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Implementation of an evidenced-based opioid treatment program to improve maternal-child outcomes in Eastern Kentucky

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CHARM-KY:
Implementation of an evidenced-based opioid treatment program to improve maternal-child outcomes in Eastern Kentucky

CAPSTONE PROJECT PAPER

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the requirements for the degree of
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By

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Project Abstract/Summary

The Kentucky River Area District Health Department proposes implementation of CHARM-Kentucky, a treatment program for pregnant women with opioid use disorder (OUD), in eastern Kentucky. Over 115 Americans die each day from an opioid overdose, resulting in approximately 42,000 deaths in 2016. In addition to an overall increase in opioid use in recent years, the use of opioids in pregnancy has also increased from 1.19 per 1,000 hospital births in 2000 to 5.63 in 2009. Opioid use during pregnancy results in poor neonatal outcomes including: low birth weight, preterm delivery, small head circumference, increased child maltreatment, and risk for long-term foster care. There are many different professionals, both medical and non-medical, that may be involved in the treatment, care, and decision-making surrounding a woman with OUD and her baby. The CHARM program combines medication-assisted therapy (MAT) with early access to prenatal care, counseling, early child welfare involvement prior to birth, parenting education, nutrition support, and social services support. Participants in the program receive prenatal care, access to MAT, participate in mandatory substance abuse counseling, submit mandatory urine drug testing, attend group educational sessions relating to addiction and parenting, and have coordination of services by a case manager. The original CHARM program in Vermont has been shown to increase the number of women receiving treatment, move women into treatment earlier in their pregnancy, increase infant birth weights, and have more infants remain in the care of their mothers. CHARM-Kentucky will operate from the Primary Care Centers of Eastern Kentucky Clinic in Hazard, a clinic serving communities significantly burdened by the opioid epidemic in Kentucky.

Target Population and Need

The Opioid Epidemic

The United States (U.S.) opioid epidemic is a serious public health problem and was designated as a public health emergency in 2017. Over 115 Americans die each day from an opioid overdose, resulting in over 42,000 deaths in 2016[1]. The rate of opioid-related deaths has dramatically increased, and is now more than three times the rate in 1999[1]. The financial impact of the epidemic is estimated at $78.5 billion annually in healthcare costs, lost productivity, and justice system involvement[2].

Opioids are class of substances that include both prescriptions drugs (e.g., morphine, oxycodone, hydrocodone, methadone, fentanyl) and illicit drugs (e.g., heroin and other synthetic drugs). Opioids are highly addictive because they create a sense of euphoria, but they also cause sedation, respiratory depression, and decreased gastrointestinal motility[3]. Opioid use disorder (OUD) is defined as "a pattern of opioid use characterized by tolerance, craving, inability to control use, and continued use despite adverse consequences[4]." Opioid use is often accompanied by an unstable lifestyle, decreased social structure, and drug-seeking behaviors, which collectively increase the risk of injury and death[5]. The increase in opioid use is associated with increases in adverse physical and mental health outcomes, including overdose, contraction of infectious diseases, risk of assault, and neonatal opioid withdrawal syndrome among infants born to opioid-abusing mothers.

This growing public health concern has prompted numerous federal agencies to respond to the crisis. The U.S. Department of Health and Human Services (DHHS) and its agencies have focused on increasing access to treatment, increasing public health surveillance, and allotting research dollars to address the issue. The Centers for Disease Control and Prevention released

the *Guideline for Prescribing Opioids for Chronic Pain* in 2016[6]. The Food and Drug Administration (FDA) issued guidance for the pharmaceutical industry to develop generic versions of abuse-deterrent formulation of opioid medications and updated warnings and safety information on existing opioid medications[7]. The Drug Enforcement Agency (DEA) rescheduled hydrocodone containing products to a more restrictive controlled substance category[8]. Many states, including Kentucky, have enacted prescription drug monitoring programs to track controlled substance prescriptions as well as improve prescribing and dispensing[9]. Despite these efforts, the opioid crisis continues to ravage the country.

Opioid Use During Pregnancy

In addition to an overall increase in opioid use in recent years, the use of opioids in pregnancy has also increased from 1.19 per 1,000 hospital births in 2000 to 5.63 in 2009[10]. Opioid drugs are small molecules that easily cross the placental barrier to the fetus[3]. Neonatal abstinence syndrome (NAS) is a withdrawal syndrome experienced by infants at birth after exposure to drugs, primarily opioids, in the womb. In 2012, a baby was born with NAS in the U.S. every 25 minutes[11].

Opioid use during pregnancy results in poor neonatal outcomes including: low birth weight, preterm delivery, small head circumference, increased child maltreatment, and risk for long-term foster care[5,10,12]. Because opioid receptors are most common in the central nervous system and gastrointestinal tract, opioid-related NAS is characterized by a high-pitched cry, tremors, irritability, fevers, weight loss, and seizures. Babies born with NAS require more expensive hospital stays, and are more likely to be covered by Medicaid[10,11]. Overall, babies that require treatment for NAS have an average stay of 17-23 days compared to an average of 24-48

hours for normal, healthy infants[5]. Babies that do not respond to non-pharmacologic therapy, such as skin-to-skin contact and low stimulus environments, are treated with medications, such as morphine and methadone, that are tapered over time. Additionally, infants with NAS that are exposed to more than one substance during development are even more difficult to treat.

Women with OUD face many barriers to treatment, but without treatment, they face increased risk of pre-term delivery, delivering low birth weight infants, and transmitting infectious diseases to their infant[13]. Laws that sanction pregnant women with OUD and the shame associated with the condition drive women away from available care or from seeking care in the first place[13]. Many women present for medical care very late in pregnancy or when they are in labor.

Medication-assisted therapy

Medication-assisted therapy (MAT) is the use of a medication – combined with substance abuse counseling – to treat OUD. MAT is recognized as the most effective treatment for OUD, including in pregnant women. MAT is widely accepted as the recommended standard of care and is recognized as best practice by the American College of Obstetricians and Gynecologists[4,5]. MAT reduces cravings and withdrawal symptoms, aiming to decrease the rates of relapse to illicit drug use. Illicit opioid use can subject the fetus to repeated withdrawal episodes between uses. Withdrawal, whether supervised or unsupervised, is not recommended because it can cause spontaneous miscarriage and is associated with higher rates of drug relapse[4,14]. The positive benefits of MAT are not only apparent during pregnancy, but continue after the child is born. Mothers who are stable on therapy are encouraged to breastfeed, further improving the health of the child[14].

Two common medications used in MAT have opioid receptor activity and are considered opioid replacement therapy. These are methadone, a long-acting opioid receptor agonist, and buprenorphine, a partial opioid receptor agonist. Methadone and buprenorphine are both taken by mouth daily. Methadone has long been the standard therapy for MAT, however, buprenorphine has been increasingly prescribed due to emerging data supporting its use[15,16]. Methadone is dispensed daily by certified opioid treatment programs. Buprenorphine can be obtained by prescription at a pharmacy. Both methadone and buprenorphine are acceptable therapy options, and the choice between agents is made by physicians based on the characteristics and needs of the patient. Although babies born to mothers stabilized on MAT may still experience NAS, the benefits of the therapy still outweigh the risks that face the fetus in unsupervised opioid use. The risks and benefits of MAT should be discussed in-depth with each individual.

The Kentucky River District

The Appalachain region of Kentucky has been at the forefront of the opioid epidemic. Per Kentucky Revised Statute 211.687, cases of NAS are required be reported to the Kentucky State Health Department[17]. From 2009-2012, the highest incidence of NAS in the U.S. was in the East South Central region, including Kentucky, Tennessee, Mississippi, and Alabama[11]. The number of newborns with NAS in Kentucky has increased 23-fold since 2001, with about 80% of these

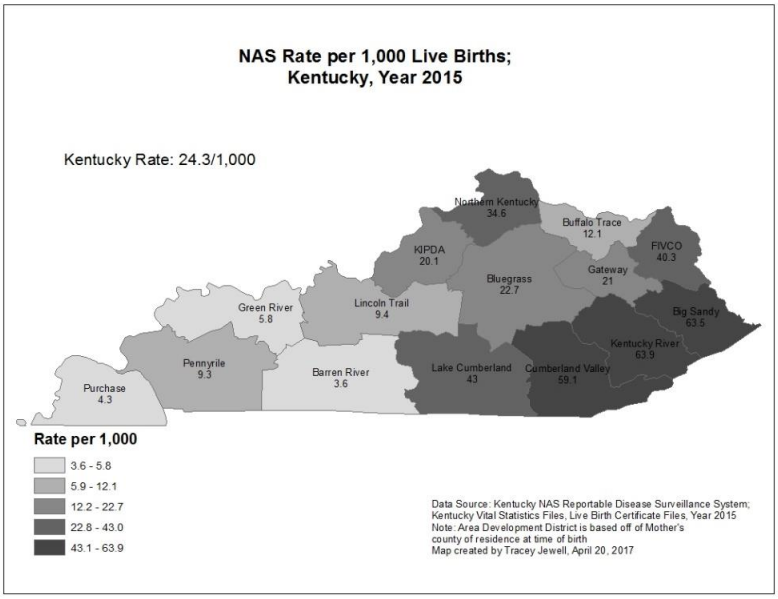

Figure 1. NAS Rate in Kentucky Area Development Districts.

births covered by Medicaid[18]. In 2015, there were over 110 cases of NAS each month across the state. As noted in Figure 1 the Kentucky River Area Development District (KRADD), an 8-county region in southeastern Kentucky, had the highest rate of NAS among all Kentucky Area Development Districts, with an estimated 43.1-63.9 cases per 1,000 births reported in 2015, compared to 24.3 at the state and national level respectively[18]. This region includes Breathitt, Knott, Lee, Leslie, Letcher, Owsley, Perry and Wolfe counties. The KRADD has been significantly impacted by the opioid epidemic. These counties are socioeconomically disadvantaged and have some of the poorest health outcomes in the nation. A comparison of relevant indicators can be found in Table 1.

Table 1. Comparison of the Social and Health Indicators of the KRADD, Kentucky, and the U.S.

	KRADD	Kentucky	U.S.
Social Indicators			
Median household income[19]	$28,416	$43,740	$53,046
Medicaid enrollment (% of population)[19,20]	42%	22%	25.4%
High school graduation, 2016[19,21]	71%	88.6%	84.1%
Drug arrests (per 100,000)[19]	1,549	1,476	
Health Indicators			
Total mortality rate (per 100,000)[22]	1,231	909	823.7
Infant mortality rate (per 100,000 live births)[23,24]	700	670	587
Proportion receiving adequate prenatal care[19]	64%	67%	77.1%
Low birth weight[19,25] (% of live births)	11%	9%	8%
Proportion of deliveries covered by Medicaid[26]	--	46%	42.6%

Healthcare services in the district, including opioid treatment centers, are limited. Respondents to the 2015 Hazard Appalachian Regional Health (ARH) Community Health Needs Assessment identified that “mental health, addiction treatment, and a birthing center” were among the services that should be provided in Perry County[27]. The Hazard ARH Regional

Medical Center Psychiatric Center is the state designated acute mental health facility for 21 counties in eastern Kentucky[27]. In 2017, there were 214 physicians certified to prescribe buprenorphine to treat up to 30 patients, and 49 physicians certified to treat up to 100 patients[28]. The only outpatient opioid treatment program in the Kentucky River District is the Behavioral Health Group Center in Hazard, KY[29]. There are only five OB/GYN providers in the entire district[19]. Hospitals in the area include: Hazard ARH Regional Medical Center, Jenkins Community Hospital, Kentucky River Medical Center (Jackson), Mary Breckenridge Hospital (Hyden), and Whitesburg ARH Hospital.

Program Approach

The CHARM Collaborative

There are many different professionals, both medical and non-medical, that may be involved in the treatment, care, and decision-making surrounding a woman with OUD and her baby. Professionals or organizations that may influence a woman's care include obstetricians, addiction specialists, child welfare workers, judicial system representatives, local hospital systems, or clinics. Each of these professionals and organizations have different priorities and policies that often lead to a disjointed or conflicting approach to ensuring the best outcome for mother and child.

The **Children and Recovering Mothers (CHARM) Collaborative** began in Vermont in 2002 as an effort to address medical disparities and improve maternal and child health outcomes in rural areas. It began when an addiction specialist opened the first methadone clinic and coordinated care with a local obstetrician. The program attempts to address the five-points of intervention framework to help reduce the potential harm of prenatal substance exposure

recommended by the National Center on Substance Abuse and Child Welfare[30]: pre-pregnancy, prenatal, birth, neonatal, and adolescence. CHARM not only addresses substance use, but also provides a coordinated, comprehensive approach to other medical and mental health conditions, and socioeconomic barriers that may co-exist with substance use disorder. Women with OUD often come from unstable backgrounds, with little social and financial support, and have a history of sexual or physical abuse[14]. This program emphasizes prevention to promote a safe pregnancy, birthing experience, and childhood. The program combines MAT with early access to prenatal care, counseling, early child welfare involvement prior to birth, parenting education, nutrition support, and social services support. Participants in the program receive prenatal care, access to MAT, participate in mandatory substance abuse counseling, submit mandatory urine drug testing, attend group educational sessions relating to addiction and parenting, and have coordination of services by a case manager. The CHARM Needs Assessment team consisting of members of key services in the program meets monthly to identify gaps in care and aid in the transitions of care of the participants. Since 2002, the Vermont CHARM Collaborative has grown to a multidisciplinary group of 11 agencies that work together across multiple clinics to identify and provide coordinated care for pregnant women with OUD and their babies from conception through the beginning of the child's life[14]. Currently, the Vermont-based CHARM Collaborative serves 200-250 women and their families annually.

This community approach to opioid addiction in pregnancy has been shown to increase access to care and improve neonatal outcomes[12,14]. The original study by Meyer and colleagues compared women at a single institution receiving medication assisted therapy (methadone administration) to women that received medication assisted therapy with improved coordination of ancillary services. This study was conducted via retrospective chart review of the patient's

medical records. Over a 6-year study period, the Vermont CHARM program increased the number of women receiving treatment for OUD at the clinic from 15 in the first two years of program implementation to 51 women in the sixth year of the program. Women also received treatment earlier in their pregnancy, starting treatment at 21.9 weeks during the first two years compared to at 4 weeks in the sixth year of the program. Infant birth weights were significantly higher in women who participated in the CHARM program compared to women who only received opioid substitution therapy; 3016 grams vs 2816 grams, respectively. More than 90% of infants born to women in the CHARM were discharged from the hospital in the care of their mother compared to 69% of infants born to mothers who were not in the program. Furthermore, women in the CHARM program were significantly more likely to retain custody of the infant at 1 year of age: 84.8% versus 62.5%.[12]. It is important to be cognizant of the fact that confounding variables may have impacted the outcomes of this study, including the increased availability and convenience of buprenorphine compared to methadone over the study period. As the authors recognize, the outcomes are likely due to the synergism of multiple factors. Based on the outcomes of this study, the CHARM program was recommended in 2016 as a collaborative strategy for treatment of pregnant women with OUD by the Substance Abuse and Mental Health Services Administration (SAMHSA)[14]. There are other U.S. programs similar to the Vermont program, including in Ohio, North Carolina, and in central Kentucky, however, there are no studies or outcomes that have been published on these programs to date.

CHARM-KY

The Kentucky River District Health Department (KRDHD) will implement CHARM-KY to meet the needs of opioid-dependent pregnant women in the KRADD. CHARM-KY will be modeled after the Vermont CHARM project with minor adaptations. Some ideas for CHARM-KY have also been adapted from PATHways/Beyond Birth, a similar program for pregnant women with OUD operating in Lexington, Kentucky through the University of Kentucky College of Nursing. The CHARM-KY Collaboration will be comprised of agencies and resources in the Kentucky River District and the state of Kentucky. These partnering agencies include: Primary Care Centers of Eastern Kentucky, Mountain Comprehensive Care, UK North Fork Valley Community Health Center, Department of Community Based Services, Perry County Drug Court, Kentucky Health Access Nurturing Development Services (HANDS), and Hazard Appalachian Regional Health (ARH) Regional Medical Center. This collaboration will provide a means to efficiently share client-specific information and coordinate care in the KRADD. A community advisory group (CAG) will be established to guide implementation of CHARM-KY. Members of the CAG will include representatives from the health departments in each county, Hazard ARH, the Center for Excellence in Rural Health, local elected officials, the justice system, the police force, a domestic violence program, and the Perry County Unlawful Narcotics Investigators, Treatment and Education program. A further description of these partnering agencies and their role in the program is discussed in **Partnerships and Collaboration**.

Figure 2. The Kentucky River Area Development District.

Figure 3. Primary Care Centers of Easter Kentucky Clinic in Hazard, KY.

The CHARM-KY program will operate from an established clinic, Primacy Care Centers of Eastern Kentucky (PCCEK), in Hazard, KY (Figure 2). The PCCEK clinic currently offers on-site services including prenatal care, women's health, pediatrics, and behavioral health[31]. The PCCEK clinic has already been providing prenatal care to our target population and will be well equipped to adopt the CHARM-KY program model. Using the clinic as a hub for CHARM-KY services will allow women to receive almost all aspects of care at one site. At this clinic, women will attend prenatal appointments, substance abuse counseling appointments, and group education sessions. Additionally, the staff at PCCEK will be trained to connect CHARM-KY participants to social services.

CHARM-KY: Enrollment and orientation

Women can be referred to the CHARM-KY program by any source: their local health department, a substance abuse counselor, a hospital emergency department, their primary care provider, a woman who is a current or former participant in the program, and/or by self-referral. It is anticipated that the majority of participant enrollment will come from word of mouth and social networks, similar to enrollment methods seen in the PATHways/Beyond Birth program[32]. Women will be incentivized to refer other women needing CHARM services with a $20 gift card for groceries.

Each health department coordinator in the KRADD and community partner organization will be given information on how to screen and refer women to CHARM-KY. All pregnant women should be screened for OUD at the initial prenatal encounter, as recommended by ACOG[4]. Health departments, primary care clinics, and other points of contact for our target population will be informed of CHARM-KY and encouraged to use a screening tool, such as the 4Ps Plus, to identify and refer women who may benefit from the program. The "4P's Plus" screening tool has been well validated for use in pregnant women to identify alcohol use and drug use, with a sensitivity of 87% and specificity of 76%[4,33]. If screening is positive, the woman's contact information will be communicated to the PCCEK clinic with her consent. The CHARM-KY program coordinator will contact the woman within three days of receiving notification from the woman or outside referral sources to establish care. During this call, the program coordinator will screen the woman for appropriateness in the program. Three attempts will be made by the PCCEK office to reach the woman to establish care.

During a woman's first clinic visit, a detailed medical and social history will be taken by the program coordinator. She will be assessed for OUD by the physician, her pregnancy will be confirmed, and she will be tested for infectious diseases, such as viral hepatitis and HIV. If pregnancy and OUD are both confirmed, the woman will be provided education on the CHARM-KY program and given the opportunity to enroll. The woman must sign the Release-of-Information Form, which states that she agrees that her personal information may be shared between all CHARM-KY agencies for coordination of care. The woman must also sign a Care Contract, which outlines the policies and expectations of both the providers and participants in the CHARM-KY program. If a woman declines to enroll in CHARM-KY, she may continue to

receive standard medical care, but it will not be coordinated for her by the CHARM-KY program.

CHARM-KY: Care during the prenatal phase

After a woman has been enrolled in the program, the woman will meet with the social worker to identify any social barriers that could interfere with the woman's recovery. The social worker will determine the woman's insurance coverage status, housing status, and history with the justice and child welfare systems. This information will be used to connect the woman to services to meet her basic needs. She will attend scheduled prenatal appointments, counseling appointments, and group education classes. It is the goal that the woman visits the PCCEK clinic a minimum of once per week until she is considered stable. The schedule for prenatal appointments will be made by the Leadership Team (see **Project Management**) in accordance with national prenatal care guidelines. In an uncomplicated pregnancy, this is typically 10 prenatal visits[34]. During weeks when a woman does not have a prenatal appointment, she will be scheduled to attend counseling or group education sessions. Group education sessions will cover parenting education topics such as care of a newborn, breastfeeding, and caring for a baby with NAS. Each session will be led by a PCCEK staff member or another professional well versed on the topic (i.e., a session on domestic violence may be led by a representative from the Kentucky Coalition Against Domestic Violence). A list of topics to be covered during education sessions can be found in Appendix C. Each woman will be given a "Care Notebook" that includes a summary of the CHARM-KY program, a list of local resources for services (i.e., medical, transportation, housing, financial), forms to record medical information and child development milestones, and frequently asked questions about pregnancy and child care. It will also include

stories and encouragement from women who have participated in the program. Prior to delivery, the woman will be educated by a nurse certified in obstetrics about what she should expect during the hospital stay (e.g., possibility of neonate admission to NICU) and what she might need to ask for (e.g., nicotine patches if she is a smoker).

In addition to prenatal care, the woman will receive services focused on mental health and OUD. The woman will be assessed and initiated on opioid replacement therapy with buprenorphine after enrollment. If she was on opioid replacement therapy outside the clinic, she will be maintained on that therapy. In addition to medication, she will be required to participate in substance abuse counseling with a certified drug and alcohol abuse counselor (CDAC). The CDAC will be staff from Mountain Comprehensive Care who will come to the PCCEK clinic to provide counseling services. Women will provide an observed urine drug screen at each appointment at the clinic in order to receive a prescription for buprenorphine. The CHARM-KY team will assess the woman for signs of relapse and the need for MAT dose adjustments during each interaction at the clinic. Women deemed to be at-risk for relapse or that have recently relapsed will be discussed at the monthly CHARM-KY meetings. The program will utilize a system of Levels to describe the level of accountability she requires. This system will allow CHARM-KY agencies to clearly identify what is required of each participant, and to identify those that require more attention. For example, if a woman has had a recent relapse or disruption to her home life, she may require a higher level of accountability from the CHARM-KY team. The Levels systems is described in Appendix A. A woman must be actively engaged in treatment and attending scheduled appointments to receive her prescription. Higher rates of program retention are anticipated due to the opportunity to obtain MAT. Relapse is an expected part of the recovery process. The program staff will work with the women in a supportive manner to work

towards recovery during difficult times. However, if a woman enrolled in CHARM-KY continuously uses illegal substances, misses pre-natal appointments repeatedly, or does not have a safe living situation, the CHARM-KY members may notify child protective services. The woman will be referred to an intensive outpatient or inpatient treatment center in the area.

CHARM-KY: Care during delivery

A goal for children born in the CHARM-KY program is to stay in the care of their mother after birth. There will be a great deal of planning prior to the birth event to increase the likelihood of that outcome. Women who have continued to use illegal substances during pregnancy or are not stable on MAT will be discussed at the monthly CHARM-KY meetings prior to delivery to make a plan for birth. This plan may include safety assessments conducted by the Department for Community Based Services Protection and Permanency to identify additional services needed or arrange alternative placement of the child after birth. This decreases the likelihood of birth crises, such as emergency custody orders, during the delivery event. Women who have attended at least 80% of their prenatal appointments and have been actively engaged in recovery, will be given a car seat.

Women with uncomplicated pregnancies will be encouraged to give birth at Hazard ARH Regional Medical Center, but they may give birth at any hospital. To standardize care for CHARM-KY babies, a protocol will be developed by the CHARM-KY Leadership Team that includes guidelines for the care coordination, the mother's pain management, screening the infant for NAS, and treatment for NAS symptoms. This protocol will be distributed to Hazard ARH Regional Medical Center and other rural hospitals in the region. When a participant arrives to Hazard ARH, the facility will contact the program coordinator within 24 hours to notify her of

the delivery. After delivery, the neonate will be screened for NAS using the validated Finnegan Neonatal Abstinence Scoring Tool[5] and monitored for a minimum of five days. During the hospital stay, a drug screen will be administered to both the mother and newborn. If the baby is diagnosed with NAS, the facility is required to report the case to the Kentucky Department for Public Health for surveillance purposes, in accordance with KRS 211.676[17]. Babies born to participants will stay in their mother's room after birth. The mother will be encouraged to take an active role in the care of the newborn with skin-to-skin contact and breastfeeding. Babies requiring treatment for NAS will be treated according to a protocol developed by CHARM-KY providers.

CHARM-KY: Care post-partum

Babies born to CHARM-KY mothers will continue to receive care until 18 months, and the mothers can continue to receive coordinated services for up to eight weeks after delivery. Women in CHARM-KY will be scheduled for an appointment within 1 week of delivery. This ensures that the mother is continuing the safe care plan following birth and that the infant is receiving appropriate medical care. At this point, the PCCEK clinic pediatric staff will assume care of the baby. The mother will remain on MAT, and continue to attend substance abuse counseling and group education sessions. CHARM-KY will partner with the health departments' Health Access Nurturing Development Services (HANDS) program to provide in-home nursing visitations to aid in the transition of parenting at home.

After a woman's participation in the CHARM-KY program ends, the case navigator helps the patient establish care with a new MAT provider. This connection to care outside of the program will prevent interruption of treatment. If a woman participated in HANDS, attended at

least 80% of the recommended appointments and clinic visits, and actively engaged in recovery, she will be given a gift certificate for 6-months worth of diapers. Additionally, she can elect to complete training to become a peer support specialist. This will allow her to remain engaged in the program, while providing valuable support to women still enrolled. In this role, she can earn $25 gift cards for additional infant supplies.

Implementation

The first quarter of the first year will be used as a program planning phase. The program planning phase will be utilized to recruit and hire staff, conduct a modified community health needs assessment, and set goals. During this phase, program coordinators from the Vermont CHARM program will be invited to Kentucky to train CHARM-KY leadership and staff. The second quarter of year one will be used to train staff and meet with the CAG. Women can enroll and participate in the program from quarter three of year one until quarter two of year three. This allows time for the staff to be adequately trained before enrolling participants. Ending enrollment with six months left in the grant allows time for staff to conduct data collection and outcome evaluation analyses. A complete Gantt Chart can be found in Appendix E. An overview of the inputs, activities, outputs, and outcomes can be found in the Logic Model in Appendix D.

CHARM-KY Adaptations

The Vermont CHARM program is over 12 years old and has had a significant amount of time to implement all pieces of the program that make up the current iteration of CHARM. CHARM-KY will be implemented as a pilot program operating from a single clinic to determine the feasibility of the program in the Appalachian region with selected community partners.

Additions to the CHARM-KY program, not present in the Vermont program, will be based on the availability and usefulness of services in the area. For example, dental services were not included in the CHARM collaboration in Vermont. Poor dental health is associated with poor birth outcomes[35]. CHARM-KY will connect women to dental services provided by individuals familiar with the program and its participants. Although the Vermont program did not utilize a home visitation service for participants, the decision to partner with HANDS was made to increase the supportive parenting services available to participants. The Vermont CHARM program originally utilized both methadone and buprenorphine for MAT. However, since the original publication, there have been many published studies supporting the use of buprenorphine over methadone[16]. Due to the barriers to administering methadone, the CHARM-KY providers will only utilize buprenorphine therapy for MAT.

Potential Barriers to Implementation

Barriers to program implementation were identified from those experienced in Vermont and at the PATHways/Beyond Birth program. An anticipated barrier to the success of CHARM-KY is the potential disagreement regarding treatment practices and legal implications between agencies involved in the program. Reconciling differing views on legal, medical, and social concerns will be important to maintain a standardized program approach. A solution to address this barrier will be to include all partnering agencies in the initial planning discussions, and going forward spend 10-15 minutes during each meeting for continuing education and cross-training among members. These mini-educational sessions will be focused on educating members of the CHARM-KY on issues important to the group. These may include: what constitutes an

intervention from child protective services, what laws prevent and allow treatment with MAT, and what services can be provided by social workers.

Another barrier anticipated in this program is the transient nature of our target population. Clinic staff will maintain multiple contact phone numbers, email addresses, and mailing addresses for women participating in the program, including asking the women permission to contact family members as needed. Many women eligible for CHARM-KY may also have been "fired" or discharged from the care of their community providers, including their OB/GYN provider, due to their substance use. This can generate a distrust of the medical system and potentially make it more difficult to engage women in care. Because few treatment facilities accept pregnant women, the CHARM-KY program will eliminate that barrier to accessing care for our target population. Our social worker will coordinate transportation and insurance coverage for women to increase the likelihood of participation. Women will be encouraged to bring other children they may have in their care to the clinic so that childcare is not a barrier. A significant barrier many women face is that they may have partners or family members who are also substance abusers. A full effort from the CHARM-KY collaboration members will be necessary to connect the woman's partner or family member with care outside the PCCEK clinic, or at minimum decrease the interference on the woman's recovery. Internal barriers faced by this population include co-existing depression, anxiety, and guilt regarding their substance use. Women will be required to see a counselor regularly, and this counselor will be utilized to build a supportive community with other women in the program. Ultimately, the clinic staff will be trained in-depth on the stressors faced by women in this population to decrease any stigmatization they may feel. To address participant drop-out, an effort will be made to contact women after they stop participation in the program to determine the reason(s). If the reason is

related to barriers to accessing care, the social worker will work with the women to resolve the issue (i.e., transportation, housing instability) in an effort to reengage her in the program. If the woman declines to become reengaged, the program coordinator will record the primary reason and use this information to guide programmatic refinements. If women do not like the program's structure, they will be connected to the nearest care provider in the area for prenatal and addiction medicine services.

Sustainability of CHARM-KY

CHARM-KY will be primarily implemented by personnel who are already providing care or services in the area. Partnering with established agencies in the region that have a vested interest in the program's outcomes will provide a larger network of support that can sustain the program in the long-term. Financially, most personnel will be reimbursed for their services by Medicaid. The program also depends heavily on Medicaid prescription drug insurance plans to pay for the participant's medications. Because of this, it is crucial that CHARM-KY maintain an active and productive relationship with the Department for Medicaid Services through the Department of Community Based Services. A potential barrier to program implementation is the capacity of professionals in the region to take on additional caseloads. This is a valid barrier that could diminish the potential impact of the program, and program leadership will need to alter program recruitment efforts based on staff capacity to handle additional participants. In the long-term, the program may need to redistribute funds in the budget to recruit more professionals to the area, including social workers and medical professionals. A future solution to this issue may be the use of telehealth to provide services from off-site providers at the University of Kentucky, for example. In 2018, the Kentucky state legislature heard bills in both the House and the Senate

regarding Telehealth Services. The use of telehealth services has been recommended to increase access for pregnant women in rural areas[36].

Partnerships & Collaboration

Community Advisory Group (CAG)

The success of CHARM-KY will be dependent on the collaboration of the multiple state and local agencies. To form a CAG, we have identified key members of the community who are familiar with the people, resources, and the way of life in the area. By including community stakeholders in the development of the intervention, we anticipate the likelihood of success in implementation. The mayor of Hazard, Jimmy Lyon, has voiced support in the past for interventions addressing the region's opioid problem and he can provide insight into the city's inner workings. Inviting the director of the Center for Excellence in Rural Health to serve on the CAG is important to learn more about program implementation in the district and what programs have been attempted in the past. Participation from the Hazard Chief of Police will garner necessary support from the criminal justice system. The LKLP Safe House in Hazard provides shelter and services to domestic violence victims and their children, a population that may be served by our intervention. Finally, asking a coordinator from each county health department to participate in the CAG is critical to making connections in all of the communities our program will reach. A complete list of CAG members can be found in Table 2.

Table 2. Community Advisory Group (CAG) Members
Administrator, Eastern Mountain Protection & Permanency/DCBS Service Region
Chairman, Perry County Board of Education
Chief of Police, Hazard, KY
Coalition Coordinator, Perry County Unlawful Narcotics Investigations, Treatment, and Education (UNITE)
Community CEO, Hazard Appalachian Regional Health Regional (ARH) Medical Center

Coordinator, Breathitt County Health Department
Coordinator, Knott County Health Department
Coordinator, Lee and Owsley County Health Department
Coordinator, Leslie County Health Department
Coordinator, Letcher County Health Department
Coordinator, LKLP Safe House Domestic Violence Program
Coordinator, Perry County Health Department
Coordinator, Wolfe County Health Department
Director, Center for Excellence in Rural Health
Field Representative for Congressmen Hal Rodgers, Hazard District
Mayor, Hazard, KY
Program Supervisor, Perry County Adult Drug Court

CHARM-KY Collaboration Partners

Collaboration partners not only provide additional insight into the community our program will serve, but they will play an active role in implementation of our intervention. All members of the collaboration already work with members of the CHARM-KY target population in some capacity. Dr. John McKinney of the PCCEK clinic has confirmed interest in the CHARM-KY program and agreed to use his clinic as the hub for services. Because his clinic already serves pregnant women with OUD, he has a vested interested in the outcomes of CHARM-KY. Local social services, including the Department of Community Based Services, are already working with our target population. Including the Perry County Protection and Permanency Family Services Office and the Eastern Mountain Family Support Services Office will facilitate the coordination of child welfare, violence prevention, nutrition support services, and Medicaid/CHIP enrollment services for CHARM-KY participants. Prescription insurance coverage for eligible women and children is vital to the success of the program. The completion of prior authorization paperwork is required by most insurance plans to cover medications, such as buprenorphine, used in MAT. Completing prior authorizations requires communication

between the pharmacy, provider, and insurance company. It can take anywhere from days to weeks, and is often a barrier to the patient accessing their prescribed medication. Uniting the Pharmacy Care Center with the other partners in this collaboration will expedite this process. Including Hazard ARH in the collaboration is important to increase communication between hospital and community providers before and during births. The HANDS program is a well-established home visitation program for new or expectant parents to help build a healthy and safe environment for the child's development, and serves over 10,000 families across Kentucky each year[37]. This existing program's experience in facilitating home visitation, working with pregnant women and new mothers, and providing connection to local services will be beneficial in implementing these aspects of CHARM-KY. Table 3 describes the roles of CHARM-KY collaboration members.

Representative	CHARM-KY Collaborative Members/Agencies	Member/Agency Role
Jordan Price, MPH	Program Coordinator; CHARM-KY	Director of CHARM-KY Collaboration Coordinator of care services for participants
Leslie Atkins, BSN, RNC-OB	Program Director; Pregnancy and Beyond program, PCCEK Clinic	Provide nursing services and education to participants
John McKinney, MD	Physician; PCCEK Clinic	Provide prenatal and mental healthcare Provide physician and nursing staff
Representative, LCSW	Case navigator; PCCEK Clinic and Mountain Comprehensive Care, Hazard	Facilitate case management and connection to social services
Jill Powell, CDAC	Clinic Coordinator; Mountain Comprehensive Care, Hazard	Provide MAT after graduation from program
Sharon Barker, DMD	Dentist; UK North Fork Valley Community Health Center	Provide dental services for participants
Valerie Smith	Supervisor; Perry County DCBS Protection and	Coordinate child welfare and violence prevention Coordinate Medicaid & KCHIP enrollment

	Permanency Family Services Office	Coordinate assistance for domestic violence victims
Francis Walters	Supervisor; Eastern Mountain DCBS Family Support Services Office	Coordinate Supplemental Nutrition Assistance and WIC Program benefits Facilitate Medicaid enrollment
Elizabeth Wells	Circuit Court Judge; Perry County Adult Drug Court	Aid in navigation for women in justice system
Jacquelyn Williams	KRAD Coordinator; Kentucky Health Access Nurturing Development Services (HANDS) Program	Provide education on parenting skills and child health Conduct home health nurse visits after birth
Margret Timothy	Director of Community Engagement; Hazard ARH Regional Medical Center	Connection to local acute care services
Karen Burt, PharmD	Pharmacist; Pharmacy Care Center and PCCEK	Provide pharmacy services and coordination of medication access

All member organizations participating in CHARM-KY must sign a memorandum of understanding to share information regarding each of the individuals enrolled. Shared information may include name, living situation, health history, psychiatric history, substance use history, criminal history, and previous encounters with child protective services. The CHARM-KY providers will meet once monthly for 2 hours to discuss patient cases and program implementation. This will increase communication between providers and enhance the coordination of care. This allows for time for team members to disclose pertinent information that they have learned regarding a participant or their situation with the larger group. During these meetings, each person involved in the project will provide status updates to identify where problems or delays in program implementation.

Performance Measures & Evaluation

Overview

The purpose of the evaluation will be to assess the program's feasibility and provide that information to CHARM-KY stakeholders. The primary goal of CHARM-KY is to improve maternal-child health outcomes in eastern Kentucky, and evaluation of our program will be guided with this outcome in mind. Conducting both process and outcome evaluation of CHARM-KY will enable program leadership to monitor the program's progress towards its goals and use that data to improve the program. Our Evaluation Team will be by comprised of our Program Director, Dr. Scott Lockard; our Program Coordinator, Jordan Rice; a current or former participant of the PATHways program in Lexington; an evaluation consultant from the Kentucky Department of Public Health; and a biostatistician from the University of Kentucky College of Public Health. Evaluation activities for CHARM-KY will be guided by input from stakeholders in our program:

- CAG members
- CHARM-KY collaboration partners
- Staff of the PCCEK clinic
- Members of our target population
- Funding agency

Formative Evaluation

Before enrolling the first participant, we will conduct a focus group with each of our stakeholder groups including (1) women from our target population, (2) proposed staff, (3) members of the CHARM-KY collaboration agencies, and (4) members of the CAG to assess the feasibility and appropriateness of CHARM-KY and its components. Potential topics of evaluation may include: What would you like this program to accomplish? How could we get you to enroll in the program? What is important to you about this program? What are your

concerns about this program? How will you use the results of the program evaluation? Program materials, such as the Care Notebook, will be evaluated in these sessions as well. Conversations will be recorded, professionally transcribed, and coded for themes by the program coordinator. Results of the focus groups will be used to inform the development of implementation and outcome measures.

Process Evaluation

The program will utilize process evaluation as recommended by the CDC[38] to determine if the program is implemented as planned, what resources are being utilized, and who is reached as a result. To evaluate implementation of our program, the Evaluation Team will monitor and analyze a variety of components, including measures related to operations, staff engagement, and participant engagement. Results from process evaluation measures will be compiled and presented to stakeholders at the collaboration meetings each quarter, and to the funding agency on an annual basis. A complete description of these components can be found in Table 4.

Process Measure	Data Source(s)	Responsible Person(s)	Time Frame
Program operations			
CAG perception of CHARM-KY program prior to program initiation	Focus group; Key informant interviews	Program coordinator	Quarter 1, Year 1
Number of staff trained on CHARM-KY	Training log	Program coordinator	Quarter 2, Year 1
Proportion of women who screen positive for OUD in the community and enroll in CHARM-KY	Referral form	Program coordinator	Quarterly
Content of group education sessions	Observation	Program coordinator	Quarterly
Participant referral source	Referral form	PCCEK manager	Quarterly
Participants seen within 1 week of referral	Intake form	PCCEK manager	Ongoing
Staff satisfaction and engagement			
Collaboration members' perception of appropriateness & effectiveness of CHARM-KY collaboration	Partnership survey	Program coordinator	Quarterly

Teamwork of CHARM-KY collaboration members	Partnership survey; Meeting minutes	Program coordinator	Quarterly
Engagement of staff at PCCEK	Staff survey	Program coordinator	Quarterly
Number of partners present at CHARM-KY meeting	Meeting attendance log	Program coordinator	Monthly
Participant satisfaction and engagement			
Proportion of women completing CHARM-KY program	Participant record	Program coordinator	Quarterly
Reason why participants left program	Participant record	PCCEK manager	Ongoing
Participants' perception of group educational sessions	Participant survey	Program coordinator	Quarterly
Number of women enrolled in CHARM-KY	Participant record(s)	Program coordinator	Monthly
Number of participants at group sessions	Group session attendance log	Group session leader	Ongoing
Number of scheduled appointments attended	Participant record	PCCEK manager	Quarterly
Number of recommended group sessions attended	Group session attendance log	PCCEK manager	Quarterly
Participant's perception of CHARM-KY	Participant survey	PCCEK manager	Quarterly
Length of enrollment in CHARM-KY	Participant record	Program coordinator	Quarterly

Data collected for the process evaluation will be obtained via the participants' medical records, referral forms, and the partnership/staff/participant surveys. During the planning phase, the program coordinator will be responsible for collecting and compiling results from the focus groups and key informant interviews. Providers in the community will complete a referral form for woman they refer to CHARM-KY, regardless if the woman chooses to enroll. The PCCEK Clinic Manager will compile referral forms on a quarterly basis. The sources will be evaluated to determine if recruitment methods should be adapted. When a woman is enrolled in the CHARM-KY program, the PCCEK manager will complete an intake form.

To monitor the engagement of key stakeholders in the program, surveys will be distributed quarterly to staff and collaboration members, and on a rolling basis to participants.

Findings from these surveys will be discussed by the Leadership Team on a quarterly basis and presented to the collaboration members. Participating women will be surveyed at their first and fifth CHARM-KY encounter, at the first visit following birth, and at the conclusion of their enrollment. This survey will evaluate the mother's perception of the program, its application and impact on her and her family, strengths of the program, and areas in need of improvement.

The monthly meeting minutes will be analyzed to determine how much time is spent discussing patient cases versus program implementation issues. Monitoring the number of participants in the group sessions will help program staff identify the need to adjust clinic days/times, topics for group discussion, and outside forces that are interfering with participation.

The CARE Notebook will be evaluated by the first five participants in the program to ensure that the resources are relevant, written at the appropriate literacy level, and that it is well received before continued use. To ensure that mothers are being adequately educated, each group educator (i.e., nurse educator, drug and alcohol counselor) should utilize the teach-back method with the program director annually. Many different professionals will be leading the group education sessions, and the program director should use a checklist to evaluate each educator's delivery and ensure fidelity across sessions. Process evaluation results will be presented at the annual CAG meetings and each quarter at the CHARM-KY member meetings.

Outcome Evaluation

The target population of this intervention is a sensitive and transient one, making outcomes comparison challenging. The outcomes measured will be similar to those evaluated in the Vermont CHARM program. The primary outcomes used to evaluate the Vermont CHARM program included: gestational age when the woman entered treatment, birth weight, infant

discharge in maternal care, and infant in maternal care at one year[12]. Baseline demographic data from women and neonates in the CHARM-KY program will be compared against data for women and their neonates who were referred to CHARM-KY, but chose not to enroll. This data will come from referral forms completed by community referral sites. The outcome evaluation of CHARM-KY will be conducted by comparing outcomes of participants to regional and state level data. The program will partner with the Kentucky Department of Public Health to obtain maternal-child health data. Data will be collected and recorded securely in REDCap. A Data Analyst from the Center for Excellence in Rural Health will extract pertinent data via chart review. Each woman will be given a unique identifier to be used in analysis. A dose effect analysis will be conducted to determine if the number of prenatal appointments, counseling sessions, use of the Care Notebook, attended has any impact on illicit drug use and birth outcome measures. A survey administered to participants will include questions from the Interpersonal Support Evaluation List to measure social support[39]. Results will be discussed with the CAG meetings annually.

Table 5. Outcome Measures.

Outcome Measure	Data Source(s)	Responsible Person(s)	Time Frame
Number of NICU admissions	Medical record	CEHR Data Analyst	Annually
Birth weight < 2500 grams	Medical record	CEHR Data Analyst	Annually
Proportion of infants delivered at < 37 weeks	Medical record	CEHR Data Analyst	Annually
Length of hospital stay	Medical record	CEHR Data Analyst	Annually
Adequate prenatal care (80% of recommended visits received)	Medical record	CEHR Data Analyst	Annually
Number of Prenatal visits attended	Medical record	CEHR Data Analyst	Annually
Self-efficacy in parenting	Participant survey	CEHR Data Analyst	Annually
Perception of positive social support	Participant survey	CEHR Data Analyst	Annually
Intent to remain sober	Participant survey	CEHR Data Analyst	Annually
Infant in maternal care at delivery discharge	Medical record	CEHR Data Analyst	Annually

Number of drug screens negative for illicit substances at delivery	Medical record	CEHR Data Analyst	Annually
Gestational age at start of CHARM-KY	Medical record	CEHR Data Analyst	Annually
Number of women sober at discharge from program	Medical record	CEHR Data Analyst	Annually
Participation rate in HANDS	CHARM record	CEHR Data Analyst	Annually
Infant in maternal care at 1 year	CHARM record	CEHR Data Analyst	Annually
Uptake of social services	CHARM record	CEHR Data Analyst	Annually

Capacity and Experience of the Applicant Organization

The mission of the Kentucky River District Health Department (KRDHD) is to "protect, maintain, and promote the health of the people of the community"[40]. This department is a regional health department that serves seven of the eight counties in the KRADD: Knott, Lee, Leslie, Letcher, Owsley, Perry and Wolfe. The application for funding aligns with the goals of the organization's mission statement to connect groups and agencies to improve the access and provision of healthcare and social services, including to pregnant women with OUD in the district.

The department has experience in implementing multiple programs in the community, including: Breastfeeding classes, Breastfeeding support groups, Ladies' Health Days, Freedom from Smoking classes, Diabetes Self-Management Education classes, Eating Health in Kentucky Cooking School, and a partnership with HANDS program. Participants in the District's Freedom from Smoking Classes are 85% more likely to quit[40]. In 2016, over 150 individuals participated in the smoking cessation classes. During Ladies' Health Days, the District coordinates physical exams, pap smears, breast exams, and appropriate lab work for participants[41]. They frequently partner with local schools to host educational programs to the public on topics such as driving

under the influence, teen pregnancy, hand hygiene, and physical activity. Most closely related to CHARM-KY is the department's experience in providing prenatal services.

The KRDHD is led by Public Health Director Dr. Scott Lockard. Dr. Lockard has over 20 years' experience in public health leadership and programming. He has served as the primary investigator on the HANDS project and was instrumental in starting needle exchange programs in the district. His experience in the field of early childhood programming will be advantageous to CHARM-KY. He has been awarded over $4 million in grant awards for community programs and public health research in the topics of women's health, published in the *American Journal of Public Health* and the *Journal of Obstetric, Gynecologic, & Neonatal Nursing*. He has led numerous community health needs assessments and shared findings with community action councils. Annually, he manages a budget of over $1,250,000 and serves as the direct supervisor of over 40 employees.

Project Management

Leadership

To meet the above goals, the CHARM-KY Collaborative will be guided by the Leadership Team. The Leadership Team will be responsible for overseeing all aspects of program implementation and evaluation. They will serve as the ultimate decision making body and represent the interests of the partners and participants. The Leadership Team will consist of:

- Tim Stockton, DrPH, MSW, CSW (CHARM-KY Program Director)
- Jordan Rice, MPH (CHARM-KY Program Coordinator)
- Leslie Atkins, RN (CHARM-KY Assistant Coordinator, PCCEK Coordinator)

Tim Stockton, DrPH, MSW, CSW, will serve as the program director (PD). Dr. Lockard earned his Master of Social Work and Doctor of Public Health from the University of Kentucky,

and is a 2011 graduate of the National Public Health Leadership Institute. Dr. Lockard currently serves as the Public Health Director for the Kentucky River District Health Department (KRDHD), and is past president of the Kentucky Health Departments Association. He will be responsible for the program design, implementation, process and outcome evaluation, and dissemination of final program results.

Jordan Rice, MPH, will serve as the project coordinator. Jordan earned her Master of Public Health from the University of Kentucky and currently serves as Public Health Program Specialist for the KRDHD. Ms. Rice has led the implementation of programs in the region including Ladies Health Days, Breastfeeding classes, and Freedom from Smoking classes. As the project director, she will be responsible for (1) management and engagement of key stakeholders, including oversight of and communication with CHARM-KY partners and the CAG, (2) staff training, (3) data collection, and (4) monitoring program implementation. Ms. Rice will organize and lead monthly meetings with the entire CHARM-KY Collaborative team to provide updates on the program and discuss care for current participants.

Leslie Atkins, BSN, RNC-OB, will serve as the Assistant Coordinator and PCCEK Coordinator. She has served as Program Director for the Pregnancy and Beyond program at the PCCEK clinic for five years. She worked for 10 years as a labor and delivery nurse before transitioning to her role at PCCEK. Ms. Adams earned her Bachelor of Science in Nursing at Morehead State University and is certified in Obstetrics. Her role in CHARM-KY will be primarily administrative; she will (1) manage the recruitment, enrollment, and management of program participants, (2) act as liaison for the PCCEK clinic to the CHARM-KY Leadership Team, and (3) oversee daily clinic operations. She will focus on participant satisfaction and care coordination.

Staff

Medical professionals, as well as mental health support staff, are key to the implementation of CHARM-KY. **Dr. John McKinney, MD,** is a dual board certified Maternal-Fetal Medicine and Addiction Medicine physician. He is a certified Buprenorphine provider in accordance with the Drug Addiction Treatment Act of 2000 and is currently a practicing partner of PCCEK. He will provide both obstetric and mental health care to program participants, including examinations, prenatal management, and providing prescriptions for MAT. **Michelle Hatton, RNC-OB,** is currently on staff at PCCEK and provides prenatal nursing care. The nurse will be responsible for conducting group classes on prenatal care, fetal development, breastfeeding, and parenting, for example. The nurse will also work closely with HANDS to coordinate post-partum in-home visitation for participants. **Jill Powell, CADC,** is a certified alcohol and drug counselor at Mountain Comprehensive Care Center in Hazard. Other staff that we will recruit for include a **social worker and a data analyst.** The data analyst will be contracted from the Center for Excellence in Rural Health to extract pertinent data from medical records and compile information for evaluation. Each month, all representatives from the collaborative agencies will meet for 2 hours to discuss participants new to the program, participants expected to give birth in the next 30 days, participants who have recently given birth, and participants that any agency has concerns about.

Budget Narrative

Grant budget period: July 1, 2018 – June 31, 2021

A. Anticipated Enrollment.

Year 1	Year 2	Year 3	TOTAL
15	30	40	**85**

The number of women who will participate in CHARM-KY is estimated from the number of live births in the KRADD annually, the rate of NAS in the region, and participation in the Vermont CHARM program. In the Vermont CHARM program, 15 women were treated during the first year, 24 during the third year, and 51 during the fifth year[12]. The average number of births in the KRADD annually from 2014-2016 was 1,367[42], and the rate of NAS in KRADD is estimated at 63.9 per 1,000 births[18]. With this data, we estimate that at least 85 women would be *eligible* for enrollment in CHARM-KY annually. This information has been used to estimate a total grant period enrollment goal of 85; with 15, 30, and 40 in the first, second, and third years of the grant respectively.

B. Personnel Salaries and Wages.

Position Title	Annual Salary	% FTE	Salary	Fringe	Total
Principal Investigator	$130,000	20%	$26,000	$7,611	**$33,611**
Program Coordinator	$80,000	70%	$56,000	$19,202	**$75,202**
Assistant Coordinator/PCCEK Manager	$52,000	30%	$15,600	$6,445	**$22,045**
Registered Nurse	$50,000	20%	$10,000	$4,211	**$14,211**

Maternal-Fetal/Addiction Medicine Physician	$225,000	20%	$45,000	$11,649	**$56,649**
Certified Alcohol and Drug Counselor	$35,000	10%	$3,500	$1,787	**$5,287**
Social Worker	$45,000	20%	$9,000	$3,999	**$12,999**
TOTAL PERSONNEL			**$168,100**	**$56,585**	**$224,685**

Table above reflects budget for Year 1.

Most the CHARM Collaborative budget will be dedicated to supporting personnel and licensed healthcare providers. The CHARM-KY principal investigator will oversee the implementation of the program, but the Program Coordinator will manage the program on a daily basis. The Program Coordinator will spend the majority of her efforts on program implementation and management of all collaboration agencies. The PCCEK Manager will coordinate the program's implementation at the PCCEK Clinic specifically, and should 1.5 to 2 days/week to work on program activities. Medical professionals are necessary for this project as they possess the training and licensure required for the diagnosis, management, and authority to write prescriptions of OUD treatment and care. A specialized license is required by Federal and Kentucky State law for medical doctors to write prescriptions for MAT, and the specialization of the dual board certified physician is ideal for the CHARM-KY program. Registered nurses are necessary to appropriately meet the specialized medical, prenatal, and behavioral health needs of individuals in this program. The medical providers will receive reimbursement equal to what they would make in their full-time position. During the first year, staff will need to be trained in program implementation. During this time, experts from the CHARM Collaborative in Vermont will be invited to speak to and train our team. Their insight into the development and implementation of this project is imperative for a successful beginning. Our budget will allow for compensation for this individual's time, travel, and lodging in Kentucky.

Contractual

CHARM-KY will contract professionals in data analysis and management to aid in program evaluation. A biostatistician from the University of Kentucky will be hired on a contractual basis to perform analysis of program data during years 2 and 3 (salary $85,000). CHARM-KY will hire a data analyst from the Center for Excellence in Rural Health to extract data from health records and record that data in REDCap during years 2 and 3 (salary $45,000).

C. Supplies.

Item	Number needed	Unit cost	Year 1	Year 2	Year 3
Monthly meeting food	Variable	$145/meeting	$1750	$1750	$1750
Care notebook	90	$30	$900	$900	$750
Save-A-Lot Gift Card	70	$20	$600	$600	$200
Car Seat	90	$100	$3000	$3000	$2500
Gift card for infant supplies	100	$25	$1000	$1125	$375
Total supplies			**$7250**	**$7375**	**$6325**

Supplies required for program implementation include materials to make the Care Notebooks, participant incentives, and food for collaboration meetings. We will overestimate supplies needed during the first year (n=30), in case there is a higher enrollment than anticipated. The following will be required for notebooks: printer paper, 3-ring binders, printer ink, pens, and notepads. During the first year, 20 notebooks will be made, with 30 and 50 made the following years based on anticipated enrollment. We estimate each notebook will cost $30 to produce.

Each participant will be given the opportunity to earn incentives. Participants will be given $20 gift cards to Save-A-Lot for each referral made. She will earn a car seat estimated at $100 prior to birth if they attend 80% of recommended sessions. If the woman decides to become a peer support specialist after graduation from the program, she can earn $25 gift cards for infant supplies, such as diapers, for each group session she conducts. Participants will also earn $25 gift cards for completing participant surveys. Food will be provided to at least 12 collaboration members at each monthly meeting at an estimated cost of $125/meeting.

C. Travel.

	Year 1	Year 2	Year 3
APHA Annual Meeting Registration	$1,000	$1,000	$1,030
Flight	$1,000	$1,000	$1,000
Lodging	$1,000	$1,000	$1,000
Local State Travel	$2,000	$1,000	$1,000
TOTAL	**$5,000**	**$4,000**	**$4,030**

Our program leadership will travel locally in the district to train personnel, promote the program, and oversee implementation. The furthest county seat from Hazard is Campton, KY in Wolfe County at 49 miles. We estimate that the Leadership Team will travel throughout the district more frequently during the first year than in subsequent years. At the standard reimbursement rate of 53.5 cents/mile, we will estimate travel throughout the district at $2,000 in year one, and $1,000 in years two and three.

Promotion and dissemination of the project and its results will be an important contribution to the public health and substance abuse community. Our project background and methods will be presented by two staff members at the American Public Health Association

annual meeting at the end of year one, preliminary outcome results at the end of year two, and final results at the end of year three. The budget will account for meeting registration, lodging, and travel to present our project findings across all three years of the grant. The 2019 annual meeting is in Philadelphia. Our grant will budget $1,000 for registration, $500/ticket for airfare, and $250/night for lodging for two rooms for nights at an estimated total attendance cost of $3,000.

D. Equipment.

CHARM-KY will require no additional equipment outside of the already established clinic; services, exams, medications and lab tests will be paid for by insurance.

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Appendix A. Description of accountability level system[32].

Level of Accountability in CHARM-KY		
Level	**Criteria**	**Prescription Policy**
1	Negative drug screens for at least 1 month and No reported relapse in the last month and 1 or less missed appointments	Prescriptions are written for a maximum of 14 days
2	Positive drug screen for illicit drug use and/or Reported relapse within the last two months and/or 2 missed appointments within the last month	Prescriptions are written for a maximum of 7 days
3	History of habitual illicit drug use and/or Reported relapse within the last month and/or 3 or more missed appointments within the last month	Prescriptions are written for a maximum of 4 days or until next appointment

Adapted from PATHways Phase System Overview.

Appendix B. Patient information and data to be collected. *This list serves as an example of data to be collected and is not conclusive*.

- Demographic
  - Number of children
  - Marital status
  - County of residence
  - Employment status
  - Education completed
  - Housing status
  - Transportation status
  - Insurance status
  - Age
- Medical (behavioral health)
  - Mental health conditions
  - Drug use (substance, route of use)
  - History of recovery attempts
- Medical (obstetrics)
- Medical (other)
  - Other health conditions
  - Tobacco use
- Neonatal
  - Birth weight
  - Gestational age at birth
  - Drug screen of neonate at birth
  - Treatment required for NAS
  - NICU admission

Appendix C. CHARM-KY Materials.

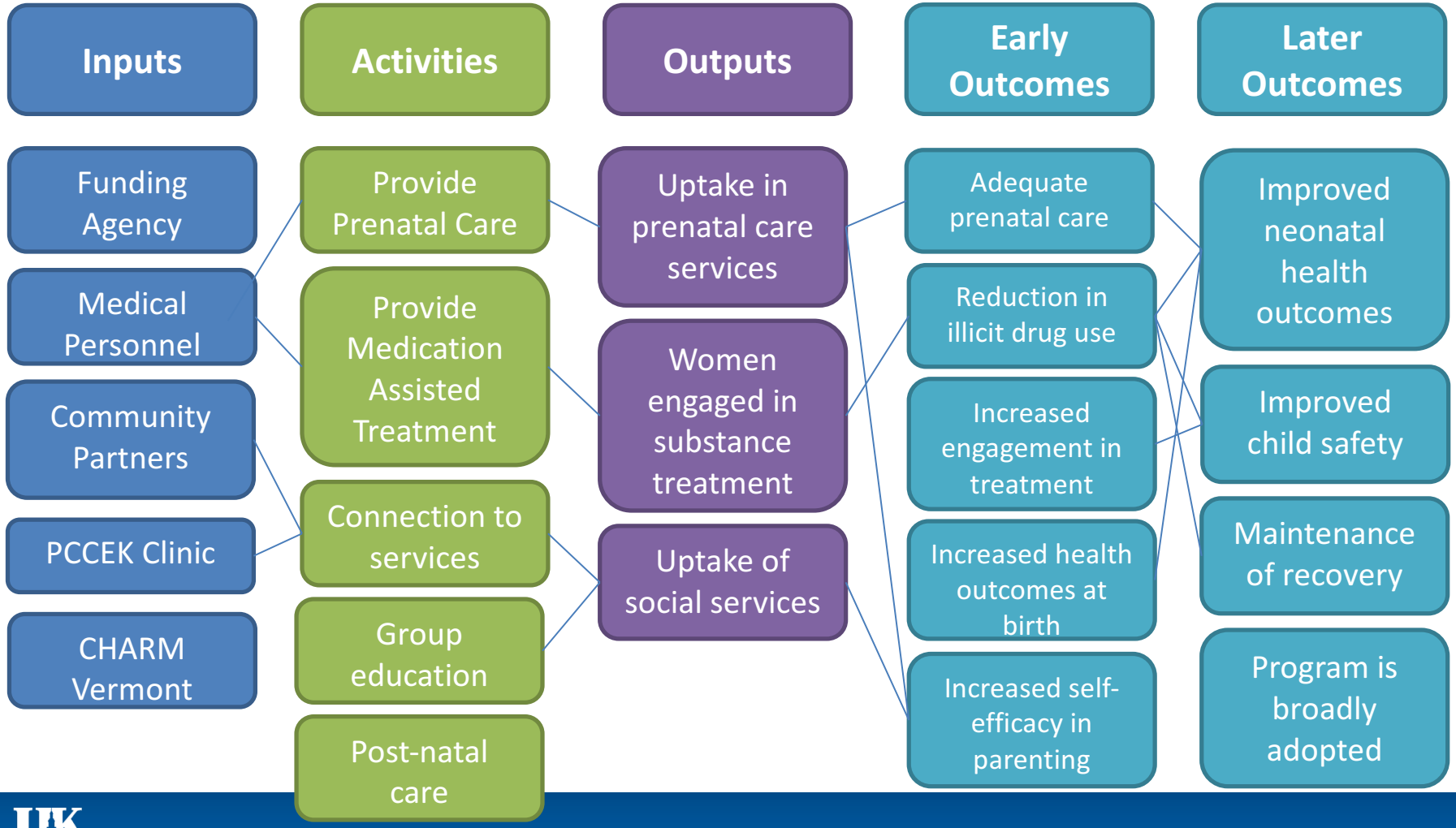
Examples of education topics:

- Breastfeeding
- Giving birth
- Nutrition for newborn
- Nutrition during pregnancy
- Birth control and family planning
- Domestic violence
- Financial planning (balancing checkbook, etc)
- Applying for jobs
- Decision making
- Smoking cessation

The Four P's Plus screening tool[33]:

•*Parents*	Did either of your parents ever have a problem with alcohol or drugs?
•*Partner*	Does your partner have a problem with alcohol or drugs?
•*Past*	Have you ever drunk beer, wine, or liquor?
•*Pregnancy*	
	–In the month before you knew you were pregnant, how many *cigarettes* did you smoke?
	–In the month before you knew you were pregnant, *how many beers/how much wine/how much liquor* did you drink?

Logic Model



July 1, 2018 - June 31, 2021

	Year 1					Year 2					Year 3				
	Effort	Salary		Fringe	Total	Effort	Salary		Fringe	Total	Effort	Salary		Fringe	Total
Personnel															
Principal Investigator	20.00%	$130,000	$26,000	$7,611	$33,611	10.00%	$133,900	$13,390	$3,889	$17,279	10.00%	$137,917	$13,792	$3,974	$17,766
Program Coordinator	70.00%	$80,000	$56,000	$19,202	$75,202	80.00%	$82,400	$65,920	$22,354	$88,274	80.00%	$84,872	$67,898	$22,774	$90,671
Assistant Coordinator/PCCEK Manager	30.00%	$52,000	$15,600	$6,445	$22,045	30.00%	$53,560	$16,068	$2,922	$18,990	40.00%	$55,166	$22,066	$3,953	$26,019
Registered nurse, Obstetrics	20.00%	$50,000	$10,000	$4,211	$14,211	20.00%	$51,500	$10,300	$1,912	$12,212	30.00%	$53,045	$15,914	$2,908	$18,822
Maternal/Fetal/Addiction MD	20.00%	$225,000	$45,000	$11,649	$56,649	20.00%	$231,750	$46,350	$5,102	$51,452	20.00%	$238,702	$47,740	$5,225	$52,965
Certified Alcohol and Drug Counselor	10.00%	$35,000	$3,500	$1,787	$5,287	20.00%	$36,050	$7,210	$1,638	$8,848	10.00%	$37,131	$3,713	$829	$4,542
Social Worker	20.00%	$45,000	$9,000	$3,999	$12,999	30.00%	$46,350	$13,905	$2,731	$16,636	30.00%	$47,740	$14,322	$2,767	$17,089
Biostatistician	0.00%					5.00%	$85,000	$4,250	$626	$4,876	10.00%	$87,000	$8,700	$1,270	$9,970
CEHR Data Analyst	0.00%					20.00%	$45,000	$9,000	$1,797	$10,797	40.00%	$47,000	$18,800	$3,664	$22,464
Trainers from Vermont					$5,000					$0					$0
Personnel Total			$165,100	$54,904	**$225,004**			$173,143	$40,546	**$229,362**			$185,445	$42,430	**$260,308**
Program Supplies	15 participants														
Monthly meeting food					$1,750					$1,750					$1,750
Incentives					$4,600	30 participants				$4,725	40 participants				$3,825
Care Notebooks					$900					$900					$750
Program Total					**$7,250**					**$7,375**					**$6,325**
Travel															
APHA Annual Meeting registration	2 staff members				$1,000					$1,000					$1,030
Flight	2 staff members				$1,000					$1,000					$1,000
Lodging	2 staff members				$1,000					$1,000					$1,000
Local travel					$2,000					$1,000					$1,000
Travel Total					**$5,000**					**$4,000**					**$4,030**
ANNUAL TOTAL					$237,254					$240,737					$270,663
GRAND TOTAL (Year 1 + 2 + 3)					**$748,655**