out in **Program Approach*: Implementation in Kenton and Campbell Counties***). This estimate is based on participation of patients in research trials of the intervention.[17] Our extensive network within the community and continued partnerships with the organizations listed above

give us confidence in large-scale implementation to meet the needs of Kenton and Campbell counties. Current standard of care in the ED setting is to treat the symptoms presented by an individual with opioid use disorder (OUD) and to provide referral resources without addressing the root cause of the problem: addiction. The proposed intervention aims to focus on the underlying disorder and initiate meaningful discussions to encourage entrance into local drug treatment programs.

Program Approach and Evidence Base

The Program: Brief Negotiation Interview with Emergency Department-Initiated Buprenorphine

In response to the declaration of the opioid epidemic as a public health emergency, the Department of Health and Human Services identified five priority efforts: improving access to treatment, advancing alternative pain management options, supporting relevant research, strengthening surveillance, and promoting overdose-reversing drugs.[18] The Brief Negotiation Interview (BNI) is a motivational interviewing strategy that was adapted by the Yale School of Medicine which aims to motivate patients with opioid dependence to enter into addiction treatment. The BNI has been combined with an evidence-based MAT curriculum- specifically buprenorphine- for more effective recovery. Buprenorphine is one of three FDA-approved drugs for treatment of OUD; it acts as an opiate-like substance in order to reduce withdrawal symptoms. The combination of BNI with MAT primarily addresses one of the five priority areas set forward by HHS: improving access to treatment. The BNI with Emergency Department (ED)-Initiated Buprenorphine has a primary goal of increasing motivation to enter treatment while integrating follow-up care management. Intervention developers identified patient reduction in self-reported opioid use, and thus reduction in HIV risk-behaviors,[19] as a secondary goal of the intervention. However, for the purpose of this proposal the secondary outcome of interest is solely self-reported opioid use.

The target population of the Brief-Negotiation Interview with ED-Initiated Buprenorphine is adults that present with moderate-to-severe opioid use disorder. The intervention is implemented in the ED, where those with opioid use disorder would likely seek care if they exhibited negative health symptoms,[13] such as symptoms of withdrawal or skin abscesses,[13] or in the case of an overdose. The BNI

is completed in 10-15 minutes by ED health providers, with previous studies specifically employing ED nurses. Through the cognitive-behavioral strategy of motivational interviewing, a counseling style that utilizes open questions to facilitate behavior change, the providers have a goal of "achieving a patient-centered agreement for treatment.[19]" The discussion addresses barriers to entering treatment and develops a plan to overcome these barriers, establishing self-efficacy within the patient and helping them feel confident in a decision to seek help for OUD.

The majority of the intervention focuses on changing provider interactions with patients by employing the Brief Negotiation Interview. The BNI was first used in 2002 for alcohol addiction, then in 2008 for substance abuse[19]. It was adapted to be relevant to opioid dependent patients in 2009 by Gail D'Onofrio and her team at the Yale Medical School. In order to address the needs of opioid dependent patients, the intervention includes four steps: rapport, feedback, motivation, and negotiation. These four steps align closely with the five principles of motivational interviewing: express empathy, develop discrepancy, avoid argumentation, roll with resistance, and support self-efficacy.[20] These elements are crucial for the target population as addiction is a sensitive subject. The decision to enter treatment cannot be forced on the participant, they must decide to commit themselves. Mutual agreement between the provider and the patient is a unique driving component of the BNI.[21] The interview portion of the intervention is initiated when a patient enters the ED, whether from drug overdose or other health complication. They are screened for opioid use as part of their general health assessment including history of prescription, presenting symptoms, and history of drug use. Presence of opioid use or withdrawal symptoms are assessed with the Clinical Opiate Withdrawal Scale. If opiate use or withdrawal is evident, then the patient is evaluated for extent of use disorder via the Mini-International Neuropsychiatric Interview (MINI). A patient that has a score higher than a 3 on the MINI and has provided an opioid-positive urine sample is considered eligible for the intervention.

First, the interventionist initiates a conversation with the patient about their opioid use and any subsequent health complications. The provider also presents buprenorphine treatment options available to the patient outside of the ED. Next, the provider asks the patient about their readiness to seek treatment on

a scale from one to ten, utilizing reflective-listening skills and inquiring about reasons why the patient is or is not willing to engage in treatment. The provider then reinforces the patient's desire and motivation by talking through ways to remove barriers and set goals, eventually obtaining a referral agreement for a treatment appointment. Finally, patients exhibiting withdrawal symptoms are given their first dose of buprenorphine while still in the ED. If withdrawal symptoms are not present, patients are sent home with a dose of buprenorphine to last until their first outpatient treatment appointment, which should take place within 72 hours of leaving the ED. A flowchart depicting this ED Buprenorphine prescription protocol can be found in **Appendix C**. The provider then completes the Opioid Referral Form for ED-Initiated Buprenorphine specific to the negotiated treatment.[19] Length of buprenorphine treatment is typically 10 weeks but is dependent on clinical stability and patient retention.[17] Adherence to program is measured at weekly follow-ups using urine tests, self-reports, and communication with local treatment centers.[19]

Treatment with buprenorphine is the second component of this intervention. It is essential to the program that the buprenorphine treatment is integrated with counseling, like any other MAT, as this will increase retention and amplify outcomes.[22] Buprenorphine was one of several drugs approved for use in treatment of opioid dependence by the Drug Addiction Treatment Act (DATA) in 2000.[23] It is a partial agonist that is commonly paired with an antagonist to prevent the development of an addiction to the drug. Partial agonists bind to the same receptors in the brain as an opioid but do not cause the same scale of response.[22] Buprenorphine is used to manage withdrawal symptoms by mimicking the problem opioid. It is also used to decrease the "pleasurable effects" of other opioids in addition to mitigating the "cycle of highs and lows" of withdrawals.[1] Buprenorphine can be administered in the form of a daily tablet, 6-month implant, cheek film, or monthly injections. This proposal will utilize daily cheek film for administration of buprenorphine as this form is not prone to abuse and easily tracked. One of the main advantages of using buprenorphine over other drugs approved for treatment of opioid use disorder is the prescription availability. When compared with methadone, buprenorphine is more widely accessible as more physicians are eligible for delivery and the drug can be picked up at most pharmacies instead of having to visit a methadone clinic.[22] There are many regulations for administration of MAT that will need

to be considered in implementation of this intervention. The Comprehensive Addiction Recovery Act and the Drug Addiction Treatment Act lay out specific vetting requirements for physicians and other medical professionals in order to receive a DEA X Waiver for prescribing privileges.[23] The Code of Federal Regulations enforces a 72-hour rule that allows physicians to prescribe narcotics with the intent of withdrawal relief for only a 72-hour period.[13] Enforcement of this rule will require partnerships and communication with community organizations to connect patients with treatment options for continuation of follow-up care during this 72-hour time frame.

The processes within the BNI with ED-Initiated Buprenorphine align with the Transtheoretical Model, or Stages of Change. This framework is often utilized in interventions addressing addiction, specifically attempting to move individuals from the pre-contemplation and contemplation stages directly into the action phase by developing a concrete plan for treatment. Participants are motivated to move between these stages and change their behavior by addressing both cognitive and environmental factors from the Social Cognitive Theory. The motivational interviewing strategy seeks to change the participant's outcome expectations, increase knowledge of both negative health effects and treatment options, and discuss perceived barriers to entering treatment. The main construct utilized within this program is increasing participant self-efficacy in their decision-making process to seek treatment. If these factors within Social Cognitive Theory can be altered, then their behavior can be changed according to reciprocal determinism.

Evidence Base

The Substance Abuse and Mental Health Services Administration's (SAMHSA) evidence-based intervention database, the National Registry of Evidence-based Programs and Practices, supports implementation of the BNI with ED-Initiated Buprenorphine. The database provides an outcome evidence rating for each listed program, from which this intervention received a rating of "effective," the highest rating, for opioid use and opioid use disorder. This rating conveys that SAMHSA found the effect of the intervention to be substantial and the evidence has "strong methodological rigor." The program was also

rated as "promising" for mental health/substance use treatment, indicating sufficient evidence to show that a substantial effect and favorable outcomes are likely.[19]

The BNI with ED-Initiated Buprenorphine was developed by Gail D'Onofrio and her colleagues at Yale Medical School. In 2015, they conducted a randomized control trial with the primary intentions of adapting the BNI to target opioid use disorder. At the time, the motivational interviewing strategy was novel in opioid-dependent populations. The study included 329 participants and looked at short-term effects of the intervention. Within thirty days of initial contact, 78% of participants in the experimental cohort were actively receiving treatment and participants' opioid use per week had decreased significantly from 5.4 days per week to 0.9 days per week[24]. The study did acknowledge a time effect and interaction effect on the results of both the self-reported illicit opioid use and participation in outpatient addiction treatment. D'Onofrio and colleagues concluded that this evaluation portrayed the feasibility and efficacy of this intervention, but that further work should focus on effectiveness and implementation strategies. A second randomized control trial conducted by the same team included 290 participants. D'Onofrio concluded in this trail that patients in the experimental group were more engaged in treatment and had fewer self-reported days of drug use two months after contact when compared to a referral-only group and a brief intervention group that did not receive buprenorphine.[17]

There is also strong evidence to support the use of buprenorphine as treatment for opioid use disorder, including FDA approval of the drug for this purpose. There have been many studies to support the use of buprenorphine as a form of MAT. The most recently approved form of drug delivery was a monthly injection of buprenorphine called Subcolade®, which was tested in clinical trials with close to 850 adults with OUD. These trials showed that patients in the experimental group had fewer positive urine reports, less self-reported drug use, and less evidence of opioid use during treatment[1]. Another clinical trial conducted in Baltimore, Maryland found a significant relationship between the availability of buprenorphine treatment and an almost 50% decrease in the number of heroin overdoses from 1995-2009.[25] There are several systematic reviews that look at the safety and effectiveness of buprenorphine in comparison to methadone, another widely accepted drug used in MAT. One conducted in the United

Kingdom included 31 systematic reviews and concluded that buprenorphine treatments are effective in opioid abuse treatment, but less cost-effective than methadone[26]. Another systematic review of reviews also supported MAT as one of the only evidence-based practices to address opioid use disorders to date[27].

Follow-up with researchers from this lab revealed that many EDs across the country have adopted portions of the program but was unsure about locations with full implementation. The current proposal will address these gaps by implementing the full strategy in St. Elizabeth EDs, with supplemental adaptations.

Adaptations

Implementation of the BNI with ED-Initiated Buprenorphine in Northern Kentucky St. Elizabeth hospitals will require several minor adaptations from the original strategy produced at Yale. Development and implementation of the project thus far has occurred exclusively within academic teaching hospitals. The St. Elizabeth Healthcare System is not affiliated with a university and thus transitioning into this environment is an adaptation from the original design. Utilizing these sites, instead of research-oriented university hospitals, could change acceptance of the program and resulting data collection, thus altering the organizational and interventionists' willingness to adopt. Organizational attitudes about implementation of the intervention will be evaluated, as discussed in the **Performance Measures and Evaluation:** ***Process Measures*** section. Implementation at St. Elizabeth also requires prescription of SUBOXONE® instead of traditional buprenorphine, according to Kentucky state law (201 KAR 9:270). SUBOXONE® combines buprenorphine with naloxone, the drug used to reverse opioid overdoses, to minimize addiction to the medication. In addition, physicians in these settings may need additional training in order to prescribe and dispense the SUBOXONE® arm of the program. Budgetary accommodations for physician training are not traditionally included in implementation of the BNI with ED-Initiated Buprenorphine but are included in this proposal.

Inclusion of sensitivity and cultural competency trainings for ED staff involved in the project is another adaptation to the original curriculum. Stigma surrounding opioid use disorder could alter

healthcare professional's perceptions of patients as they enter the ED. This has been identified by the original authors as one of the crucial factors affecting uptake of the method into EDs.[13] Misconceptions of addiction as a moral failing prevent initiation of treatment with patients presenting with OUD. Harvard Medical School partnered with the National Institute on Drug Abuse to offer three publicly available Continuing Medical Education courses online that combine to form the Opioid Use Disorder Education Program.[28] One of these modules, *Understanding Addiction*, will be utilized to reset the perspective that professionals in the St. Elizabeth Healthcare System have about the patients that they treat. This module gives an overview of life with OUD, describes the basic neurobiological functioning of an individual with a substance use disorder, and addresses the stigmas surrounding this population. One of the primary goals of the module is to change the perception of opioid use to recognition of OUD as a chronic disease.[28] The module has been accredited by the appropriate councils for continuing education credit in a variety of professions including medicine, nursing, physician assistant, and social work. The module will be supplemented with discussion as well as personal testimonies from individuals who were previously diagnosed with OUD and are now in recovery. This adaptation will ensure that the program is inclusive, provides a safe and supportive environment, and presents trauma-informed care.

The interventionists used in the evidence base of the BNI with ED-Initiated Buprenorphine were ED-staffed nurses and research assistants. The strategy was intended to become part of the standard patient screening and discharge flow, but high traffic within the department makes in-depth discussion and promotion of treatment for patients more difficult. Preliminary interviews with ED nurses have revealed that their current job demands would not allow them adequate time to implement the BNI in its entirety. Alternatively, utilization of ED social workers as interventionists will allow patients to experience the program more fully. This intervention will also integrate well with the current duties of ED social workers. Their training equips them with cognitive-behavioral strategies such as motivational interviewing, as well as skills to encourage empathizing in interactions with vulnerable populations. Additionally, their ability to refer patients to necessary resources will allow them to address common co-occurring risk factors in the target population such as homelessness and unemployment.

Implementation in Kenton and Campbell Counties

St. Elizabeth Healthcare was identified as a key asset in combatting substance use in the Northern Kentucky CHIP. Our locations throughout the Northern Kentucky area give us access to a wide intersection of the community. Three sites fall within Kenton and Campbell counties and will be the implementation locations for the proposed intervention: Edgewood, Ft. Thomas, and Covington. We will be utilizing the existing Emergency Medicine infrastructure and staff in each location. St. Elizabeth Healthcare has a separate Alcohol and Drug Treatment Center, which will serve as the location for the 10-week buprenorphine administration and follow-up assessments. We will work with our community partners to determine an appropriate schedule to hold buprenorphine follow-ups at the Alcohol and Drug Treatment Center. While adaptations are being made for implementation of the BNI with ED-Initiated SUBOXONE®, St. Elizabeth is committed to maintaining the fidelity of the evidence-based program. Each ED social worker will complete a fidelity checklist as they administer the program and our Project Coordinator will complete random implementation observations using the BNI Adherence and Competence checklist to ensure accurate delivery. Annual booster training sessions will also keep the evidence-based intervention in tact throughout the implementation period. The Project Coordinator will monitor these fidelity checklists on a quarterly basis and make adjustments to implementation as needed for quality improvement. A logic model depicting intervention inputs, outputs, and outcomes can be found in **Appendix D**.

The six-month planning and readiness period upon initial funding will largely consist of concentrated training efforts. All training materials are free and available to the public on the Yale School of Medicine Website. An extensive training manual specific to use of BNI with opiate disorders[21] is available along with generalized training presentation slides, videos, and case studies. The University of Cincinnati Corrections Institute offers a "Training-the-Trainer" course specific to motivational interviewing, which will be utilized to reinforce the knowledge of our contracted Health Educator. We will also work closely with individuals who have previously implemented the BNI with ED-Initiated Buprenorphine at the University of Cincinnati Medical Center to ensure that all training materials are

interpreted correctly and applied realistically. These individuals will work with the Health Educator to form a Curriculum Team for training our interventionists and other crucial ED staff. Each ED will participate in two 8-hour training sessions, including motivational interviewing strategies, BNI implementation logistics, and a sensitivity and cultural competency training. Booster trainings will be offered at 6-months and one year following initial implementation at each intervention site. We will also promote completion of the DEA X Waiver training during this period. In addition, the planning period will be utilized to connect with both old and new community partners. We anticipate hosting several CAB meetings and an initial community partner meeting to orient key stakeholders to the project and receive community feedback. Lastly, baseline data collection mechanisms will be established and initiated during the 6-month planning phase. A full depiction of the project timeline can be found in the Gantt Chart in **Appendix E.**

Recruitment of individuals with OUD will be convenience-based as they enter the three ED's for other services. Each individual will be consented prior to being screened for opioid use. The consent process will emphasize the success of MAT programs and supports available in the community. If eligible and willing, each participant will receive compensation in the form of a $15 Walmart gift-card for participation. Retention of participants will include an incentive, in the form of a $20 Walmart gift card, halfway through the follow-up period, and a $25 Walmart gift-card upon completion of the 10-week program. Long term follow-up at 6 and 12 months will be incentivized with $15 and $25 Walmart gift cards, respectively. Another key aspect of participant retention is interventionist characteristics. The nature of the target population for the BNI with ED-Initiated SUBOXONE® requires integration of team members that are not only equipped with skills particular to the disorder but also empathic to the needs of the population.

The BNI motivates participants to reach a mutual agreement to enter into treatment and as such connection to treatment is a crucial piece of implementation. St. Elizabeth will be utilizing both the Northern Kentucky Heroin Hotline and FindHelpNowKY.org to find local, available addiction treatment for participants. An extensive network of addiction treatment centers exists within the Greater Cincinnati

area, and efforts to build capacity within these centers has been a top community priority. Representatives from each of the community treatment centers within a 20 miles radius of St. Elizabeth Healthcare will be invited to participate in an informational session and roundtable discussion during the planning and readiness period. We hope to establish rapport with each of the treatment centers as well as protocols for data collection and participant monitoring for the purpose of this proposal.

Continuation of implementation following completion of the funding period is of utmost importance. Integration of the strategy into the standard ED protocol of the three intervention sites will promote program sustainability, as will use of many established workers in the ED. The greatest challenge to sustainability is provision of SUBOXONE® to uninsured participants. Following completion of the funding period, St. Elizabeth will make efforts to meet this gap in funding through other external sources and community partners. As such, continual community involvement is a crucial part of intervention implementation. We will rely heavily on pre-existing coalition networks, specifically the Northern Kentucky Heroin Response Impact Task Force, for communication and dissemination of project development as well as integration and sustainability efforts. We will gather a Community Advisory Board (CAB) in order to receive input from St. Elizabeth employees, community members, and other local public health executives during the planning period. A list of potential CAB members is included in *Table 2.* A physician from the University of Cincinnati ED is included in the CAB due to their experience implementing the proposed program and proximity to St. Elizabeth. Several members of the St. Elizabeth Healthcare System will represent groups of staff that will be heavily involved in implementation efforts. Local politics and law enforcement are important members of the CAB due to the legal implications of opioid use. A representative from the NKY Health Department will connect our project with other opioid-related community efforts, specifically projects such as the syringe exchange. Lastly, individuals in recovery will provide necessary guidance to ensure that materials are culturally appropriate, non-stigmatizing, and meet the needs of the target population.

Table 2: **Potential CAB Members**			
Physician, St. Elizabeth Emergency Medicine	Charge nurse, St. Elizabeth Emergency Medicine	Officer, Kenton County Police Department	Officer, Campbell County Police Department
Individuals with OUD in recovery (x2)	Director, NKY Health Department	Pharmacist, St. Elizabeth Emergency Medicine	City council representatives (x2)
Addiction therapist, St. Elizabeth Alcohol and Drug Treatment	ED social worker, St. Elizabeth Healthcare	Physician, University of Cincinnati Emergency Medicine	

Potential challenges to implementation of the BNI with ED-Initiated SUBOXONE® include ED staff attitudes toward participants, integration of social workers as the interventionist, retention of participants, and changes in opioid-related policies and procedures. The first two concerns will be addressed through training efforts and will be continually monitored by the Project Coordinator. During the baseline data collection, participants will complete a locator form with up to three contacts for communication if the participant's primary phone or address become invalid. We hope that these outreach efforts will maintain adequate participation. While we cannot predict community-wide changes in opioid efforts, close communication with community partners and members of our CAB will allow us to adapt when changes arise. Lastly, proximity to Cincinnati will provide us with the benefits of an urban area but could cause complications regarding participants crossing state lines. We anticipate monitoring movement of our participants and will work with our CAB and community partners to handle issues that may arise regarding this complication.

Performance Measures and Evaluation

There are several levels of outcomes to be evaluated with this implementation of the BNI with ED-Initiated SUBOXONE® in Kenton and Campbell counties. Primary outcomes of interest are self-efficacy to enter treatment immediately following intervention, and consequent engagement in formal

addiction treatment. Our goal is for 80% of participants to have improved self-efficacy following intervention and for 70% of participants to come to a mutual agreement for treatment. The secondary outcome for evaluation is illicit opioid use following interaction with the intervention. The specific goal for reduction of opioid use is to reduce average days of use by 80%. The long-term outcome of interest is change in mortality rate attributable to accidental poisoning by opiates. This outcome evaluation will be supplemented with a process evaluation to investigate effectiveness of implementation and willingness of the three intervention sites put this program into practice.

Process Evaluation

The Project Coordinator will collect process data semi-annually in order to assess implementation effectiveness. This will not only serve as a quality control check for maintaining fidelity of the program, but also ensure that the needs of the interventionists and providers are being met for quality improvement purposes. Constructs for this evaluation will be based on the Consolidated Framework for Implementation Research (CFIR), which outlines implementation outcomes, such as acceptability, adoption, feasibility, cost, and sustainability, while considering both the inner and outer setting of the intervention.[29] Primary outcomes for the process evaluation of the BNI with ED-Initiated SUBOXONE® are fidelity to the original intervention through adherence to proper motivational interviewing strategies, acceptability of implementation in the workplace, patient participation, and actual cost of implementation. Adaptations to the original program will also be evaluated through process measures, looking specifically at completion of DEA X Waiver training by physicians, organizational acceptability, and transition of the interventionist role to ED social workers. These measures are listed in *Table 3*, with evidence of reliability and validity of survey measures provided in *Table 4*.

Table 3: Process Measures and Collection Methods	
Process Measure	**Measurement Method**
% of eligible participants who complete BNI	Compare number of participants who are eligible and initiate the BNI to the number of completed interviews
Follow-up dose – number of buprenorphine sessions participants attend	Compare number of follow-up treatments completed by each participant
Observational fidelity	Random observation of interventionists by Project Coordinator
Written fidelity measures	Collection and examination of intervention checklists with detailed interventionist notes
Interventionist acceptability	Survey - Evidence-Based Practice Attitude Scale (EBPAS-50) Focus groups
Organization acceptability	Survey - Organizational Readiness to Change Assessment (ORCA) Key informant interviews
Physician DEA X Waiver completion	Compare number of physicians with DEA X Waiver to physicians without
Time required for intervention	Interventionist self-report of time spent delivering BNI
Cost of implementation	Interventionist time reports Amount spent on SUBOXONE® for uninsured participants

Interventionist and organizational acceptability will be assessed through focus groups and key informant interviews at the end of the first year of implementation within each ED in order to make adjustments for the remaining funding period. This data, specifically from measures of fidelity, will also be used for continuous quality improvement which will inform implementation adjustments within annual booster training sessions.

Table 4- Description of Process Measure Surveys (not in original article)		
Name of selected measure:	EBPAS-50[30]	ORCA[31]
Brief description of the measure:	This tool assesses an interventionist's attitudes around adopting evidence-based practices, including openness to innovation, perceptions of utility, and consistency over time.	This is a structured survey to assess an organization's readiness to change and implement evidence-based practices. This will be completed by hospital administrators.
How is it administered?	Survey	Survey

Number of items:	15	77
Response category format:	0-4 Likert Scale (0= Not at All, 4= To a Very Great Extent)	1-5 Likert Scale (1= very weak, 5= very strong)
Evidence for validity:	Acceptable exploratory and confirmatory factor analyses, support for content validity	Exploratory factor analysis loaded all included items onto three factors
Evidence for reliability:	reliability coefficients of .91	Cronbach's alpha for three subscales: 0.74 for evidence, 0.85 for context, and 0.95 for facilitation
Is scoring algorithm provided by authors?:	Yes	No
Is the measure publicly available?:	Yes	Yes
Is the measure available for download? If so, from where?:	Aarons, G.A. (2004). Mental Health Provider Attitudes Toward Adoption of Evidence-Based Practice: The Evidence-Based Practice Attitude Scale (EBPAS). *Ment. Health Serv Res.*, *6*(2), 61-74.	https://www.gem-beta.org/public/MeasureDetail.aspx?mid=1373&cat=2

Outcome Evaluation

The outcome evaluation of the BNI with ED-Initiated SUBOXONE® will address the following areas of interest: self-efficacy, engagement in treatment, illicit drug use, and overdose mortality rate. As described in the **Evidence Base** section, the original evaluation used a randomized control trial, but in this iteration of the program we will conduct a cluster-randomized stepped-wedge experimental design. In a cluster-randomized stepped-wedge design, implementation occurs one location at a time so that all three EDs will begin in the control group and all three will receive the intervention by the end of the funding period. This design aligns well with the overall goals of the project by quelling ethical concerns of withholding the intervention from control locations and by enhancing feasibility of training and implementation costs. The three EDs will be randomized for timing of implementation. The stepped-wedge period of separation between each location will be six months, with the first location implementing

the intervention six months into the funding period and the final location beginning implementation after 18 months. A visual representation of this design can be found in **Appendix F.** Evaluation will examine both effectiveness within each location pre- and post-intervention, as well as larger community-wide outcomes.

Participants who are deemed eligible at each ED will be provided an intake survey prior to engagement in the intervention. This survey will collect demographic information such as age, gender, and race, and will inquire about history of substance use, number of past overdoses, and history of addiction treatment. The intake survey will also include the Description of Self-Efficacy measure to assess their baseline self-efficacy to enter treatment. Data collected at intake will serve as pre-test data in place of having access to participants prior to their admittance to the ED. Post-test data will be collected as repeated measures throughout the 10-week SUBOXONE® visits, as well as at 6- and 12-month long-term follow-ups with participants. A description of each measure can be found below in *Table 5*.

Table 5 - Pre-Test Post-Test Measures
*Measures used in the original evaluation will be denoted with a *.*

Outcome	Measure	Description	Frequency
Self-efficacy	Decision self-efficacy scale	This is a general measure to supplement the readiness-to-change ruler. It gauges the participant's confidence in their ability to change their own life. Details provided in *Table 6*.	Before and after administration of the BNI, at every SUBOXONE® visit.
Engagement in treatment*	Self-Report	This would be a form filled out prior to buprenorphine administration by each participant. It would ask for their treatment status as well as where they were receiving treatment from (to gauge if extent of our partnership network is appropriate).	At every SUBOXONE® visit, 6- and 12-month follow-up.
Engagement in treatment*	Treatment Enrollment	This is an objective report from partnerships with local treatment centers to check if participants are actually engaged in addiction treatment.	Weekly reports until end of 10-week follow-up.

Illicit drug use*	Self-Report	This will be a provider verbally asking the participant how many times they had used illicit opiate substances since the last visit.	At every SUBOXONE® visit, 6- and 12-month follow-up.
Illicit drug use*	Urine sample	This is an objective measure of chemical substances in the participants' systems.	At every SUBOXONE® visit, 6- and 12-month follow-up.

Many of the measures are objective, such as urine samples or treatment enrollment, and are supplemented by self-report. In addition, the self-efficacy measure will be completed immediately after implementation to gauge effectiveness of the motivational interviewing strategy. Details about the selected self-efficacy measure can be found below in *Table 6* and the measure itself can be found in **Appendix I**.

Table 6 - Description of Self-Efficacy Measure *(not in original article)*	
Name of selected measure:	Decision Self-Efficacy Scale (Bunn) Information from https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decision_SelfEfficacy.pdf
Brief description of the measure:	Measures self-confidence or belief in one's abilities in decision making.
How is it administered?	In-person interview
Number of items:	11
Response category format:	0 -4 Likert scale (0= not confident at all, 4=very confident)
Evidence for validity:	Divergent validity established as significant
Evidence for reliability:	Internal consistency alpha coefficient: 0.92
Additional psychometric properties:	The scale is correlated with: decisional conflict subscales of feeling informed (r=0.47) and supported (r=0.45).
Is scoring algorithm provided by authors?:	Yes

Is the measure publicly available?:	Yes
Is the measure available for download? If so, from where?:	Yes; https://decisionaid.ohri.ca/docs/develop/Tools/Decision_SelfEfficacy.pdf

In addition, overdose mortality data will be collected throughout the stepped-wedge timeline. This is a statistic that is continually collected by the Northern Kentucky Health Department, as well as the Kentucky Injury and Prevention and Research Center, and is readily available for comparison. Mortality rates attributable to opioid overdose are generally reported yearly and as such the time points prior to intervention will display annual statistics. We will work closely with the health department to monitor collection of mortality data and establish monthly post-intervention time points until the end of Y3.

Final Thoughts and Limitations

It will be important to follow other substance misuse programming development within the two counties over the project timeline in order to reduce historical bias in our evaluation of outcomes. Partnerships with the Northern Kentucky Heroin Response Impact Task Force and the NKY Regional Prevention Alliance will keep us informed of evolving community efforts. The program coordinator will also review applicable laws, policies and developing procedures relevant to our intervention on a regular basis. Members of our CAB, specifically law enforcement and city council representatives, will also keep us updated with evolving local laws surrounding data collection and patient privacy.

Limitations to this evaluation strategy have been considered and will be addressed accordingly. Attrition is a concern for the long-term follow-up data collection at 6- and 12-months due to transient living and communication accommodations common among the target population. The original evaluation, however, was able to complete follow-ups at 6- and 12-months with 80% and 75% response rates, respectively.[17] Relationship establishment during the 10-week Buprenorphine treatment and financial incentives are crucial to reduce attrition over time. The low number of clusters in our cluster-

randomized stepped-wedge design is a limitation of this evaluation by lowering the power of our analysis. We acknowledge this flaw but plan to move forward as the design provides more depth for our analysis, and possible causation connections, while other experimental designs that were considered do not. We expect further challenges, as well as successes, to be identified through analysis of our process measures and we will address these as they arise.

Capacity and Experience

Founded in 1861, St. Elizabeth Healthcare is one of the oldest and most established health systems in the Cincinnati area. Our 158 years of service in the community has allowed us to impact countless lives and grow as an organization to encompass five facilities across Northern Kentucky: Covington, Edgewood, Florence, Ft. Thomas, and Grant. Our extensive network of hospitals and health centers in the area provide us the necessary infrastructure and confidence in the large-scale scope of implementation, as well as the ability to efficiently deal with staff turnover, which has been minimal over the last several years. Our vision for the community is to "provide comprehensive and compassionate care that improves the health of the people we serve." Implementation of the BNI with ED-Initiated SUBOXONE® fits with our mission by expanding services to individuals in need, filling a gap in the currently available services for more comprehensive care, and supporting larger community efforts and partnerships. Utilization of evidence-based care strategies is central to fulfilling this vision.

St. Elizabeth has demonstrated a high capacity for implementation of programs specific to substance use through our Baby Steps program, an intervention that has been successfully providing resources, evidence-based treatment, and support for expecting mothers with a substance use disorder, for over two years. We have also implemented prevention programs throughout our facilities such as the Domestic Options for Violent Emergencies (DOVE) program and the Freshstart smoking cessation program. Community outreach through mobile clinics has also proven a successful technique to serve the Greater Cincinnati area as demonstrated by our active CardioVascular Mobile Health Unit and Mobile Mammography Unit. These efforts also demonstrate our effective and efficient use of external funding.

We have obtained a profit more years than not as an organization and participate in the annual standardized audit reviews required of all hospitals to ensure fiscal responsibility.

Our leadership team is committed to combatting the opioid crisis within our community, as demonstrated through a variety of partnerships and public action. The CHIP discussed above (**Target Population and Need: Community Resources**) displays the extensive, diverse partnership network that has been established in order to present a community-wide, coordinated effort toward systematic change in regard to substance use. Many of our previously established partnerships will be maintained and utilized for the proposed program. Specific plans for communication with partners are detailed in **Partnerships and Collaborations**. Coordinating guidance from community partners and assessing organizational and interventionist attitudes are essential practices for effective implementation within our healthcare system. St. Elizabeth has been a crucial partner at the forefront of Northern Kentucky community efforts through contributions to the CHIP and strategic plans, legislative advocacy for treatment funding expansion, establishment of a help-seeking hotline, and partnerships to develop syringe exchange programs in multiple counties in the area. EDs within the St. Elizabeth Healthcare System have been pinpointed as a critical site for interaction with individuals with opioid use disorder. St. Elizabeth also serves as the data source for many of the goals and outcomes outlined in the CHIP and as such maintains extensive, rigorous data monitoring and dissemination mechanisms. In addition, St. Elizabeth conducts internal Community Health Needs Assessments and Implementation Plans on a biennial basis, which is supplemented with ongoing internal quality improvement investigations.

Lastly, in accordance with the St. Elizabeth Healthcare Diversity Statement and Code of Conduct, we are committed to serving the entire community, regardless of sex, race, ethnicity, religion, age, ability, sexual orientation, or gender identity. We strive to honor the dignity of every human being who comes to us for healing. The same standard of inclusivity is present in all employment operations of the organization. These policies will be enforced in full for the duration of the project period.

Partnerships and Collaborations

Community partnerships are crucial for successful implementation of the proposed project. St. Elizabeth is currently well connected with community organizations that serve the target population, as discussed in **Target Population: *Community Resources*** and **Capacity and Experience**. The organizations with which we have previously partnered have successfully contributed to ongoing harm reduction implementation efforts in the community. New partners, such as KIPRC and the University of Cincinnati, have also contributed to ongoing efforts to combat the opioid epidemic. We will rely on previously formed coalitions, specifically the NKY Heroin Response Impact Task Force and NKY Regional Prevention Alliance, so as to not overburden key stakeholders who are already involved in opioid-related community efforts. A summary of our partnering organizations can be found in *Table 7*. Each partnering organization has expressed their commitment to the project through Letters of Support, which can be found in **Appendix G**. Many, but not all, of our partners will also participate in our CAB. Large-scale implementation will be possible by involving other hospitals and health centers within the St. Elizabeth Healthcare Network if this project is successful. We will also disseminate results through the Kentucky Hospital Association and Catholic Health Association of the United States.

Table 7: Community Partnerships

Organization	Expertise	Roles
Kentucky Injury and Prevention Center (KIPRC)	Data collection and treatment referrals	KIPRC will be able to provide community-level data about overdose deaths and ED visits in both Kenton and Campbell counties. We will also be utilizing findhelpnowky.org to find long-term treatment for participants, which was developed by KIPRC.
NKY Heroin Response Impact Task Force & NKY Regional Prevention Alliance	Involvement with target population and community coalitions	These coalitions are very well connected with harm reduction and other opioid efforts in the NKY area. They will be our primary partners for concerns regarding the target population and changing policies/programming in the area that would affect implementation. They will also aid in execution of the sensitivity and cultural competency training by making it specific to NKY and putting a face to addiction in the community.

Northern Kentucky Health Department	Health education and data collection	Fostering a relationship with the NKY Health Department will allow us to contract their health educator to complete various trainings with our interventionists throughout the funding period. The Health Department also currently collects valuable community-level data that will contribute to our outcome evaluation.
University of Cincinnati Medical Center	Implementation of intervention	Individuals who have experience as interventionists for the BNI and individuals involved in the training of interventionists at UC will serve on our Curriculum Team to ensure that our training is comprehensive and applicable to reality.
University of Cincinnati College of Medicine Division of Public Health Sciences	Education	Partnership with the university community, specifically within the Division of Public Health Sciences, will aid in recruitment of GRAs for the project. Our biostatistician will also be from UC Public Health.
Kentucky Hospital Association & Catholic Health Association (CHA) of the United States	Hospital network	Upon successful implementation of this project, St. Elizabeth can utilize its membership in and partnership with KHA and CHA to disseminate findings and scale up implementation efforts.

Continuous communication with our partner organizations will be necessary in order to account for rapidly developing policy, resources, and attitudes surrounding the target population. Outside of communication with individual organizations, we will distribute a monthly newsletter with updates from our projects as well as significant developments from our partners. We will also host quarterly Zoom conference calls to discuss implementation barriers, community factors, and promote collaboration between partners.

Project Management

Many of the individuals who will be involved in implementation of the BNI with ED-Initiated SUBOXONE® are currently employed by the St. Elizabeth Healthcare System. Even still, this project will require personnel who are dedicated to the target population and are understanding of their needs, which is why the addition of the sensitivity and cultural competency training is crucial. Outside

individuals who will supplement existing staff for this project are the Project Coordinator and Graduate Research Assistants. We will work to reduce turnover amongst interventionists but acknowledge that some turnover amongst the GRAs and ED social workers is to be expected. Each new staff member will receive the same quality of training as initial team members. Details of staff training can be found in **Program Approach:** ***Implementation in Kenton and Campbell*** *Counties.* In order to mitigate turnover, we will regularly communicate with individuals working on the project, request staff and interventionist feedback, and acknowledge outstanding accomplishments through employee spotlights in the St. Elizabeth Healthcare newsletter. We will maintain communication amongst the Project Director, Project Coordinator, and GRAs through biweekly meetings. Interventionists within each hospital will have monthly meetings with the Project Coordinator to discuss implementation successes and challenges. An overview of the management structure for the project can be found in **Appendix H.**

Leslie Knope, MD, MPH, will serve as the Project Director for the proposed intervention. She obtained her MD from the Medical college of Pennsylvania, followed by completion of an MPH during her residency at the University of Cincinnati. Dr. Knope currently practices as a board-certified physician in the St. Elizabeth Edgewood Emergency Department, also serving as the Section Chairman of Emergency Medicine for the St. Elizabeth Healthcare System Medical Executive Committee. She has been engaged in other interventions particular to this population such as naloxone training and distribution within St. Elizabeth EDs. She will assume primary responsibility for implementation of the program, as well as provide oversight for financial management of the project budget. She will also complete the training to receive a DEA X Waiver as a practicing physician. Dr. Knope will be one of the representatives of this proposal attending the Annual Regional Training required for the grant and will attend the Annual Program Director Meeting through the funding period.

Cady Cornell, MPH, will serve as the Project Coordinator for the BNI with ED-Initiated SUBOXONE® as implemented in the St. Elizabeth Healthcare System. She received her MPH from the University of Kentucky College of Public Health in 2019. Her responsibilities include direct oversight of the three locations (Edgewood, Ft. Thomas, and Covington) as well as project staff, conducting CAB

meetings, and executing evaluation of the project. She will coordinate with the implementation sites to provide support, supplies, and anything else necessary for the project. She will also manage community partnerships and maintain communication with key stakeholders to ensure that needs of the community are prioritized. Alongside the biostatistician, she will complete evaluation of the project and translate results into appropriate formats for both the community and academic presentations. Her evaluation responsibilities will also include conducting focus groups and key informant interviews to assess organizational attitudes. She will be attending the Annual Regional Training with Dr. Knope, as well as presenting results from the project at the APHA Annual Meeting and the SAMHSA National Leadership Forum.

ED social workers will assume the responsibility of direct contact with the target population through the role of primary interventionists. They will complete trainings for delivery of the intervention as well as the sensitivity and cultural competency training. Responsibilities of the interventionists include completing extended screening measures once a patient has been identified, completing the BNI with each patient, and referring the patient to treatment and when appropriate. The interventionist will also interact with physicians to ensure that patients are receiving the proper medication-assisted treatment. Their current responsibilities within the ED will be useful for referring participants to resources for common co-occurring risk factors such as homelessness and unemployment. For this project, five ED social workers will be trained at each location to ensure that an interventionist is always on site.

Two Master of Public Health students from the University of Cincinnati will serve as Graduate Research Assistants (GRAs). Their primary responsibility will be data collection for the evaluation process of the project. They will also assist the Project Coordinator with planning logistic concerns of the program, as well as conference and manuscript preparation. They will work 20 hours/week, with flexible hours for participation in evening community events and CAB meetings. They will be interacting with project participants throughout the 10-week follow-up period for data collection. As such, MPH students involved in the project will also complete sensitivity and cultural competency training alongside ED Social Workers. The requested funding period is longer than the MPH program at the University of

Cincinnati and so GRA turnover is expected. Hiring of new GRAs and consequent training will take place at the end of the second year of funding.

ED Physicians will be initiating Buprenorphine treatment with the patients. This will require physicians to complete an eight-hour training to receive a DEA X Waiver in order to prescribe the opioid agonist. This training will be completed through the Providers Clinical Support System (PCSS). Once approved for a MAT waiver, ED physicians are not required to do anything outside of their normal responsibilities to the patients. For this project, training will be offered to 10 physicians at each of the three hospitals. Incentives from within St. Elizabeth will promote completion of the DEA X Waiver training by all ED physicians as part of their Continuing Medical Education (CME) within 5 years of initial funding.

Ann Perkins, CHES, a health educator from the Northern Kentucky Health Department will be contracted throughout the funding period to complete trainings with staff and interventionists involved in the project. Ms. Perkins completed her Bachelor of Science in Health Promotion and Education at the University of Cincinnati in 2010. She has been involved with multiple community coalition efforts, including overdose education and naloxone distribution as well as aiding in compilation of the NKY Hates Heroin handbook. She will serve as our primary trainer for the proposed intervention and as such will conduct an 8-hour sensitivity and cultural competency training with all involved individuals already working in the three EDs, as well as GRAs. A second 8-hour training with ED social workers will train them on motivational interviewing techniques, implementation of the BNI, and data collection. Ms. Perkins will participate in an additional Training-the-Trainer session specific to motivational interviewing at the University of Cincinnati, to ensure readiness for her leadership in training our interventionists. The stepped wedge timeline will spread out the training schedule and ease implementation for the health educator, making the initial education of each ED cluster fall every six months for the first two years. The health educator will also complete booster trainings with each ED following their initial training.

Benn Wyatt, PhD, from the University of Cincinnati Division of Public Health will serve as the biostatistician on the project. He completed his PhD in Biostatistics at Pennsylvania State University. He

has previously served on the UC Opioid Task Force, an interdisciplinary team that works to engage all on-campus healthcare professionals in a conversation about evidence-based treatment and prevention practices. He has also contributed to several studies surrounding overdose mortality in the Greater Cincinnati area as a biostatistician. His responsibilities include analysis of individual and community level data. He will also oversee execution of the stepped wedge cluster-randomized trial to overcome implementation barriers and ensure adequate statistical power through rigorous design fidelity.

Appendix

Appendix A: Budget Justification

A. Salaries and Wages*

*Salaries increase at a rate of 3% per project year.

Position Title/Name	Annual Salary	% FTE	Salary Requested	Fringe Requested	Total Requested
Project Director	*$150,639* *$155,158* *$159,813*	*10%* *5%* *5%*	*$15,064* *$7,758* *$7,991*	*$3,819* *$1,967* *$2,026*	*$18,883* *$9,725* *$10,017*
Project Coordinator	*$55,000* *$56,650* *$58,350*	*100%* *100%* *100%*	*$55,000* *$56,650* *$58,350*	*$17,868* *$18,404* *$18,956*	*$72,868* *$75,054* *$77,305*
ED Social Workers *(Y1 x 5)* *(Y2-3 x 15)*	*$53,270* *$54,868* *$56,514*	*15%* *10%* *10%*	*$7,991* *$5,487* *$5,651*	*$2,625* *$1,802* *$1,857*	*$53,075* *$113,439* *$112,620*
MPH Graduate Students (x 2)	*$32,000* *$32,960* *$33,949*	*100%* *100%* *100%*	*$32,000* *$32,960* *$33,949*	*$9,031* *$9,302* *$9,581*	*$41,031* *$42,262* *$43,530*
Total Y1 *Hospital 1* *Hospitals 2 & 3* **Y2** *Hospital 1* *Hospitals 2 & 3* **Y3** *Hospital 1* *Hospitals 2 & 3*					**$185,857** $53,075 $0 **$240,480** $36,445 $76,994 **$243,472** $36,445 $36,445

Leslie Knope, MD, MPH, Project Director (10%/5%/5%). Dr. Knope is the Director of Emergency Services for the St. Elizabeth Healthcare System. She will dedicate 10% of her time during Y1 while the project is getting started and then 5% FTE for Y2-Y3. Her extensive work

within St. Elizabeth Emergency medicine will allow her to oversee implementation of the proposed program in an efficient and effective manner. She will assume primary responsibility for implementation of the program, as well as provide oversight for financial management of the project budget. She will also complete the training to receive a DEA X Waiver as a practicing physician.

Cady Cornell, MPH, Project Coordinator (100%). Ms. Cornell will contribute 100% FTE for all three years of funding. She will oversee daily operations of the project, as well as conduct the process and outcome evaluation with consultation from the contracted biostatistician. In addition, she will conduct CAB meetings and coordinate with the implementation sites to provide support, supplies, and anything else necessary for the project. She will also manage community partnerships and maintain communication with key stakeholders to ensure that needs of the community are prioritized. Ms. Cornell will report directly to Dr. Knope and supervise the GRAs.

ED social workers, St. Elizabeth Healthcare (15%/10%/10%). ED social workers that are currently employed within the St. Elizabeth Healthcare System will serve as this project's interventionists. They will dedicate 15% of their time during the first year of implementation at their respective EDs to account for training. Following the first year, ED social workers will dedicate 10% effort, which was calculated based on the proportion of opioid-related cases present in the ED in previous years. Each ED will have 5 social workers that will be trained on this project. They will have direct contact with the target population and will execute screening measures, the consent process, and the BNI motivational interviewing strategy. They will also refer participants to additional treatment and other resources for co-occurring risk factors. The interventionist will also interact with physicians to ensure that patients are receiving the proper medication-assisted treatment.

Graduate Assistants, University of Cincinnati (100%). Two students from the MPH program at the University of Cincinnati will be selected as Graduate Assistants. They will each spend 20 hours per week on the project, for a combined 100% effort, through the grant period. They will provide direct assistance to the Project Coordinator. Specific duties will include data collection and analysis, literature reviews, community correspondence, and manuscript preparation.

Fringe Benefits. Fringe benefits were calculated using an established rate and accounting for health insurance. The components of Fringe Benefits are laid out below.

Fringe Benefits Calculations		
Benefit	**Staff**	**GRAs**
Retirement	10%	N/A
Social Security	7.65%	7.65%
Other Fringe	3.6%	1.2%
Total Percent	**21.25%**	**8.85%**
Health/Life Insurance		
Employee	**$5,688/year**	**$2,166/year**

B. Supplies

Item Requested	**Number Needed**	**Unit Cost**	**Y1 Amount Requested**	**Y2 Amount Requested**	**Y3 Amount Requested**
SUBOXONE®	**16mg + 16mg x 10weeks x pt/year**	**$8.12**	**$69,275 (can cover 30%)**	**$223,636 (can cover 32%)**	**$223,636 (can cover 32%)**
Laptop	**3**	**$1,000**	**$3,000**	**-**	**-**

Projector	**3**	**$100**	**$300**	**-**	**-**
Printer paper/ink	**-**	**-**	**$250**	**$250**	**$250**
Office supplies	**-**	**-**	**$100**	**$100**	**$100**
Total			**$72,925**	**$223,986**	**$223,986**

Much of the budget will go toward a standby fund for SUBOXONE®. The MAT drug is currently covered by most insurance policies, but the nature of the target population would lead us to believe that many will not be covered by insurance. The rate of uninsured citizens in Kenton and Campbell counties is 26%[32], but we have budgeted to pay for as many individuals as possible. After every other budget line was accounted for, the proposed budget has allocated $69,275 for SUBOXONE® in Y1 which will cover roughly 30% of the 200 participants. In Y2 and Y3 we have allocated $223,636 for SUBOXONE®, which will cover 32% of the 600 participants in each year. These estimates give us a buffer between the current uninsured rate and what we will be able to provide. This is also a conservative estimate, as the drug treatment plan will vary by participant and some may not need the full 16mg per day for the entirety of the 10-week follow-up. Other required supplies will be utilized to print necessary materials for implementation and facilitate training within each location. Printed materials will include training manuals, individual assessments, and fidelity checklists. The laptops will be distributed amongst the Project Coordinator and two GRAs for work purposes. We have included the cost of a projector for each ED in order to enhance the training space for video demonstrations. Office supplies will include pens, staplers, paper clips, etc.

C. Travel

	Expense	Y1	Y2	Y3
Annual Program Director Meeting	Airfare	$300	$300	$300
	Lodging	$400	$400	$400
	Per diem	$71 x 3 days = $213	$71 x 3 days = $213	$71 x 3 days = $213
	Number of attendees	1	1	1
	Total	**$913**	**$913**	**$913**
Annual Regional Training	Airfare	N/A	$300	$300
	Lodging	N/A	$400	$400
	Per diem	N/A	$71 x 3 days = $213	$71 x 3 days = $213
	Number of attendees	0	2	2
	Total	$0	**$1,826**	**$1,826**

We wish to present our findings at two conferences during Y3: SAMHSA National Leadership Forum and APHA Annual Meeting. The SAMHSA National Leadership Forum and Prevention Day is held each Summer in Washington, DC. The APHA Annual Meeting will take place in Denver, CO in the Fall of Y3. Travel expenses for these conferences include airfare from Cincinnati, lodging, and per diem. The travel funds requested will allow our Project Coordinator to attend both conferences and our Project Director to attend APHA. In addition, we have allocated funds for travel, lodging, and per diem for Dr. Knope to attend the required Annual Program Director Meeting as well as the Annual Regional Training with the Project Coordinator in Y2 and Y3. Total travel expenses are listed below.

SAMHSA National Leadership Forum and Prevention Day	
Airfare	$250
Lodging	$200 x 3 nights = $600
Registration	$250
Per Diem	$71 x 3 days = $213
Number of Attendees	1
Total	**$1,313**

APHA Annual Meeting	
Airfare	$250
Lodging	$200 x 3 nights = $600
Registration	$530
Per Diem	$76 x 4 days = $304
Number of Attendees	2
Total	**$3,368**

Year	Total Expense
Y1 (Annual Director Meeting)	**$913**
Y2 (Annual Director Meeting, Annual Regional Training)	**$2,739**
Y3 (Annual Director Meeting, Annual Regional Training, SAMHSA, APHA)	**$7,420**
Total	**$11,072**

D. Contractual

	Y1	Y2	Y3
Health Educator contract	$3,333	$3,333	$3,333
Biostatistician contract	$2,334	$2,334	$2,334
Total	**$5,667**	**$5,667**	**$5,667**

The individuals who will be contracted for sections of time during the funding period include a health educator, Ann Perkins, from the NKY Health Department and a biostatistician, Dr. Ben Wyatt, from the University of Cincinnati. Ms. Perkins will be utilized periodically throughout the funding period as a trainer for critical ED staff. These trainings include an 8-hour intervention implementation training and an 8-hour sensitivity and cultural competency training. She will complete these at each site twice during the respective ED's planning period. She will also be responsible for completing annual booster trainings with our interventionists to ensure program fidelity. We utilized the average hourly wage of a health educator, combined with an incentive for the NKY Health Department, to calculate the cost of her contract. The biostatistician will be consulted at the beginning of the funding period to direct initiation of the cluster-randomized stepped-wedge evaluation design. Dr. Swanson will also be consulted at the end of Y3 to aid in data analysis. His contract was calculated on the assumption of $1,000 per day of work, with no more than 40 hours of consultation throughout the grant period.

E. Other

	Y1	Y2	Y3
GRA tuition	$28,936	$30,383	$31,902
University of Cincinnati motivational interviewing training	$1,000	N/A	N/A
St. Elizabeth Treatment Center incentive	$15,000	$15,000	$15,000
Physician training incentive	$15,000	-	-
Participant incentives	$19,000	$55,000	$55,000
Total	**$78,936**	**$100,383**	**$101,902**

We will be paying tuition for the two GRAs on the project based on the University of Cincinnati's metro-student graduate tuition rate. This cost of tuition does not cover university-related fees. Our Health Educator, Ann Perkins, will be participating in a Training-the-Trainer session specific to motivational interviewing that is offered by the University of Cincinnati Corrections Institute. The $1,000 designated here will cover registration and food costs for the week-long training. The next budget line is allocated as an incentive for the St. Elizabeth Alcohol and Drug Treatment Center. This is the location where participants will come to receive their SUBOXONE® prescription refills and complete individual data collection. We are incentivizing the Center because while these activities are not outside the Center's normal duties, the proposed project will significantly increase the number of patients that walk through their doors. The incentive is meant to aid in increasing capacity of the Center, as well as compensate the physicians who will be renewing prescriptions. While participation in the training to receive a DEA X Waiver is free to physicians, we will be incentivizing completion to cover the 8 hours of missed work. This was calculated by incentivizing 10 physicians at each of the 3 EDs at a rate

of $500 per day. Participant incentives are the final piece of this section of the budget. Participants will receive compensation in the form of a $15 Walmart gift-card for participation within the ED. Retention of participants also includes an incentive of a $20 Walmart gift card halfway through the follow-up period and a $25 Walmart gift-card upon completion of the 10-week program. Long term follow-up at 6 and 12 months will be incentivized with $15 and $25 Walmart gift cards, respectively. The participant incentive total for Y1 was calculated under the assumption of 200 participants within the one ED receiving initial implementation. Incentives for Y2-Y3 account for the full 600 participants per year and implementation at all three EDs. This calculation also assumes completion of the 10-week follow-up by 83% of participants.

	Year 1	**Year 2**	**Year 3**
A. Personnel	$185,857	$240,480	$243,472
B. Supplies	$72,925	$223,986	$223,986
C. Travel	$913	$2,739	$7,420
D. Contractual	$5,667	$5,667	$5,667
E. Other	$78,936	$100,383	$101,902
Total	**$344,298**	**$573,255**	**$582,447**
3-Year Total	**$1,500,000**		

Appendix B: Maps (Figures 1 & 2)

Figure 1: Statistically significant overdose death rate increase from 2016 to 2017

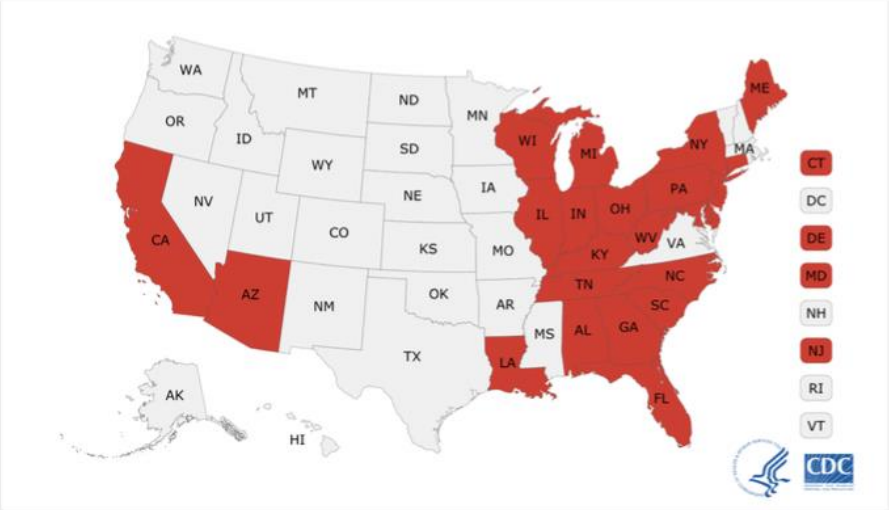
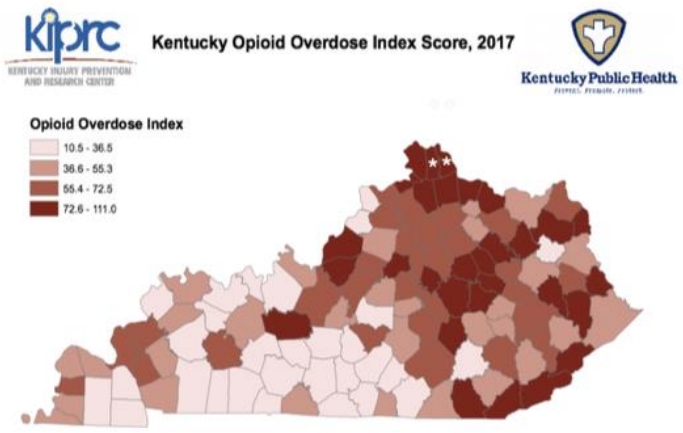
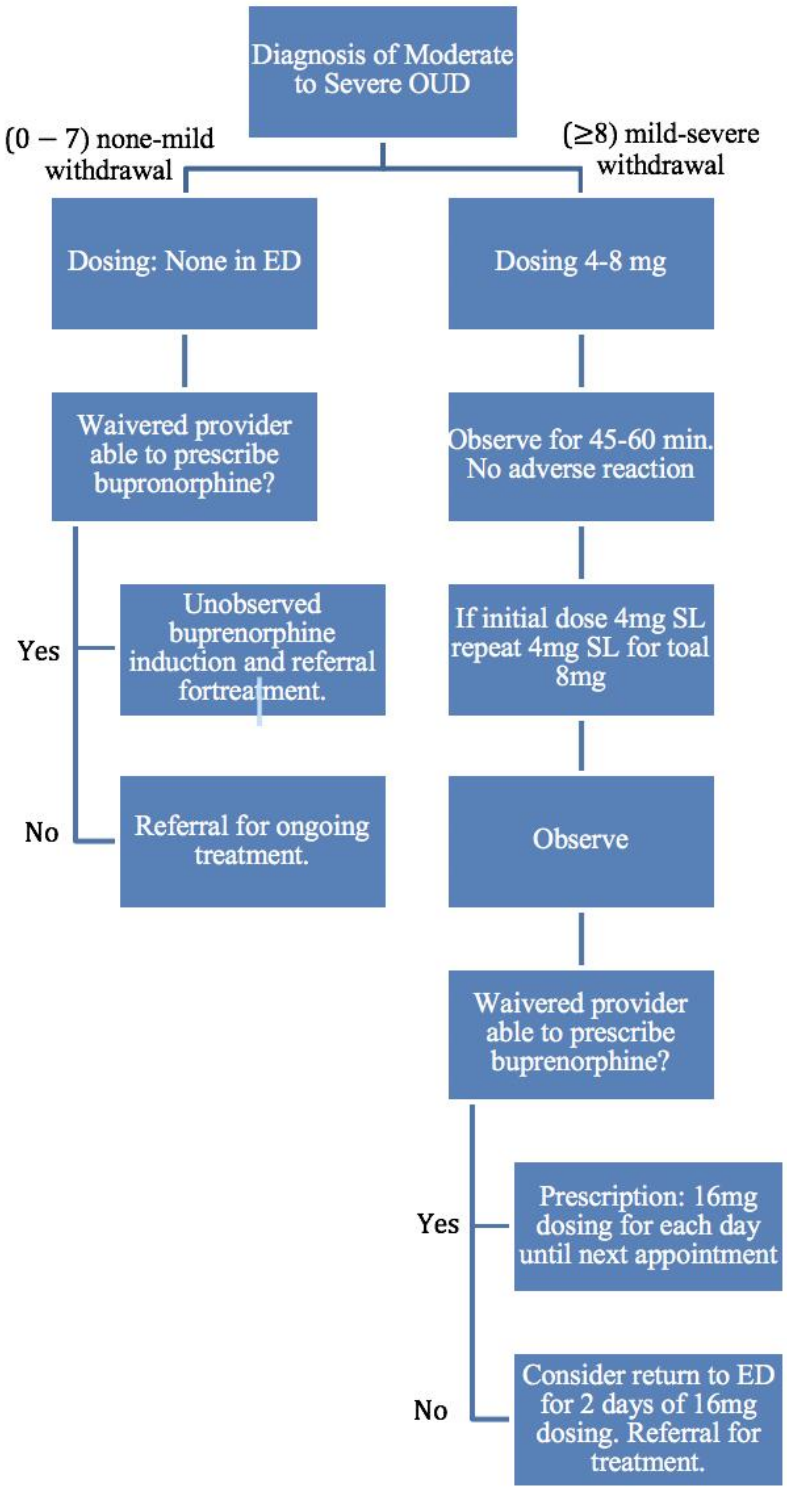


Figure 2: Kentucky Opioid Overdose Composite Risk by County

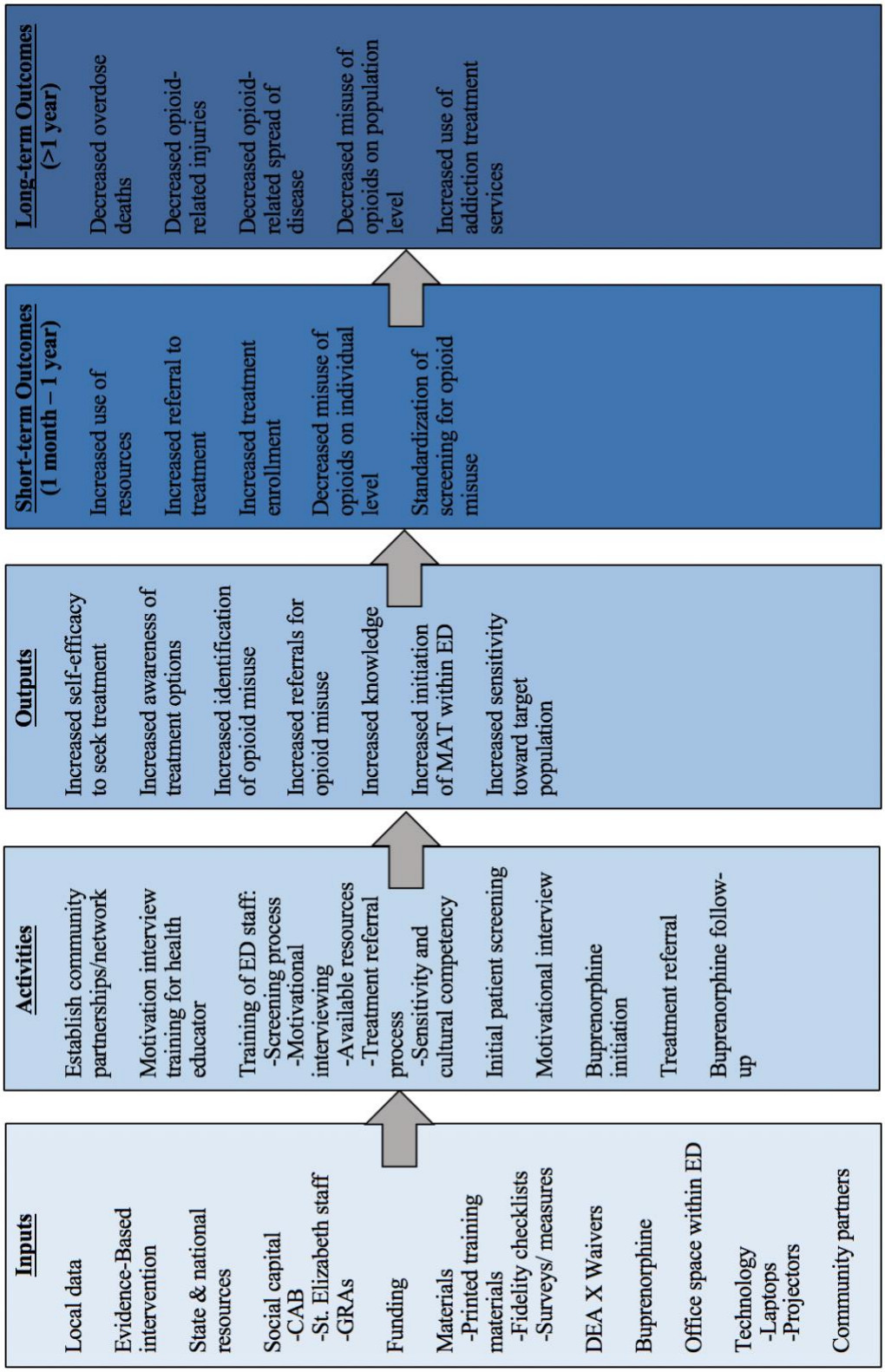
*(Kenton and Campbell denoted by *)*



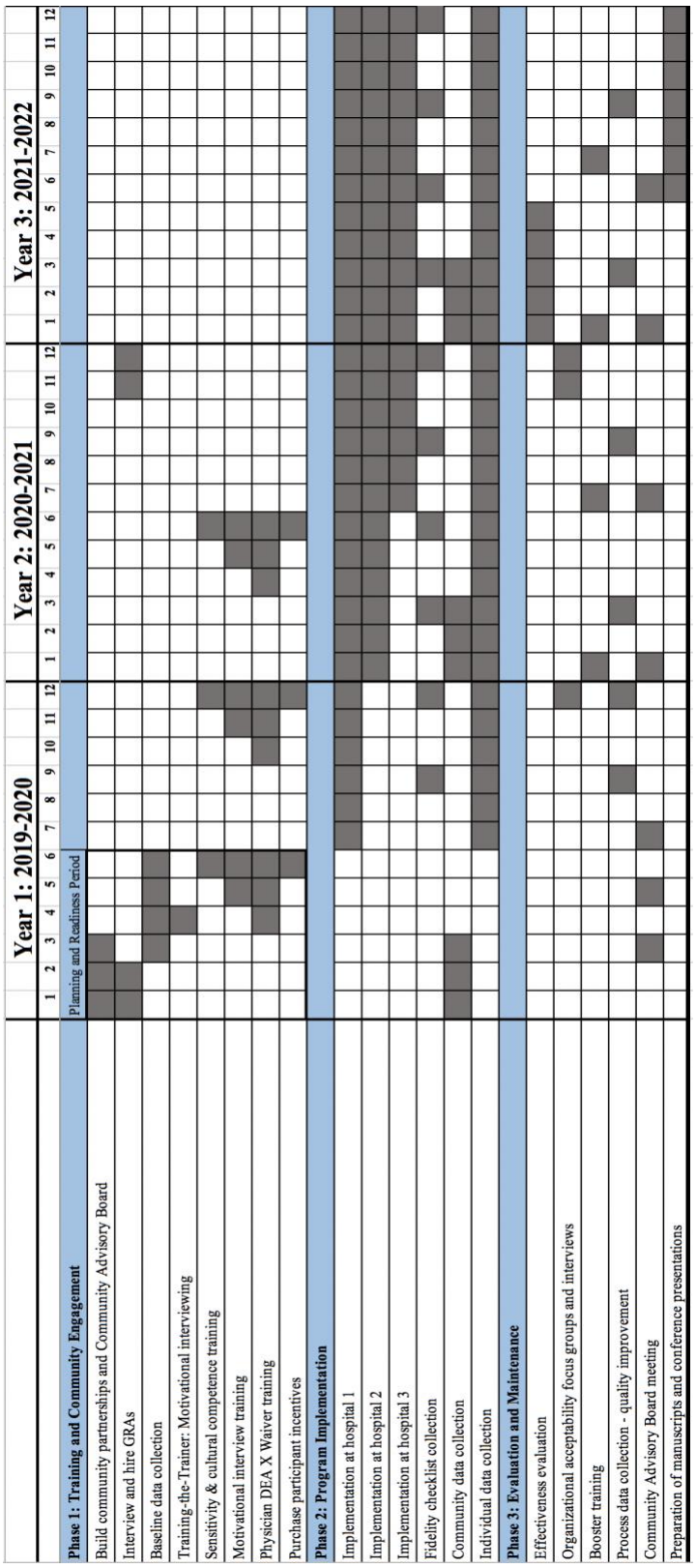
Appendix C: ED Buprenorphine Prescription Flowchart[21]



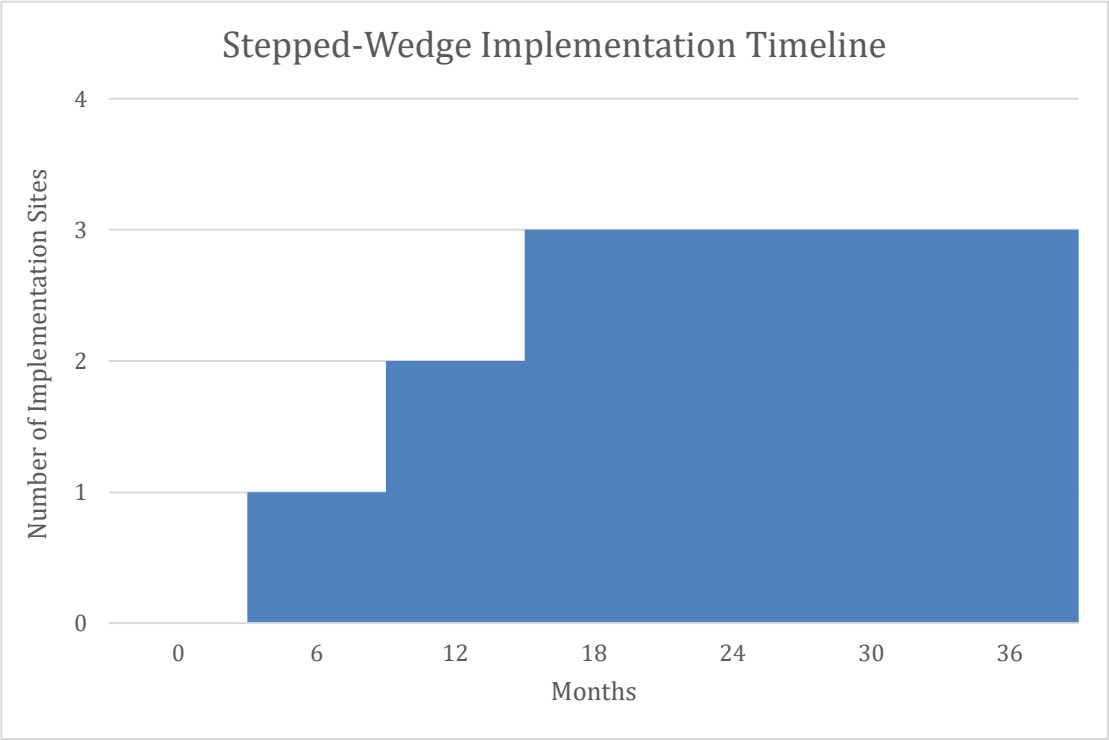
Appendix D: Logic Model for the BNI with ED-Initiated SUBOXONE®



Appendix E: Gantt Chart for the BNI with ED-Initiated SUBOXONE®



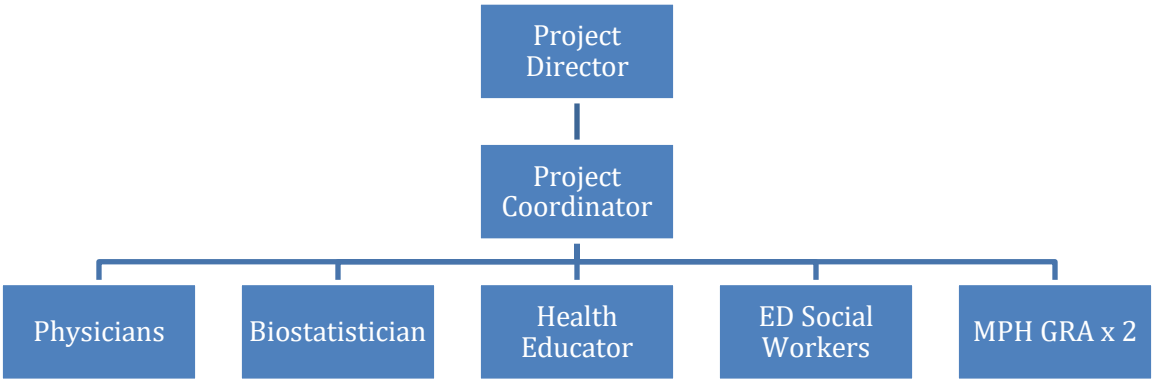
Appendix F: Cluster-Randomized Stepped-Wedge Evaluation Design



Appendix G: Letters of Support

1. Barry Houchin, JD, Chairman of the Board, St. Elizabeth Healthcare
2. William Devine, MD, MBA, CEO, St. Elizabeth Edgewood
3. Hannah Mann, MD, MBA, CEO, St. Elizabeth Covington
4. Bradley Miles, MD, MPH, CEO, St. Elizabeth Ft. Thomas
5. Elijah Ritter, Coordinating Council Member, NKY Heroin Impact Response Task Force
6. Susan M. Hack, PhD, Director, NKY Regional Prevention Alliance
7. Joseph Brown, MD, MPH, District Director of Health, Northern Kentucky Health Department
8. Christina Johnston, PhD, Director, Kentucky Injury and Prevention Center
9. Julie Porter, MD, MPH, MEd, University of Cincinnati Emergency Medicine
10. Matt Turner, PhD, Program Director of Public Health, University of Cincinnati School of Medicine Division of Public Health Sciences
11. Otis J. Thomas, Director, Member Relations, Kentucky Hospital Association
12. Allison Schuh, Director, Member Relations, Catholic Health Association of the United States

Appendix H: Project Management Structure



Appendix I: Decision Self-Efficacy Scale

My confidence in making an informed choice

Below are listed some things involved in making an informed choice. Please show how confident you feel in doing these things by circling the number from 0 (not at all confident) to 4 (very confident) for each item listed below.

I feel **confident** that I can:

1.	Get the facts about the medication choices available to me	**not at all confident**	0	1	2	3	4	**very confident**
2.	Get the facts about the benefits of each choice	**not at all confident**	0	1	2	3	4	**very confident**
3.	Get the facts about the risks and side effects of each choice	**not at all confident**	0	1	2	3	4	**very confident**
4.	Understand the information enough to be able to make a choice	**not at all confident**	0	1	2	3	4	**very confident**
5.	Ask questions without feeling dumb	**not at all confident**	0	1	2	3	4	**very confident**
6.	Express my concerns about each choice	**not at all confident**	0	1	2	3	4	**very confident**
7.	Ask for advice	**not at all confident**	0	1	2	3	4	**very confident**
8.	Figure out the choice that best suits me	**not at all confident**	0	1	2	3	4	**very confident**
9.	Handle unwanted pressure from others in making my choice	**not at all confident**	0	1	2	3	4	**very confident**
10.	Let the clinic team know what's best for me	**not at all confident**	0	1	2	3	4	**very confident**
11.	Delay my decision if I feel I need more time	**not at all confident**	0	1	2	3	4	**very confident**

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