

Educational Care Binder to Improve Appointment Attendance After Prenatal Exposure to

Methadone

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Approved May 2019 by the faculty of UMKC in partial fulfillment of the requirements for the

degree of Doctor of Nursing Practice

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Abstract

Long-term effects such as vision abnormalities, motor concerns, developmental delay, cognitive issues, and behavioral difficulties have been associated with prenatal methadone exposure. Follow up care is a valuable resource to identify concerns early and initiate interventions prior to development of long-term complications. The purpose of this evidence-based project was to determine if an educational care binder improved adherence to specialty follow up appointments for infants prenatally exposed to methadone. The project was conducted using a quasi-experimental design with a convenience sample and a retrospective comparison group. Two infants prenatally exposed to methadone and their caregivers were identified to participate in this project. The setting occurred at the regional drug endangered children clinic in a Midwestern metropolitan area. An educational care binder was given to caregivers that included an introduction to the clinic and its providers, education on the potential long-term effects of prenatal methadone exposure, and the benefits of follow up care. Appointment attendance rates were collected and compared with pre-intervention rates. Attendance rates were unchanged with 50% of both the intervention participants and the comparison group attending the two recommended follow up appointments. Follow up care is a valuable resource to identify concerns early and initiate interventions prior to development of long-term, potentially irreversible, complications.

Keywords: prenatal methadone exposure, educational care binder, appointment attendance

Educational Care Binder to Improve Appointment Attendance After Prenatal Exposure to Methadone

Heroin and prescription opioid use by pregnant women has increased significantly in the past ten years contributing to the substantial burden caused by substance abuse (Beckwith & Burke, 2015; Hudak, Tan, The Committee on Drugs, & The Committee on Fetus and Newborn, 2012). Methadone is an opioid receptor agonist used to assist with narcotic addiction recovery from opioid drugs by altering the way the nervous system and brain interpret pain and lessening the symptoms of withdrawal and euphoria derived from opioids (Hudak et al., 2012; Ross, Graham, Money, & Stanwood, 2015; Substance Abuse and Mental Health Services Administration [SAMHSA], 2015). When used as prescribed, methadone has been associated with more consistent maternal drug levels, improved prenatal care, less drug seeking behavior, and improved neonatal outcomes (Baldacchino, Arbuckle, Petrie, & McCowan, 2014; Kelty & Hulse, 2017; Levine & Woodward, 2018; The American College of Obstetricians and Gynecologists [ACOG], 2016). Though outcomes are improved, significant immediate and long-term negative effects are associated with prenatal methadone exposure (Baldacchino et al., 2014; Beckwith & Burke, 2015; Kelty & Hulse, 2017; Levine & Woodward, 2018; Maguire et al., 2016). This paper reports an evidence-based project to address the long-term effects of prenatal methadone exposure through improved follow up appointment attendance. Please see Appendix A for definition of terms used throughout this paper.

Background and Significance

Pregnant women entering methadone treatment therapy (MTT) increased from two percent in 1992 to 28 percent in 2012, this is an increase from 351 pregnant women to 6,087 pregnant women (Substance Abuse and Mental Health Services Administration [SAMHSA], 2016). The cost associated with infant and maternal hospitalizations secondary to substance use

in 2012 was approximately \$944 million (SAMHSA, 2016). Though it is recommended and commonly used, methadone can have significant consequences on the newborn with up to 95% of exposed infants experiencing withdrawal symptoms and approximately 50% requiring treatment for neonatal abstinence syndrome (NAS) (Baldacchino et al., 2014; Gawronski et al., 2014; Kelty & Hulse, 2017; Maguire et al., 2016). It is estimated that over 10,000 babies are born in the United States every year with NAS secondary to exposure to opioids and opioid receptor agonists, such as methadone (Maguire et al., 2016; Velez, Jansson, Schroeder, & Williams, 2009). Over the last two decades, the number of infants diagnosed with NAS increased from 1.2 per 1,000 births to 5.8 per 1,000 births (SAMHSA, 2016). In addition to NAS there is increased risk for neonatal death and significant long-term effects including, visual, motor, cognitive and behavioral problems (Baldacchino et al., 2014; Beckwith & Burke, 2015; Cohen, Morley, & Coombs, 2015; Gawronski et al., 2014; Humbarger et al., 2016; Kelty & Hulse, 2017; Levine & Woodward, 2018; Maguire et al., 2016; McGlone & Mactier, 2015; McGlone et al., 2013; Velez et al., 2009). Issues are further compounded by environmental factors such as low maternal education, low socioeconomic status and continued substance use (Baldacchino et al., 2014; Beckwith & Burke, 2015; Humbarger et al., 2015; Kelty & Hulse, 2017; Levine & Woodward, 2018; Logan, Brown, & Hayes, 2013; Maguire et al., 2016; McQueen & Murphy-Oikonen, 2016; McGlone & Mactier, 2015). Follow up care is a valuable resource for infants prenatally exposed to methadone to identify concerns early and initiate interventions prior to development of long-term complications (Beckwith & Burke, 2015; Kelty & Hulse, 2017; Kocherlakota, 2014; Levine & Woodward, 2018).

Local Issue and Diversity Considerations

Opioid use has increased 11-fold in the Midwest (SAMHSA, 2016). According to the Substance Abuse and Mental Health Services Administration (SAMHSA), individuals who use

methadone are predominately Caucasian and live in metropolitan areas (Substance Abuse and Mental Health Services Administration [SAMHSA], 2014). During April 2017 through March 2018, eight infants in a Midwest metropolitan area were monitored for prenatal methadone exposure at the regional Drug Endangered Children (DEC) clinic. Newborn drug screen results during the same time frame report 24 infants testing positive for methadone for this area, indicating that 67% of infants prenatally exposed to methadone were not followed by a DEC specialist (United States Drug Testing Laboratories (USDTL) Representative, personal communication).

Problem and Purpose

Inadequate follow up care after in utero exposure to methadone may result in a lack of early intervention for long-term complications, poor access to available resources and negative outcomes (Beckwith & Burke, 2015; Hudak et al., 2012; Kocherlakota, 2014; Maguire et al., 2016). The growing opioid epidemic has received wide media coverage lately, increasing awareness for the general public. In response to this, providers at the DEC clinic verbalized a specific need for infants prenatally exposed to methadone and requested development of an educational tool to be given to their caregivers. The purpose of this project was to determine if an evidence based educational care binder improves adherence to follow up appointments at the DEC clinic for infants prenatally exposed to methadone (see Appendix B for the Logic model).

Facilitators and Barriers

The facilitator for this project was an advanced practice nurse practitioner at the regional DEC clinic. The primary barrier to the project was the challenges associated with working with a substance dependent population. The caregivers in this project had differing backgrounds with one recovering from prescribed pain medication addiction and the other recovering from addiction to illicit substances. The transitional nature of their lifestyles and distrust for medical

professionals make long term follow up difficult (Beckwith & Burke, 2015; Levine & Woodward, 2018; Maguire et al., 2016). Confounding factors such as low socioeconomic status, polysubstance use, and mental health conditions further complicate interactions (Baldacchino et al., 2014; Beckwith & Burke, 2015; Levine & Woodward, 2018; Maguire et al., 2016).

Economically, project costs were easily manageable and promoted sustainability for the project (see Appendix C). Another factor promoting the sustainability of the intervention is the support of the providers at the DEC clinic and their investment in improving outcomes for infants prenatally exposed to methadone.

Review of the Evidence

Inquiry

The question for this project was, in families with newborns prenatally exposed to methadone, does receiving a care binder with education on the effects of methadone and benefits of follow-up care compared to families who do not receive the care binder, improve attendance at follow-up appointments for drug endangered children within the first four months of life?

Search Strategies

A literature search was performed to identify evidence relevant to this project. The following keywords were used: appointment adherence, care binder, care coordination, drug endangered children, pediatric follow up appointments, in utero methadone exposure, in utero opioid exposure, missed appointments, neonatal abstinence syndrome, parental education, prenatal methadone, and substance exposed infants. Databases searched included the following: Cumulative Index to Nursing and Allied Health (CINAHL), Medline, and PubMed. A search of references identified additional studies.

Studies considered were relevant to the long-term effects of prenatal methadone or opioid exposure, recommended follow up care, and promoted adherence to follow up care

appointments. They were excluded if dated prior to January 2008, prenatal exposure was to substances other than methadone or opioids, or if they were directed toward inpatient treatment of exposure. Twenty-six studies were included with 15 identified as cohort studies at a level 4 evidence using the *Rating System for the Hierarchy of Evidence for an Interventional Inquiry* (see Appendix D; Melnyk & Overholt, 2015, adapted). Of the remaining 11 studies, two were systematic reviews of randomized control trials with level one evidence, one systematic review of experimental and observational studies with level two evidence, four controlled clinical trials without randomization with level three evidence, two systematic reviews of case-control and descriptive studies, one systematic review of a qualitative study with level five evidence, one qualitative study with level six evidence, and one expert consensus report with level seven evidence (see Appendix E).

Synthesis of Evidence

After reviewing the literature, three primary subtopics were identified. The negative, long-term effects that prenatal methadone exposure presents to infants is foundational with 11 studies supporting this subtopic. Appointment adherence promotion with care coordination was supported by five studies. Effective education and the need for health literacy with engagement and perception of health with knowledge of risks was supported by eight studies.

Effects of methadone exposure and need for ongoing follow up care. Long-term effects that have been associated with prenatal methadone exposure include increased risk for sudden infant death syndrome, increased hospital admissions, increased usage of emergency departments, vision abnormalities, motor concerns with developmental delay, cognitive issues, and behavioral difficulties (Baldacchino et al., 2014; Beckwith & Burke, 2015; Cohen, et al., 2015; Humbarger et al., 2015; Kelty & Hulse, 2017; Levine & Woodward, 2018; Maguire et al., 2016; McGlone & Mactier, 2015; McGlone et al., 2013; Velez et al., 2009). In addition to the

physiologic effects of prenatal methadone exposure, infants are affected by several confounding factors such as, poor parenting, maternal mental health, foster placement, low socioeconomic status, chronic stress, and polysubstance use, further complicating the health and development of exposed infants and warranting closer follow up (Baldacchino et al., 2014; Beckwith & Burke, 2015; Humbarger et al., 2015; Kelty & Hulse, 2017; Levine & Woodward, 2018; Logan et al., 2013; Maguire et al., 2016; McQueen & Murphy-Oikonen, 2016; McGlone & Mactier, 2015).

Visual abnormalities. Forty percent of opioid exposed infants failed a visual assessment at six months of age (Maguire et al., 2016; McGlone & Mactier, 2015; McGlone et al., 2013; McGlone et al., 2014). The most common problems reported are strabismus, reduced visual acuity and nystagmus (Maguire et al., 2016; McGlone et al., 2013; McGlone et al., 2014). Abnormal development and maturity of vision is associated with long-term issues with hand-eye coordination, depth perception, concentration, and learning, in addition to visual disturbances (Konijnenberg & Melinder, 2015; Maguire et al., 2016; McGlone et al., 2013; McGlone et al., 2014).

Motor concerns with developmental delay. Motor deficits and developmental delay in infants prenatally exposed to methadone have been reported to increase with age (Beckwith & Burke, 2015; Humbarger et al., 2016; Logan et al., 2013; Maguire et al., 2016; McGlone et al., 2013). Delays are more common after 12 months of age, though hypertonia and dysregulated patterns causing delays with communication and milestones such as, sitting and crawling, have been demonstrated (Humbarger et al., 2016; Logan, Brown, & Hayes, 2013; Maguire et al., 2016; Velez et al., 2009).

Cognitive issues and behavioral concerns. Decreased language development, learning difficulties, sleep disorders, and lower IQ scores have been associated with prenatal exposure to methadone (Baldacchino et al. 2014; Beckwith & Burke, 2015; Humbarger et al., 2016; Levine

& Woodward, 2018; Maguire et al., 2016). Poor memory recall, decreased improvement performance ability, and issues with inhibitory/behavior regulation that persists after age two are associated with development of conduct disorder issues, hyperactivity, impulsivity, anxiety, disruptive and aggressive behavior, poor social skills and poor school performance later in childhood (Beckwith & Burke, 2015; Jensen, 2014; Konijnenberg & Melinder, 2015; Levine & Woodward, 2018; Maguire et al., 2016). These characteristics of executive function have been measured in children prenatally exposed to methadone who consistently demonstrated lower functioning abilities with decreased IQ scores and poor problem-solving skills (Konijnenberg & Melinder, 2015; Levine & Woodward, 2018).

Follow up care. The importance of follow up is repeatedly emphasized and should include multiple, comprehensive assessments to facilitate early identification with intervention, and referral for needs as they arise (Beckwith & Burke, 2015; Kelty & Hulse, 2017; Kocherlakota, 2014; Levine & Woodward, 2018). Follow up should include growth and nutrition with interventions provided for findings such as failure to thrive, short stature or microcephaly (Humbarger et al., 2016; Kocherlakota, 2014; McGlone & Mactier, 2015). Because this population may be at risk for delayed motor or cognitive milestone development, in depth developmental testing is recommended with referral to therapies as delays are identified (Beckwith & Burke, 2015; Humbarger et al., 2016; Velez et al., 2009). Early intervention is aimed to prevent progression of long-term, irreversible problems (Beckwith & Burke, 2015; Velez et al., 2009). Psycho-behavioral assessments identify concerns such as hyperactivity, impulsivity, and attention deficits, and should include assessment of executive functioning to monitor for self-regulation and problem-solving needs (Kocherlakota, 2014; Konijnenberg & Melinder, 2015; Levine & Woodward, 2018). Early ophthalmological assessments are needed to diagnose and treat nystagmus, strabismus, refractive errors, and other visual deficits before

permanent changes occur (Kocherlakota, 2014; Maguire et al., 2016; McGlone et al., 2013; McQueen & Murphy-Oikonen, 2016).

It is difficult to determine if long-term effects are solely related to the prenatal methadone exposure, or an accumulative effect with the addition of at risk environmental and socioeconomic elements (Baldacchino et al., 2014; Beckwith & Burke, 2015; Kelty & Hulse, 2017; Levine & Woodward, 2018; Logan et al., 2013; Maguire et al., 2016; McQueen & Murphy-Oikonen, 2016). Close follow up care assesses for ongoing substance abuse while also providing safety assurance (Beckwith & Burke, 2015; Kocherlakota, 2014; Levine & Woodward, 2018; Maguire et al., 2016; McQueen & Murphy-Oikonen, 2016; Velez et al., 2009). Family support and functioning is an important assessment that should be included with follow up care to promote healthy parent-child attachment, to determine need for services, and to provide referral to community resources when available (Baldacchino et al., 2014; Kocherlakota, 2014; Maguire et al., 2016; Smith, Wilson, & Committee on Substance Use and Prevention, 2016).

Appointment attendance promotion. It is well established that infants prenatally exposed to methadone represent a vulnerable population that benefits from frequent and early follow-up (Beckwith & Burke, 2015; Jensen, 2014; Kocherlakota, 2014; Levine & Woodward, 2018; Maguire et al., 2016; McQueen & Murphy-Oikonen, 2016; Velez et al., 2009). Scheduled appointments with multiple specialties may initially be numerous depending on the severity of negative effects, and caregivers can become overwhelmed and overburdened leading to missed appointments (Kocherlakota, 2014; Maguire et al., 2016; McQueen & Murphy-Oikonen; Schneiderman, Kennedy, & Sayegh, 2016a; Schneiderman, Smith, Arnold-Clark, Fuentes, & Kennedy, 2016b). Not attending scheduled appointments results in poorer outcomes, poorer quality of life, missed opportunities for early intervention, increased emergency department

usage and preventable hospital admissions (Kelty & Hulse, 2017; McGrady et al., 2015; National Quality Forum [NQF], 2010).

Care coordination. Care coordination enhances appointment attendance through communication promotion, consistency, and trust by assisting with plan of care development, facilitating multidisciplinary and multispecialty communication, assisting with appointment coordination, and connecting families with community resources (Klitzner, Rabbitt, & Change, 2010; Kocherlakota, 2014; NQF, 2010; Taylor et al., 2013). Care coordination programs can be costly, requiring grants and special funding, making widespread availability difficult without resources (Klitzner et al., 2010; Taylor et al., 2013). Supportive methods for care coordination, such as a care binder, that provide a written plan of care, medication lists, self-management education, scheduled follow up appointments, and a community resource list, are an economical option to provide education and consistent communication, as well as promote appointment attendance (Klitzner et al., 2010; NQF, 2010; Taylor et al., 2013).

Effective education. Caring for a newborn with effects from prenatal methadone exposure can be challenging and is further complicated by continued methadone use, maternal emotions of guilt and potential mental health and socioeconomic challenges (Baldacchino et al., 2014; Beckwith & Burke, 2015; Maguire et al., 2016; Velez et al., 2009). Education regarding withdrawal symptoms, infant supportive care, and importance of follow up care empowers caregivers, promotes adherence to health recommendations, and improves infant outcomes (Glick et al., 2017; Hudak et al., 2012; Jensen, 2014; Maguire et al., 2016). Parental engagement, accurate health perceptions, knowledge of potential risks and handout supports written at appropriate health literacy levels ensure effective education, promote adherence to health recommendations and optimize outcomes (Adams, 2010; Glick et al., 2017; Molfenter, 2013; Usher, McShane, & Dwyer, 2015).

Health literacy and engagement. For parents, health literacy is the ability to understand education about their child's health and make appropriate decisions on their behalf and has been directly linked with adherence to health recommendations (Adams, 2010; Kumar et al., 2010; Scotten, 2015). When education is poorly communicated, or the health literacy level is low, misunderstandings, errors and nonadherence are frequent consequences (Glick et al., 2017; NQF, 2010; Scotten, 2015). When health literacy is considered, health education is concise and focused, in plain language, with minimal medical terminology, and with methods and materials to enhance comprehension (Adams, 2010; Glick et al., 2017; Kumar et al., 2010; NQF, 2010; Scotten, 2015). Comprehension should be confirmed by utilizing the teach-back method of repeating what was explained (Adams, 2010; Scotten, 2015). A respectful, nonjudgmental approach promotes honesty and openness for questions and clarification and encourages parental engagement (Scotten, 2015).

Perception of health and knowledge of risks. Knowledge has been shown to improve parenting skills and family outcomes among substance using parents by empowering and motivating change through adherence to health recommendations (Maguire et al., 2016; Scotten, 2015; Usher et al., 2015). Consideration for change is more likely to occur when risks are explained, and significance is fully understood (Adams, 2010; Samuels et al., 2015; Sheridan et al., 2010; Wiens et al., 2016; Williams et al., 2013). When parents do not recognize or appreciate the magnitude of the condition, they are less likely to adhere to the recommendation or attend scheduled appointments (Adams, 2010; Samuels et al., 2015; Sheridan et al., 2010; Wiens et al., 2016; Williams et al., 2013).

Handout support. Verbalizing instructions unaccompanied by repetition or additional material reinforcement has been ineffective for knowledge retention and recommendation adherence (Glick et al., 2017; Scotten, 2015; Sheridan et al., 2010; Wiens et al., 2016). Care

binders present a centralized location for organization of educational handouts, plan of care goals, supportive intervention recommendations, appointment reminders and community resource lists (Klitzner et al., 2010; NQF, 2010; Taylor et al., 2013; Wiens et al., 2016). In addition to providing visual reinforcement for caregivers, the care binder empowers caregivers to manage the child's care, improves appropriate resource utilization, and promotes communication and consistency within a child's care team (Klitzner et al., 2010; NQF, 2010; Taylor et al., 2013).

Theory

The theory that was used for this project was the Health Belief Model (HBM). This model was developed in 1966 by a group of social-psychologists to identify why health recommendations were not followed and develop interventions to address those issues (Carpenter, 2010). The six concepts of the model, perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy, aligned with this project to provide education for caregivers, enabling accurate perceptions on the susceptibility and severity of prenatal methadone exposure and on the perceived benefits of follow up care in order to motivate adherence to appointment recommendations (see Appendix F) (Carpenter, 2010; Rosenstock, 1974, adapted).

The HBM is a common theoretical guide for studies looking to develop or apply an adherence improving intervention (Carpenter, 2010; Jones, Smith, & Llewellyn, 2014). Multiple studies that applied the HBM in the design report improved health behaviors and adherence, however, inconsistencies existed regarding full use of the model and all constructs bringing the model's efficacy into question (Carpenter, 2010; Jones et al., 2014). Interventions should be thoroughly detailed in studies using the HBM to clearly identify successful elements (Jones et al, 2014).

Methods

IRB Approval

The Institutional Review Board (IRB) assigned to the regional DEC clinic was utilized for this EBP project. A site agreement was obtained between this IRB and the University of Missouri – Kansas City School of Nursing and Health Studies. The IRB approved a quasi-experimental feasibility research study with a retrospective non-education group and a prospective education group.

Ethical Considerations

The infant population for this project was a vulnerable population that required careful ethical consideration (Terry, 2018). The many confounding factors that frequently accompany prenatal methadone exposure such as, poverty, high-risk environments, and polysubstance use further classified the population as vulnerable (Maguire et al., 2016). Confidentiality was essential for this project as any breach of trust may reflect poorly on DEC clinic providers and interfere with follow up at the clinic, resulting in poor long-term outcomes for the infants and their families (Terry, 2018). The student investigator has an adopted daughter that was exposed to substances prenatally. This may have presented a conflict of interest and potentially could have developed into a paternalistic mindset. To address this possibility, the student investigator did not have direct contact with the infants or their caregivers.

Funding

The expenses for this project were anticipated to be minimal (See Appendix B). A potential funding option for this project was to obtain a SAMHSA grant. Through SAMHSA, funds are available for programs that focus on substance use disorders, including community-based programs that address local drug crises. Many of the deadlines for these grants were at the beginning of the year, however, which created challenges in identifying, applying, and obtaining

approval for a grant that would be available within the time frame needed. Consequently, the student investigator provided personal funds to cover costs.

Setting and Participants

The setting for this project primarily occurred at the regional DEC clinic in a Midwestern metropolitan area. A secondary setting was the local neonatal intensive care unit (NICU). This NICU provided the referrals to the DEC clinic and initiation of the intervention began there.

Participants included infants prenatally exposed to methadone and their caregivers. Inclusion criteria included prenatal exposure to methadone with a referral to the DEC clinic. Exclusion criteria included prenatal exposure to substances other than methadone and non-English speaking caregivers. The sampling method utilized was a convenience sampling to recruit the specific population the intervention was designed to support (Terry, 2018). Three to five participants were expected based on statistics from 2017.

Intervention

Educational Care Binder. Prior to the initiation of the project, the student investigator worked with the DEC clinic providers, as well as public relations personnel to develop an educational care binder that was used as the intervention during the project. The care binder began with a non-threatening introduction to the clinic and to the providers. Historically, the clinic was erroneously associated with the Department of Human Services and Child Protection Services. Some caregivers were resistant to attending appointments due to fear of custody removal. The clinic providers wanted caregivers to accurately understand their role in the infant's care. Education on the potential long-term effects of prenatal methadone exposure was detailed in an understanding and nonjudgmental way. Many caregivers experience guilt for the symptoms their infants are experiencing due to the methadone exposure (Baldacchino et al., 2014; Beckwith & Burke, 2015; Maguire et al., 2016; Velez et al., 2009). Information was

directed toward education and not assigning blame. The benefits of follow up care was presented to empower caregivers with the knowledge and tools needed for them to assist their infants to be as successful as possible. Additional sections were provided to include a medical information section for information individualized to the infant, an appointment section where caregivers can write appointment dates and times and collect handouts provided at each visit, and a question and comment section where caregivers will be able to write notes.

Procedure. Participant recruitment was dependent on referrals from the providers in the NICU. Any infant referred to the DEC clinic for prenatal methadone exposure between the summer of 2018 and the end of the year in 2018 was included in the project. Institutional Review Board recommendations determined that informed consent was not needed. The NICU care coordinators distributed the care binder in the NICU and reviewed the contents with caregivers during the discharge process. Caregivers were encouraged to bring the care binder to all appointments.

All scheduled appointments during the first four months of life were monitored for attendance. The DEC clinic recommends follow up every three months for the first year of life and more frequently if concerns are noted. Both participants enrolled in the project should have attended a minimum of two visits by four months of age. After performing a chart review, the attendance rates of participants were compared with the attendance rates of the four infants followed by the DEC clinic for prenatal methadone exposure in the beginning of 2018. Improved attendance rates after receiving the care binder would have suggested an effective intervention (see Appendix G for the Intervention Flow Diagram; see Appendix H for Timeline Flow Chart).

Change Process and Evidence Based Practice Model

The Change Curve Model was used for the change organizational theory of this project. The first three stages of Stagnation, Preparation, and Implementation had already been experienced at the DEC clinic prior to initiation of the project (Melnyk & Fineout-Overholt, 2015). The clinic providers were emotionally invested and ready to commit to change when the student investigator originally met with them. This project pulled the clinic into the fourth stage of change, the stage of Determination (Melnyk & Fineout-Overholt, 2015). The development of the educational care binder provided a small success to encourage perseverance into the final stage of Fruition and completion of the project (Melnyk & Fineout-Overholt, 2015). Because the clinic providers requested this intervention, motivation is high to continue the change in practice after completion of the project.

The evidence-based practice model used for this project was the Stetler Model of Evidence-Based Practice. The initial phases of preparation, validation and comparative evaluation/decision making, were implemented in the early stages of project development and the translation/application phase occurred with completion (Stetler, 2001). The model is appropriate for individual practitioner projects, such as this one, and provided applicable structure and guidance for development (Stetler, 2001).

Project Design

The IRB overseeing projects implemented at the DEC clinic approved a non-randomized, quasi-experimental design (see Appendix I). Because the target population size was small and time was restricted for project implementation and completion, randomization was not feasible. There were no studies identified to provide a published comparison group, therefore, infants meeting the same inclusion criteria, who were seen earlier in the year prior to the intervention implementation, were used as a historical comparison group. Though a randomized control trial is preferred to determine if the outcome is the direct result of the intervention, quasi-

experimental is a practical design to determine if the care binder used in this project improved appointment attendance rates.

Validity

A number of factors impacted the internal validity of this project. Validity was greatly strengthened when the IRB approved the project without need for consent to be obtained. There were only two care coordinators that presented the care binders which helped to minimize variation in the presentation process. Consideration of the focused substance for this project impacted external validity and generalizability. Though often misused, methadone is a prescribed substance that is also used appropriately as prescribed. Further studies are necessary to determine the applicability to substances other than methadone.

Outcomes

The primary outcome for this project was attendance at follow up appointments with the DEC clinic. The desired outcome was to improve attendance adherence. Ideally, all participants would have attended a minimum of two appointments during the project timeline. Participant attendance data was collected during the first four months of life and then compared with the data for appointment attendance from the comparison group. Data was collected by conducting chart reviews, and no additional measurement instrument was required.

Data Quality

The outcome measures for this project have been frequently used in similar studies. A power analysis was not performed due to the expected small sample. The time restraint placed on this project and the dependence on outside referral created limitations that did not allow for a larger number of participants. There were no specific studies identified that used an educational care binder with infants prenatally exposed to methadone or any other substances, and there were no published data for comparison. Errors in collection and missing data were potential threats to

the quality of data for this project. The experience and expertise of the DEC clinic staff helped to strengthen the quality of the data.

Analysis Plan

Statistical Package for the Social Sciences (SPSS) was the program software used for organizing and analyzing the data for this project. Descriptive statistics were used to describe the basic characteristics of the data and summarize the demographic data of the participants. Information regarding single substance use versus poly substance use and parental care versus foster care was collected to establish validity among the participant groups (see Appendix J for the data collection template).

Results

Setting and Participants

The setting for this project primarily occurred at the regional DEC clinic with referrals and initiation of the intervention occurring at the local NICU. Two participants who met the inclusion criteria were identified between October 2018 and December 2018. Both participants tested positive for methadone as well as additional substances at birth. Both required a transfer to the NICU and were referred to the DEC clinic for follow up after discharge. Due to the high risk, vulnerable population involved with this project, minimal demographic data is reported.

Intervention Course

Development and printing of the educational care binder was completed and ready for distribution at the end of October 2018 (see Appendix K for final educational care binder inserts). After the care binders were given to the NICU care coordinators, the binder content, the inclusion criteria, and the process for distribution were reviewed. The care binders were provided to caregivers during the NICU discharge process when the coordinators reviewed all

follow up appointments. The NICU coordinators notified the student investigator each time the binder was distributed.

Outcome Data

A chart review revealed that four infants who tested positive for methadone as well as other substances at birth were referred from the NICU to the DEC clinic from January 2018 to July 2018. Of this comparison group, two infants attended both of the follow up visits recommended in the first four months of life and two infants did not (see Appendix L). In the intervention group, the first participant attended the initial appointment at the DEC clinic as scheduled. They did not attend the second appointment nor contact the clinic to reschedule. The second participant attended both of the recommended follow up visits (see Appendix M).

Discussion

Successes

Successes of this project were not readily clear. Originally it appeared that the project disproved any benefit of the care binder and that there were no successes to report. However, despite the apparent lack of improvement in appointment attendance, the providers at the DEC clinic have expressed gratitude to have the binder available. Though the effects of prenatal exposure to methadone education included in the binder did not improve attendance rates at the specialty follow up appointments for the two infants in this project, the DEC clinic providers felt it is still beneficial for caregivers to use the care binder as a care collaboration tool and anticipate using the accompanying sections of the binder for other populations cared for at the clinic. Further studies are needed to accurately determine the impact of the binder.

Study Strengths

The DEC clinic was an appropriate site for this project as it is the only specialized clinic in the region for children prenatally exposed to substances. The providers at the DEC clinic

personally requested this project and are invested in improving the outcomes for the project population. They provided support and expertise during the development of the educational care binder and insight to the most effective setting and timing for distribution of the binder. The NICU care coordinators routinely assisted with follow up arrangements and were personally involved with scheduling appointments for the caregivers at the DEC clinic ensuring that all infants meeting the inclusion criteria would be included in the study.

Result Comparison

There were no studies identified in the literature search that provided a direct comparison for this project. The data collected was compared to a retrospective comparison group that was identified by a DEC clinic provider after conducting a search of patients who were seen at the DEC clinic for prenatal methadone exposure in 2018 prior to the project implementation. The results for the intervention group were unchanged from the comparison group with 50% of infants in both groups attending both of the recommended follow up appointments at the DEC clinic.

Limitations

Internal Validity Effects

The small population volume for this project resulted in an inability to establish clinical or statistical significance. The care binders were distributed to both participants and their caregivers at the same location and during the same discharge process. Though this supported consistency with distribution, each care binder was provided by a different care coordinator potentially resulting in different presentations of the care binder information and the importance of continued, long-term follow up.

External Validity Effects

The high-risk, vulnerable characteristics associated with the project population may affect the generalizability of the intervention. However, the care binder would likely be transferable to other substances enabling the provider to use it with other patients seen at the DEC clinic. It could be replicated at other sites without difficulty and would be easily edited to focus on a population other than prenatal substance exposure, further strengthening the validity of the project.

Sustainability

The DEC clinic providers were pleased with the care binder and have made arrangements to finance and print additional binder inserts. The care binders will be used for a new project that has recently been initiated by the project facilitator. She has arranged to work with a local obstetrician to identify pregnant women with a methadone prescription and provide prenatal education sessions on the potential long-term effects of prenatal exposure. She plans to distribute care binders during this time to reinforce the education. The DEC clinic providers have access to the original templates and are able to make adjustments as needed changes are identified.

Efforts to Minimize Limitations

The primary limitation for this project was population volume due to the dependence on exposure and admission to the NICU for inclusion. In anticipation of this, efforts were made to prepare in advance to allow for as much recruitment time as possible. Due to challenges with the care binder design and print and study approval at the site, the recruitment time was decreased to a month and a half rather than the originally planned five months. Though the number was always anticipated to be small, the shortened recruitment time resulted in the final population volume to be smaller than expected. This directly affected the ability to determine the effect of the intervention.

Interpretation

Expected and Actual Outcomes

It was expected that participants receiving the care binder would attend the recommended follow up appointments at the DEC clinic resulting in a higher attendance rate in the intervention group. The actual outcomes revealed no change in attendance rates with the same number of infants attending follow up appointments after receiving the care binder as infants who did not receive the care binder. This outcome may be related to the small participant volume, or other variable factors, rather than an ineffective intervention.

Intervention Effectiveness and Revision

Based on the limited results achieved with the project, the intervention effectiveness findings are not valid, although the intervention appears to be ineffective. The small population volume does not allow for determination of clinical or statistical significance. With more time and additional participants, more accurate data could be collected to determine the true impact of the care binder.

Two modifications were identified that may have improved the effect of the care binder on appointment attendance. Rather than presenting the care binder and the education on the effects of methadone in the NICU, the obstetrical or methadone therapy setting may be more appropriate. During the NICU discharge process the caregivers are given a wealth of information on basic newborn cares in addition to patient specific needs. Many may feel overwhelmed and unable to retain all of the information provided. If the education for prenatal methadone exposure were provided prior to the birth of the infant, caregivers may be able to better retain and comprehend the education's significance.

The second potentially beneficial modification may be to have the DEC clinic providers review the care binder rather than NICU care coordinators. Though skilled at preparing

caregivers for discharge, they are more focused on general newborn care rather than specific effects of prenatal methadone exposure. The DEC clinic providers may better impress the importance of follow up care and are knowledgeable to answer any questions that may arise.

Impact to Health System, Costs and Policy

Specialized follow up after prenatal exposure to methadone allows for early identification and intervention prior to irreversible long-term complications develop. These complications may require costly therapies and services. Intervening early to avoid the development of these complications may have great economic impact when long term therapies and services are not needed. With no change in appointment attendance, this project did not immediately demonstrate any benefits to the health system. A larger population volume would have revealed more information to determine any affect the care binders may have.

The project costs were anticipated to be minimal. The actual costs for the project were less than expected (see Appendix N). Multiple challenges occurred when working with the site personal relations contact and the graphic designers to develop the care binder. Those challenges delayed implementation of the intervention by two months. As a result, the student investigator was not charged for printing the binder inserts. The only remaining cost for the student investigator was the purchase of the three-ringed binders themselves. With such a small population volume, only two binders were required. A total of ten binders had been purchased and the remaining eight binders along with the remaining 23 binder inserts were left with the DEC clinic providers to distribute. Additional binder inserts are available for the DEC clinic to order through their site print shop for a minimal cost. Prior to completion of the study the clinic purchased an additional 25 binder inserts and funding was supplied through the clinic cost center.

Conclusion

Dissemination of these findings occurred April 12, 2019 at the Arkansas Nurse Practitioner Association 4th annual spring conference in the form of a poster presentation. Additionally, a manuscript will be submitted for publication to bring further awareness to the issue and promote conversation for ways to better care for this population. This paper will also be included on the doctoral repository for other doctoral students to review.

Infants prenatally exposed to methadone are at risk for long term complications and benefit from close follow up care with providers who specialize in substance affected infants. Confounding factors associated with prenatal methadone exposure place infants at risk for failure to attend recommended appointments. Providing education on long term effects and benefits of early identification and intervention empowers caregivers. The educational care binder is an organizational tool that reinforces verbal education, improves knowledge retention, promotes adherence to health recommendations, and encourages caregivers to participate in the infant's plan of care. Once developed and designed, care binders are an easily replicated tool that are inexpensive to produce and simple to provide.

The current practice at the regional DEC clinic is to follow infants who are referred to them by the local NICU. This practice creates a gap in care for infants not needing intensive monitoring after birth. Follow up care may be improved if contact could be made with pregnant women in the obstetrical or MTT setting prior to delivery. Additional studies would be beneficial with larger participant numbers and with infants exposed to substances other than methadone.

References

- Adams, R. (2010). Improving health outcomes with better patient understanding and education. *Risk Management and Healthcare Policy*, 3, 61-72.
<http://dx.doi.org/10.2147/RMHP.S7500>
- Baldacchino, A., Arbuckle, K., Petrie, D., & McCowan, C. (2014). Neurobehavioral consequences of chronic intrauterine opioid exposure in infants and preschool children: a systematic review and meta-analysis. *BMC Psychiatry*, 14(1), 104-116.
<http://dx.doi.org/10.1186/1471-244X-14-104>
- Beckwith, A., & Burke, S. (2015). Identification of early developmental deficits in infants with prenatal heroin, methadone, and other opioid exposure. *Clinical Pediatrics*, 54(4), 328-335. <http://dx.doi.org/10.1177/0009922814549545>
- Carpenter, C. (2010). A meta-analysis of the effectiveness of Health Belief Model variables in predicting behavior. *Health Communication*, 25, 661-669.
<http://dx.doi.org/10.1080/10410236.2010.521906>
- Cohen, M., Morley, S., & Coombs, R. (2015). Maternal use of methadone and risk of sudden neonatal death. *Acta Paediatrica*, 104(9), 883-887. <http://dx.doi.org/10.1111/apa.13046>
- Gawronski, K., Prasad, M., Backes, C., Lehman, K., Gardner, D., & Cordero, L. (2014). Neonatal outcomes following in utero exposure to buprenorphine/naloxone or methadone. *SAGE Open Medicine*, 2. <http://dx.doi.org/10.1177/2050312114530282>
- Glick, A., Farkas, J., Nicholson, J., Dreyer, B., Fears, M., Bandera, C., ... Yin, S. (2017). Parental management of discharge instructions: A systematic review. *PEDIATRICS*, (2).
<http://dx.doi.org/10.1542/peds.2016-4165>

- Hudak, M., Tan, R., THE COMMITTEE ON DRUGS, & THE COMMITTEE ON FETUS AND NEWBORN (2012). Neonatal drug withdrawal. *PEDIATRICS*, *129*(2), e540-e560.
<http://dx.doi.org/10.1542/peds.2011-3212>
- Humbarger, O., Galanto, D., Saia, K., Bagley, S., Wachman, E., & Brogly, S. (2016). Childhood health and development in a cohort of infants exposed prenatally to methadone or buprenorphine. *Addiction Research and Therapy*, *7*(1). <http://dx.doi.org/10.4172/2155-6105.1000263>
- Jensen, C. (2014). Improving outcomes for infants with NAS. *The Clinical Advisor*, *17*(6), 85-91. Retrieved from <https://issuu.com>
- Jones, C., Smith, H., & Llewellyn, C. (2014). Evaluating the effectiveness of health belief model interventions in improving adherence: A systematic review. *Health Psychology Review*, *8*(3), 253-269. <http://dx.doi.org/10.1080/17437199.2013.802623>
- Kelty, E., & Hulse, G. (2017). A retrospective cohort study of the health of children prenatally exposed to methadone, buprenorphine or naltrexone compared with non-exposed control children. *The American Journal on Addictions*, *26*, 845-851.
<http://dx.doi.org/10.1111/ajad.12642>
- Klitzner, T., Rabbitt, L., & Change, R. (2010). Benefits of care coordination for children with complex disease; A pilot medical home project in a resident teaching clinic. *The Journal of Pediatrics*, *156*(6), 1006-1010. <http://dx.doi.org/10.1016/j.jpeds.2009.12.012>
- Kocherlakota, P. (2014). Neonatal abstinence syndrome. *PEDIATRICS*, *134*(2), e547-e561.
<http://dx.doi.org/10.1542/peds.2013-3524>
- Konijnenberg, C., & Melinder, A. (2015). Executive function in preschool children prenatally exposed to methadone or buprenorphine. *Child Neuropsychology*, *21*(5), 570-585.
<http://dx.doi.org/10.1080/09297049.2014.967201>

- Kumar, D., Sanders, L., Perrin, E., Lokker, N., Patterson, B., Gunn, V., ... Rothman, V. (2010). parental understanding of infant health information: health literacy, numeracy, and the Parental Health Literacy Activities Test (PHLAT). *Academic Pediatrics, 10*(5), 309-316. <http://dx.doi.org/10.1016/j.acap.2010.06.007>
- Levine, T., & Woodward, L. (2018). Early inhibitory control and working memory abilities of children prenatally exposed to methadone. *Early Human Development, 116*, 68-75. <http://dx.doi.org/10.1016/j.earlhumdev.2017.11.010>
- Logan, B., Brown, M., & Hayes, M. (2013). Neonatal abstinence syndrome: Treatment and pediatric outcomes. *Clinical Obstetrics and Gynecology, 56*(1), 186-192. <http://dx.doi.org/10.1097/GRF.0b013e31827feca4>
- Maguire, D., Taylor, S., Armstrong, K., Shaffer-Hudkins, E., Germain, A., Brooks, S., ... Clark, L. (2016). Long-term outcomes of infants with neonatal abstinence syndrome. *Neonatal Network, 35*(5), 277-286. <http://dx.doi.org/10.1891/0730-0832.35.5.277>
- McGlone, L., & Mactier, H. (2015). Infants of opioid-dependent mothers: Neurodevelopment at six months. *Early Human Development, 91*(1), 19-21. <http://dx.doi.org/10.1016/j.earlhumdev.2014.10.006>
- McGlone, L., Hamilton, R., McCulloch, D., Boulton, R., Bradnam, M., Weaver, L., & Mactier, H. (2013). Neonatal visual evoked potentials in infants born to mothers prescribed methadone. *PEDIATRICS, 131*(3), e857-e863. <http://dx.doi.org/10.1542/peds.2012-2113>
- McGlone, L., Hamilton, R., McCulloch, D., MacKinnon, J., Bradnam, M., & Mactier, H. (2014). Visual outcome in infants born to drug-misusing mothers prescribed methadone in pregnancy. *British Journal of Ophthalmology, 98*(2), 238-245. <http://dx.doi.org/10.1136/bjophthalmol-2013-303967>

- McGrady, M., Ryan, J., Gutierrez-Colina, A., Fredericks, E., Towner, E., & Pai, A. (2015). The impact of effective paediatric adherence promotion interventions: systematic review and meta-analysis. *Child: Care, Health and Development*, 41(6), 789-802.
<http://dx.doi.org/10.1111/cch.12271>
- McQueen, K., & Murphy-Oikonen, J. (2016). Neonatal abstinence syndrome. *The New England Journal of Medicine*, 375(25), 2468-2479. <http://dx.doi.org/10.1056/NEJMra1600879>
- Melnik, B., & Fineout-Overholt, E. (2015). *Evidence-based practice in nursing and healthcare: a guide to best practice* (3rd ed.). Philadelphia, PA: Wolters Kluwer Health.
- Melnik, B., & Fineout-Overholt, E. (2015). *Evidence-based practice in nursing and healthcare: A guide to best practice* (3rd ed.). Philadelphia: Wolters Kluwer. The levels of evidence adapted by Lindholm, L., (2017) from Melnyk & Fineout-Overholt, Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions (p. 11).
- Molfenter, T. (2013). Reducing appointment no-shows: Going from theory to practice. *Substance Use & Misuse*, 48(9), 743-749. <http://dx.doi.org/10.3109/10826084.2013.787098>
- National Quality Forum. (2010). *Preferred practices and performance measures for measuring and reporting care coordination*. Retrieved from
https://www.qualityforum.org/Publications/2010/10/Preferred_Practices_and_Performance_Measures_for_Measuring_and_Reporting_Care_Coordination.aspx
- Rosenstock, I. (1974). Historical origins of the Health Belief Model. *Health Education & Behavior*, 2(4), 328-335. <http://dx.doi.org/10.1177/109019817400200403>. The Health Belief Model adapted by Doner, T., (2018) from Rosenstock, Health Belief Model (p. 334).

- Ross, E., Graham, D., Money, K., & Stanwood, G. (2015). Developmental consequences of fetal exposure to drugs: What we know and what we still must learn. *Neuropsychopharmacology*, *40*(1), 61-87. <http://dx.doi.org/10.1038/npp.2014.147>
- Schneiderman, J., Kennedy, A., & Sayegh, C. (2016a). Qualitative study of foster caregivers' views on adherence to pediatric appointments. *Journal of Pediatric Health Care*, *31*(1), 104-110. <http://dx.doi.org/10.1016/j.pedhc.2016.05.001>
- Schneiderman, J., Smith, C., Arnold-Clark, J., Fuentes, J., & Kennedy, A. (2016b). Pediatric return appointment adherence for child welfare-involved children in Los Angeles California. *Maternal and Child Health Journal*, *20*(2), 477-483. <http://dx.doi.org/10.1007/s10995-015-1845-4>
- Scotten, M. (2015). Parental health literacy and its impact on patient care. *Primary Care: Clinics in Office Practice*, *42*(1), 1-16. <http://dx.doi.org/10.1016/j.pop.2014.09.009>
- Stetler, C. (2001). Updating the Stetler Model of research utilization to facilitate evidence-based practice. *Nursing Outlook*, *49*(6), 272-279. <http://dx.doi.org/10.1067/mno.2001.120517>
- Substance Abuse and Mental Health Services Administration. (2014). Treatment Episode Data Set: Admissions 2014. Retrieved from <https://www.datafiles.samhsa.gov/study-dataset/treatment-episode-data-set-admissions-2014-teds-2014-ds0001-nid16950>
- Substance Abuse and Mental Health Services Administration. (2015). Methadone. Retrieved from <https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone>
- Substance Abuse and Mental Health Services Administration. (2016). A collaborative approach to the treatment of pregnant women with opioid use disorders. Retrieved from Retrieved from https://ncsacw.samhsa.gov/files/Collaborative_Approach_508.pdf
- Taylor, A., Lizzi, M., Marx, A., Chilkatowsky, M., Trachtenberg, S., & Ogle, S. (2013). Implementing a care coordination program for children with special healthcare needs;

- Partnering with families and providers. *Journal for Healthcare Quality*, 35(5), 70-77.
Retrieved from <https://journals.lww.com>
- Terry, A. (2018). *Clinical Research for the Doctor of Nursing Practice* (3rd ed.). Burlington, MA: Jones & Bartlett Learning.
- The American College of Obstetricians and Gynecologists. (2016). ACOG statement on opioid use during pregnancy. Retrieved from <https://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statement-on-Opioid-Use-During-Pregnancy>
- Usher, A., McShane, K., & Dwyer, C. (2015). A realist review of family-based interventions for children of substance abusing parents. *Systematic Reviews*, 4(1), 177-188.
<http://dx.doi.org/10.1186/s13643-015-0158-4>
- Velez, M., Jansson, L., Schroeder, J., & Williams, E. (2009). Prenatal methadone exposure and neonatal neurobehavioral functioning. *Pediatric Research*, 66(6), 704-709.
<http://dx.doi.org/10.1203/PDR.0b013e3181bc035d>
- Wiens, M., Kumbakumba, E., Larson, C., Moschovis, P., Barigye, C., Kabakyenga, J., ... Ansermino, J. (2016). Scheduled follow-up referrals and simple prevention kits including counseling to improve post-discharge outcomes among children in Uganda: A proof-of-concept study. *Global Health: Science and Practice*, 4(3), 422-434.
<http://dx.doi.org/10.9745/GHSP-D-16-00069>

Appendix A

Definition of Terms

Adherence: The act of following health recommendations.

Drug Endangered Children (DEC): Children at risk for being harmed or neglected due to substance use or abuse.

Educational Care Binder: A three ringed binder that organizes the education on long-term effects of methadone and the benefits of follow up care.

Follow up care: For the purpose of this project, follow up care is care received by a DEC specialist

Long-term Effects of Methadone: Effects from methadone that occur beyond the neonatal period

Prenatal Exposure to Methadone: Infants born to mothers who used methadone either as prescribed or illicitly

Appendix B

Logic Model for DNP Project					
Student: Tria Doner					
Inquiry, PICOTS: In families with newborns exposed to methadone in utero, does receiving a care binder with education on the effects of methadone and benefits of follow-up care compared to families who did not receive the care binder, improve attendance at follow-up appointments for drug endangered children within the first four months of life?					
Inputs	Intervention(s) <i>Activities</i>	Outputs <i>Participation</i>	Outcomes -- Impact		
			<i>Short</i>	<i>Medium</i>	<i>Long</i>
<p>Evidence, sub-topics</p> <ol style="list-style-type: none"> Effects of in utero methadone exposure and need for ongoing follow up care Appointment adherence promotion Effective Education <p>Major Facilitators or Contributors</p> <ol style="list-style-type: none"> DEC clinic providers DEC clinic data manager <p>Major Barriers or Challenges</p> <ol style="list-style-type: none"> Participant recruitment – dependent on referral to the DEC clinic Participant retention – premise of the project is lack of follow up Funding for materials 	<p>EBP intervention which is supported by the evidence in the Input column</p> <p>A care binder provided to caregivers with introduction to clinic, education on risks and effects of prenatal exposure to methadone and explanation of importance for follow up care</p> <p>Major steps of the intervention (brief phrases)</p> <ol style="list-style-type: none"> Develop information to be included in the binder Binder provided and reviewed at initial interaction by DEC clinic providers Monitor number of appointments attended 	<p>The participants</p> <p>Infants exposed prenatally to methadone and their caregivers</p> <p>Site</p> <p>Regional DEC clinic in a Midwest Metropolitan area</p> <p>Time Frame</p> <p>August, 2018 to November, 2018</p> <p>Consent or assent Needed</p> <p>Awaiting IRB recommendations</p> <p>Other person(s) collecting data</p> <p>DEC Clinic data manager</p> <p>Others directly involved in consent or data collection</p> <p>DEC clinic providers will obtain consent if required</p>	<p>(Completed during DNP Project)</p> <p>Outcome(s) to be measured</p> <p>Primary: Increase in number of follow up appointments attended</p> <p>Measurement tool</p> <ol style="list-style-type: none"> Appointment attendance rate <p>Statistical analysis to be used</p> <ol style="list-style-type: none"> Independent t-test 	<p>(after student DNP)</p> <p>Outcomes to be measured</p> <p>Increase in early identification and intervention for negative consequences of in utero methadone exposure</p>	<p>(after student DNP)</p> <p>Outcomes that are potentials</p> <p>Decrease in negative long-term effects from in utero methadone exposure</p>

Appendix C

Proposed Project Cost Table

Tria Doner – Student Investigator				
Funding to be Determined				
Project Start Date 8/20/18				
Item	Cost/Unit	Quantity	Amount (\$)	Notes
Salary – Tria Doner, DNP Graduate Student	\$0.00		\$0.00	Student will not be compensated for time
Education Binder	\$2.50	10	\$25.00	1-inch binder
Color Copies	\$0.42	100	\$42.00	Copies include introduction to the clinic and providers, effects of methadone, benefits of follow up, and personalization forms
Print on Dividers	\$2.80/set	10	\$28.00	
Total			\$95.00	

Appendix D

Rating System for the Hierarchy of Evidence For an Interventional Inquiry (Modification by Dr. Lindholm for course N5613)	
Level I	Evidence from a systematic review or meta-analysis of all relevant RCTs. <i>Evidence-based clinical practice guidelines based on systematic reviews of RCTs</i> .*
Level II	Evidence obtained from well-designed RCT. <i>Quantitative systematic review of well-designed controlled trial without randomization.</i>
Level III	Evidence obtained from well-designed controlled trial without randomization (<i>quasi-experimental</i>). <i>Quantitative systematic review of case-control, cohort, or correlational studies.</i>
Level IV	Evidence from well-designed case-control or cohort study (<i>or cross-sectional study</i>)
Level V	Evidence from systematic review of <i>quantitative</i> descriptive (<i>no relationships to examine</i>) or qualitative studies.
Level VI	Evidence from a single <i>quantitative</i> descriptive (<i>no relationships to examine in the study</i>) or qualitative study
Level VII	Evidence from the opinion of authorities and/or reports of expert committees

Melnyk, B.M. & Fineout-Overholt, E. (2015). *Evidence-based practice in nursing and healthcare*. Philadelphia Lippincott Williams & Wilkins.

**Italics, appropriate in this category, modification by LL 2017 based on opinions from experts to place SR at one level higher than single study design level.*

Appendix E

Appendix E

Evidence Table

In families with newborns exposed to methadone in utero, does receiving a care binder with education on the effects of methadone and benefits of follow up care compared to families who did not receive the education binder, improve attendance at follow up appointments for drug endangered children during the first 4 months?

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
Subtopic: Effects of in utero methadone exposure and need for follow up						
<p>Kelty & Hulse. (2017). A retrospective cohort study of the health of children prenatally exposed to methadone, buprenorphine or naltrexone compared with non-exposed control children</p>	<p>To assess the health and resource use of children age 5 years and younger who were prenatally exposed to opioids</p>	<ul style="list-style-type: none"> • Retrospective controlled cohort study • Level 4 • Health outcomes 	<ul style="list-style-type: none"> • 774 children • 67 naltrexone, 198 methadone, 122 buprenorphine, 387 control • Western Australia 	<p>Various Australian medical official registries and databases</p>	<ul style="list-style-type: none"> • Increased mortality, hospital admissions, and ED visits, no difference in outpt mental health, cancer or reportable diseases • Descriptive statistics, critical p value of 0.5 	<ul style="list-style-type: none"> • Indicates higher risk for morbidity and mortality in population resulting in increased need for follow up • Comparison to control does not consider confounding factors

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
Levine & Woodward. (2017). Early inhibitory control and working memory abilities of children prenatally exposed to methadone	To examine early executive functioning of children exposed to in utero methadone and later emotional and behavioral adjustment	<ul style="list-style-type: none"> • Prospective longitudinal study • Level 4 • Inhibitory control and working memory 	<ul style="list-style-type: none"> • 156 children • 68 methadone exposed, 88 non-methadone • New Zealand 	Snack delay, three boxes tasks and caregiver completed strengths and difficulties questionnaire	<ul style="list-style-type: none"> • Methadone exposed had poorer inhibitory control, hyperactivity and peer relationship problems • χ^2 tests, <i>t</i> test, one-way ANOVA 	<ul style="list-style-type: none"> • Indicates need for follow up care in this population • Sample retention and selection bias were issues in this study
Humbarger et al. (2016). Childhood health and development in a cohort of infants exposed prenatally to methadone or buprenorphine	Compare long-term outcomes of infants exposed to methadone vs buprenorphine	<ul style="list-style-type: none"> • Retrospective cohort study • Level 4 • Long term outcomes, including routine visits 	<ul style="list-style-type: none"> • 247 infants prenatally exposed to opioid agonist therapy • 196 – methadone, 51 – buprenorphine • Boston Medical Center clinics 	ICD – 9 codes	<ul style="list-style-type: none"> • No significant differences between the groups at 2 years of age • Wilcoxon rank sum test for generalized linear models for 	<ul style="list-style-type: none"> • Confirms long-term effects indicating need for follow up • Does not compare to non-exposed control, small sample size, does not adjust for confounders

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
Maguire et al. (2016). Long-term outcomes of infants with neonatal abstinence syndrome	To review the long-term outcomes of infants with NAS beyond the neonatal period	<ul style="list-style-type: none"> • Systematic review of case-control and descriptive studies • Level 5 • Long-term outcomes of NAS beyond neonatal period 	<ul style="list-style-type: none"> • 23 research papers included • Infants diagnosed with NAS • Outpatient following discharge from nursery or NICU 	Not listed individually, variables grouped by areas of concern	<ul style="list-style-type: none"> • 8 areas of concern identified for long-term outcomes • Statistics for individual studies not included in review 	<ul style="list-style-type: none"> • Areas of concern indicate need for ongoing follow up care • Lower on evidence hierarchy, decreased quality of review when appraised
Beckwith & Burke. (2015). Identification of early developmental deficits in infants with prenatal heroin, methadone, and other opioid exposure	Examine development after opioid exposure	<ul style="list-style-type: none"> • Retrospective controlled cohort study • Level 4 • Development 	<ul style="list-style-type: none"> • 28 infants withdrawing from opioids • 16 males, 12 females • Inpatient rehab program 	Bayley Scales of Infant and Toddler Development	<ul style="list-style-type: none"> • Exposure associated with weaknesses in language and cognition • Independent-sample <i>t</i> test & χ^2 of independence 	<ul style="list-style-type: none"> • Results point to need for early intervention • Population received intense therapies during hospitalization, population in project will not receive these, very small sample size

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
Cohen et al. (2015). Maternal use of methadone and risk of sudden neonatal death	To determine correlation with methadone exposure and increased risk of SIDS	<ul style="list-style-type: none"> • Retrospective cohort study • Level 4 • SIDS deaths with history of methadone exposure 	<ul style="list-style-type: none"> • 128 neonatal autopsies • 32 were SIDS, 10 had history of methadone • Sheffield Children's Hospital in the UK 	Database of the histopathology department	<ul style="list-style-type: none"> • 37.5% of SIDS cases had history of methadone use or other drugs of addiction • No description of statistics provided 	<ul style="list-style-type: none"> • Identifies another need for follow up and important of safe sleeping education in this population • Most babies had been exposed to multiple risk factors, poor report of study
Konijnenberg & Melinder. (2015). Executive function in preschool children prenatally exposed to methadone or buprenorphine	Investigate executive function in children of women receiving opioid maintenance therapy	<ul style="list-style-type: none"> • Cohort study • Level 4 • Executive functioning related to short term memory and inhibition 	<ul style="list-style-type: none"> • 66 children • Aged 48-57 months, 24 exposed to methadone, 11 to buprenorphine, 31 comparison • Norway 	Neuropsychological tests, Behavior Rating Inventory of Executive Function – Preschool version (BRIEF-P), Wechsler Preschool and Primary Scale of Intelligence-Revised (WPPSI-R)	<ul style="list-style-type: none"> • Exposed children performed lower on tasks of short-term memory and inhibition • .01 = small effect size, .06 = medium effect size, .14 = large effect size, ANOVAs Pearson's χ^2 tests 	<ul style="list-style-type: none"> • Reports executive functioning deficits in infants exposed to methadone and possible future development of behavioral concerns • small sample size, confounding factors

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
McGlone & Mactier. (2015). Infants of opioid-dependent mothers: neurodevelopment at six months	To describe infant neurodevelopment	<ul style="list-style-type: none"> • Prospective cohort study • Level 4 • Infant neuro-development 	<ul style="list-style-type: none"> • 107 infants • 81 infants with mothers on MMT, 26 control • Large inner city maternity unit in Glasgow 	Griffith Mental Developmental Scale	<ul style="list-style-type: none"> • Scores lower in all domains indicating poorer neuro-development • Mann-Whitney tests, Kruskal-Wallis tests 	<ul style="list-style-type: none"> • Methadone exposed infants merit close surveillance throughout infancy • Small sample size
Baldacchino et al. (2014). Neurobehavioral consequences of chronic intrauterine opioid exposure in infants and preschool children: a systematic review and meta-analysis	Determine the strength and consistency of neurobehavioral impairment in cognitive and psychomotor function	<ul style="list-style-type: none"> • Systematic review with meta-analysis of case control studies • Level 3 • Neurobehavioral outcomes 	<ul style="list-style-type: none"> • 5 studies • Opioid exposed infants & preschoolers 	Multi-domain model	<ul style="list-style-type: none"> • No significant impairments, all had poorer outcomes than controls, all studies moderate to weak quality • Cohen's <i>d</i> statistics, <i>Q</i> statistic, <i>I</i>² index, significant <i>p</i> level 0.01, 	<ul style="list-style-type: none"> • Confounding factors may lead to need for follow up care rather than exposure itself • Small sample size, does not include infants with NAS

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
<p>McGlone et al. (2013). Neonatal visual evoked potentials (VEPs) in infants born to mothers prescribed methadone</p>	<p>To clarify the effects in utero drug exposures, including methadone, has on neonatal flash VEPs</p>	<ul style="list-style-type: none"> • Prospective cohort study • Level 4 • Flash VEPs 	<ul style="list-style-type: none"> • 134 infants • 84 infants exposed to methadone, 50 control • Princess Royal Maternity in Glasgow 	<p>Neonatal VEP recording</p>	<ul style="list-style-type: none"> • Altered visual electrophysiology, delay in visual maturation • Anderson-Darling, Mann-Whitney, Kruskal-Wallis tests, χ^2 tests 	<ul style="list-style-type: none"> • Indicates need for follow up and early visual assessments, linked with long-term visual, motor, and learning problems • Small sample size
<p>McGlone et al. (2014). Visual outcome in infants born to drug-misusing mothers prescribed methadone in pregnancy</p>	<p>To describe clinical visual outcomes at 6 months</p>	<ul style="list-style-type: none"> • Prospective cohort study • Level 4 • Visual outcomes 	<ul style="list-style-type: none"> • 107 infants • 81 drug exposed infants and 26 comparison infants • Princess Royal Maternity in Glasgow 	<p>Clinical visual assessment and pattern-onset visual evoked potentials</p>	<ul style="list-style-type: none"> • 40% failed visual assessment, 25% strabismus, 22% decreased visual acuity, 11% nystagmus • χ^2 tests, Fisher's exact tests, Anderson-Darling, Mann-Whitney, Kruskal-Wallis tests 	<ul style="list-style-type: none"> • Confirms link between methadone and visual disturbances • Infants not limited to methadone only, several were polysubstance exposure

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
<p>Velez et al. (2009). Prenatal methadone exposure and neonatal neurobehavioral functioning</p>	<p>To describe the neurobehavioral and self-regulation effects of in utero methadone exposure</p>	<ul style="list-style-type: none"> • Controlled cohort study • Level 4 • Neurological consistency, behavioral functions, regulation ability 	<ul style="list-style-type: none"> • 77 women on MMT with their infants • Opiate dependent mothers, infants - no complications • Inpatient exam room 	<p>NICU Network Neurobehavioral Scale (NNS)</p>	<ul style="list-style-type: none"> • Dose of methadone not a factor, days on methadone affected multiple variables • Spearman correlation matrix - NNS scores, ANOVA 	<ul style="list-style-type: none"> • Establishes a need for close follow up and monitoring due to neurobehavioral consequences • Small sample size and minimal study details
<p>Subtopic: Appointment adherence promotion</p>						
<p>McGrady et al. (2015). The impact of effective paediatric adherence promotion interventions: systematic review and meta-analysis</p>	<p>To quantify the impact of effective adherence promotion interventions on patients, families and the healthcare system</p>	<ul style="list-style-type: none"> • Systematic review of RCTs • Level 1 • Patient level, family level, and health system level outcomes 	<ul style="list-style-type: none"> • 20 studies + 8 <i>post hoc</i> • Children ≤ 18 years with chronic health condition • Clinics, homes, EDs, schools 	<p>Not listed individually, various measuring methods</p>	<ul style="list-style-type: none"> • Adherence interventions led to better quality of life, improved caregiver outcomes & improved family functioning • Standardized mean difference with 95% CI 	<ul style="list-style-type: none"> • Establishes benefit for adherence promotion interventions • Population different than project population, interventions not detailed

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
Molfenter. (2013). Reducing appointment no-shows: Going from theory to practice	Identify practices used to reduce no show rates in addition clinics and how effective they are	<ul style="list-style-type: none"> • Cohort study • Level 4 • Practices used to reduce no show and their effectiveness 	<ul style="list-style-type: none"> • 67 substance use outpatient clinics • 10 states participating in the Strengthening Treatment Access and Retention – State Initiative (STAR-SI) program 	Electronic administrative data sets	<ul style="list-style-type: none"> • Behavioral engagement strategies and adding capacity had most effect, improvement from 37% no show rate to 20% post intervention • Descriptive statistics, ANOVA 	<ul style="list-style-type: none"> • Engages substance using population to prevent no shows to appointments • Patients are in addiction treatment programs, rather than maintaining substance use as with methadone
Samuels et al. (2015). Missed appointments: Factors contributing to high no-show rates in an urban pediatrics primary care clinic	To identify factors that are associated with missed pediatric appointments	<ul style="list-style-type: none"> • Cohort study • Level 4 • Reason for missed appointment 	<ul style="list-style-type: none"> • 386 surveys • Parent who had missed an appt the previous week • A large, urban, pediatric primary care clinic 	• Telephone survey	<ul style="list-style-type: none"> • Multiple reasons identified including perception of “excellent health” • Descriptive statistics, χ^2 tests, Fisher’s exact test, ANOVA, & Kruskal-Wallis, significant p value 0.05 	<ul style="list-style-type: none"> • Explains reasons for no show and areas to address to promote attendance • Study refers to well child visits in primary care office, not project population

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
Schneiderman et al. (2015). Qualitative study of foster caregivers' views on adherence to pediatric appointments	To understand how foster caregivers view adherence to pediatric appointments	<ul style="list-style-type: none"> • Qualitative study • Level 6 • Caregiver's perceptions 	<ul style="list-style-type: none"> • 28 caregivers • 13 related, 15 unrelated foster caregivers • Community Assessment and Treatment Clinic in Lost Angeles 	Telephone interviews with 3 general questions	<ul style="list-style-type: none"> • 3 primary themes identified with one being "necessity of pediatric care" • Content analysis 	<ul style="list-style-type: none"> • Identifies knowledge of need for care as a reason for non-attendance, foster population similar • Small sample size
Schneiderman et al. (2015). Pediatric return appointment adherence for child welfare-involved children in Los Angeles California	To understand how caregivers with children in the child welfare system perceive adherence to appointment visits	<ul style="list-style-type: none"> • Controlled cohort study • Level 4 • Return appointment adherence, relationship of adherence to child, caregiver and reminder call 	<ul style="list-style-type: none"> • 87 children within the welfare system • Primarily Latino • The primary health care clinic for children in the California welfare system 	Telephone questionnaire with 6 behavioral questions and 5 knowledge questions	<ul style="list-style-type: none"> • 39% did not attend appointment, foster and birth parent the same, improved rates when scheduled within 2 months of initial appointment • χ^2 test, <i>t</i> test 	<ul style="list-style-type: none"> • Provides insight into perceptions and guides interventions to promote adherence, • Lower level of evidence, different population than project population

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
Subtopic: Education intervention						
Glick et al. (2017). Parental management of discharge instructions: A systematic review	To review literature related to knowledge and execution of discharge instructions	<ul style="list-style-type: none"> • Systematic review of experimental and observational studies • Level 2 • Knowledge and execution of discharge instructions 	<ul style="list-style-type: none"> • 65 research studies included • Parents receiving discharge instructions for their child • In patient or Ed 	Listed individually per study, not collectively	<ul style="list-style-type: none"> • Frequent errors related to knowledge of instructions, many studies showed that more than half missed follow up appts • Statistics listed for individual studies, not collectively 	<ul style="list-style-type: none"> • Increased error with low health literacy, written education with verbal decreased errors, disease-specific written instructions and decreased error • Not specific to population
Wiens et al. (2016). Scheduled follow-up referrals and simple prevention kits including counseling to improve post-discharge outcomes among children in Uganda: A proof of concept study	To evaluate effectiveness of discharge education interventions at improving outcomes	<ul style="list-style-type: none"> • Controlled clinical trial • Level 3 • Follow up visits 	<ul style="list-style-type: none"> • 216 children • Admitted to inpatient • 2 large children's hospitals in Uganda 	Medical chart, satisfaction survey	<ul style="list-style-type: none"> • 85% attended at least one follow up compared to 31% pre-intervention • Descriptive analyses, logistic regression 	<ul style="list-style-type: none"> • Written education improved follow up care adherence • Population different than project population

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
<p>Usher et al. (2015). A realist review of family-based interventions for children of substance abusing parents</p>	<p>To uncover factors that produce results from programs aimed at improving psychosocial outcomes for children with substance abusing parents</p>	<ul style="list-style-type: none"> • Systematic review of qualitative studies • Level 5 • Interventions and effectiveness in programs for children with substance abusing parents 	<ul style="list-style-type: none"> • 32 studies • 7 interventions programs based on 2 family addiction theories 	<p>Realist review methodology</p>	<ul style="list-style-type: none"> • 4 patterns or pathways: 1) opportunities for positive interactions, 2) supportive peer-peer relationships, 3) power of knowledge, 4) strategies responsive to socio-economic needs • Specific statistics not provided 	<ul style="list-style-type: none"> • Discussed the importance of engagement with substance using populations • Engagement related so specific intervention programs, may not be generalized to universal health education
<p>Williams et al. (2013). Parental education on asthma severity in the emergency department and primary care follow-up rates</p>	<p>To improve parental understanding of asthma severity and increase follow up attendance</p>	<ul style="list-style-type: none"> • Controlled clinical trial • Level 3 • Adherence to follow up care 	<ul style="list-style-type: none"> • 216 children • Diagnosed asthma • Urban pediatric ED 	<p>Post intervention telephone surveys</p>	<ul style="list-style-type: none"> • Improved follow up rates for families who received asthma severity education • χ^2 test, statistical p value $<.05$ 	<ul style="list-style-type: none"> • Establishes connection with understanding severity and follow up adherence • Different population

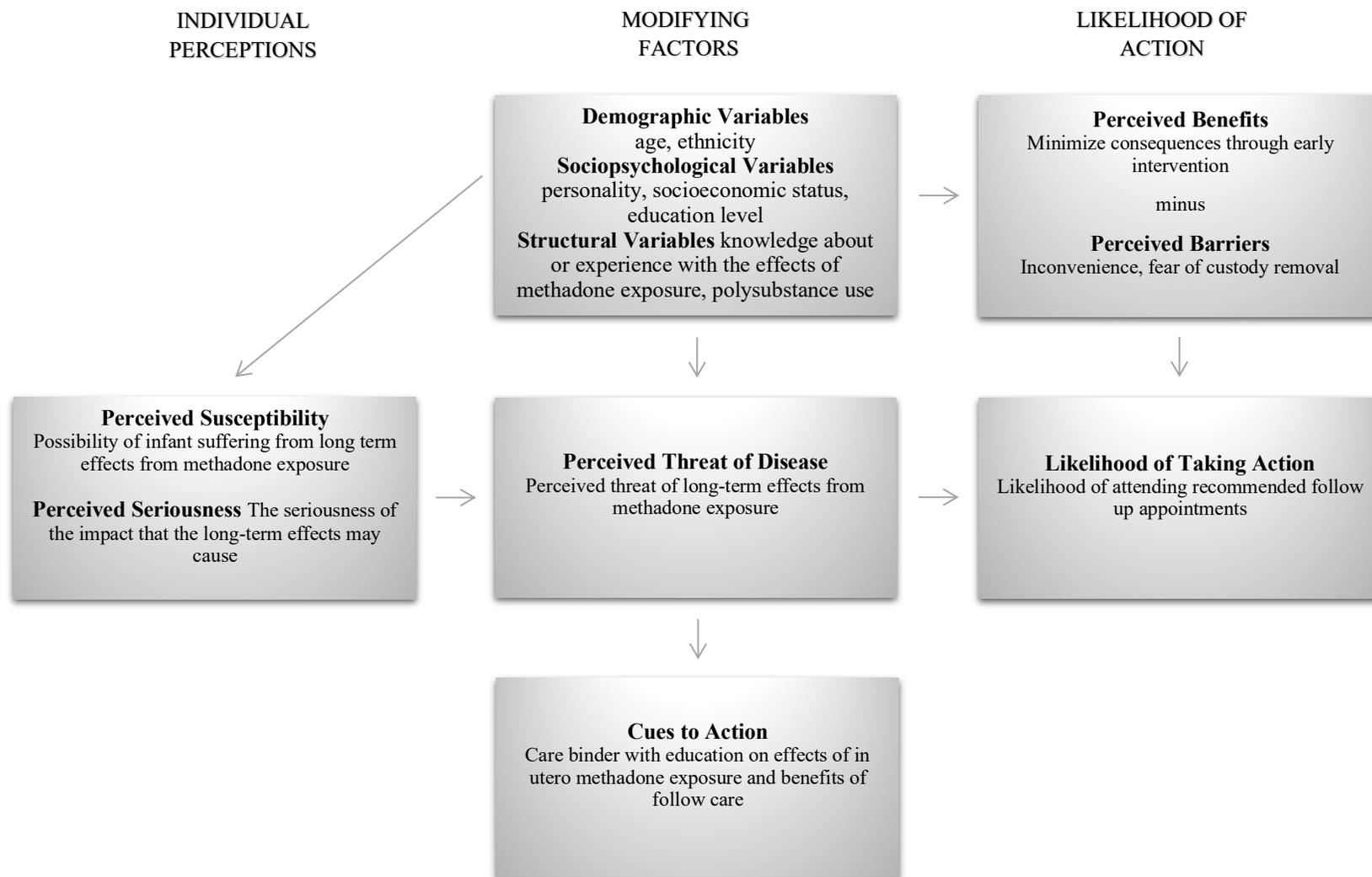
Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
<p>Taylor et al. (2012). Implementing a care coordination program for children with special healthcare needs: Partnering with families and providers</p>	<p>To determine effect of a coordination counselor and supporting tools connect patients, families and providers with services for coordinated care</p>	<ul style="list-style-type: none"> • Controlled clinical trial • Level 4 • Coordinated care connection 	<ul style="list-style-type: none"> • 439 binders, 91 with coordination counselor • Children with special health care needs • 430 bed children’s hospital with 50 outpatient clinics 	<p>Patient cross sectional survey</p>	<ul style="list-style-type: none"> • Patients who worked with a care coordinator along with secondary tools such as a care binder reported improved care coordination • Pearson χ^2 test 	<ul style="list-style-type: none"> • Describes benefits to the care binder • Different population than project population, includes addition of care coordinator that is not included in project
<p>Klitzner et al. (2010). Benefits of care coordination for children with complex disease: a pilot medical home project in a resident teaching clinic</p>	<p>To study the integration of comprehensive care coordination in children with complex diseases</p>	<ul style="list-style-type: none"> • Controlled clinical trial • Level 3 • Alterations in medical resource usage 	<ul style="list-style-type: none"> • 30 children • Children with special health care needs • Pediatric Continuity Clinic in Los Angeles, CA 	<p>Electronic medical record</p>	<ul style="list-style-type: none"> • Decreased ED visits • Descriptive statistics, Kolmogorov-Smirnov test, Student <i>t</i> test, Wilcoxon rank-sign test, 2-tailed <i>P</i> value <.05 is statistically significant 	<ul style="list-style-type: none"> • Utilizes the project intervention in the study • Additional interventions studied, the results indicated less ED usage, not increased follow up attendance, small sample size, different population

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
<p>Kumar et al. (2010). Parental understanding of infant health information: Health literacy, numeracy, and the Parental Health Literacy Activities Test (PHLAT)</p>	<p>To assess parental health literacy skills and validate a new parental literacy scale</p>	<ul style="list-style-type: none"> • Cross sectional study • Level 4 • Health literacy level, literacy scale 	<ul style="list-style-type: none"> • 182 caregivers • Caregivers for infants <13 months • Pediatric clinics at 3 academic centers 	<p>The new PHLAT, then compared with previously validated instruments</p>	<ul style="list-style-type: none"> • 99% adequate health literacy, only 17% were better than 9th grade level • Descriptive statistics, statistically significant <i>p</i> value <.001 	<ul style="list-style-type: none"> • Reviews importance of health literacy, provides direction for developing education at an appropriate health literacy level • Convenience sample, may not be generalizable
<p>National Quality Forum. (2010). Preferred practices and performance measures for measuring and reporting care coordination</p>	<p>To promote care coordination across settings and providers by endorsing a set of preferred practices and performance measures</p>	<ul style="list-style-type: none"> • A consensus report • Level 7 • Quality of care coordination 	<ul style="list-style-type: none"> • 11 measure sources • Various domains 	<p>Performance practices determined by the steering committee</p>	<ul style="list-style-type: none"> • 5 domains of focus detailed • No statistics used 	<ul style="list-style-type: none"> • Recommendations appropriate to apply to project intervention • Low level of evidence, not population specific, project site is not primary care/medical home

Article	Purpose of Study or Review	<ul style="list-style-type: none"> • Research Design • Evidence Level • Variables 	<ul style="list-style-type: none"> • Sample • Population • Setting 	Measurement of Variables	<ul style="list-style-type: none"> • Results • Data Analysis 	<ul style="list-style-type: none"> • Findings Relevant to Project • Limitations
<p>Sheridan et al. (2010). The effect of giving global coronary risk information to adults</p>	<p>To determine if knowledge of CHD risks is effective in primary prevention and improved outcomes</p>	<ul style="list-style-type: none"> • Systematic Review of RCTs • Level 1 • Accuracy of risk perception, intent to start therapy, adherence to therapy 	<ul style="list-style-type: none"> • 18 studies • 1 RCTs, 3 quasi-experimental studies • Clinical and community settings 	<p>Not listed individually</p>	<ul style="list-style-type: none"> • Risk information and education increased accuracy of perceived risk and intent to start therapy, • No specific statistical tests identified 	<ul style="list-style-type: none"> • Establishes a connection with risk information and education and intent for therapy and care • Different population and risk than project

Appendix F

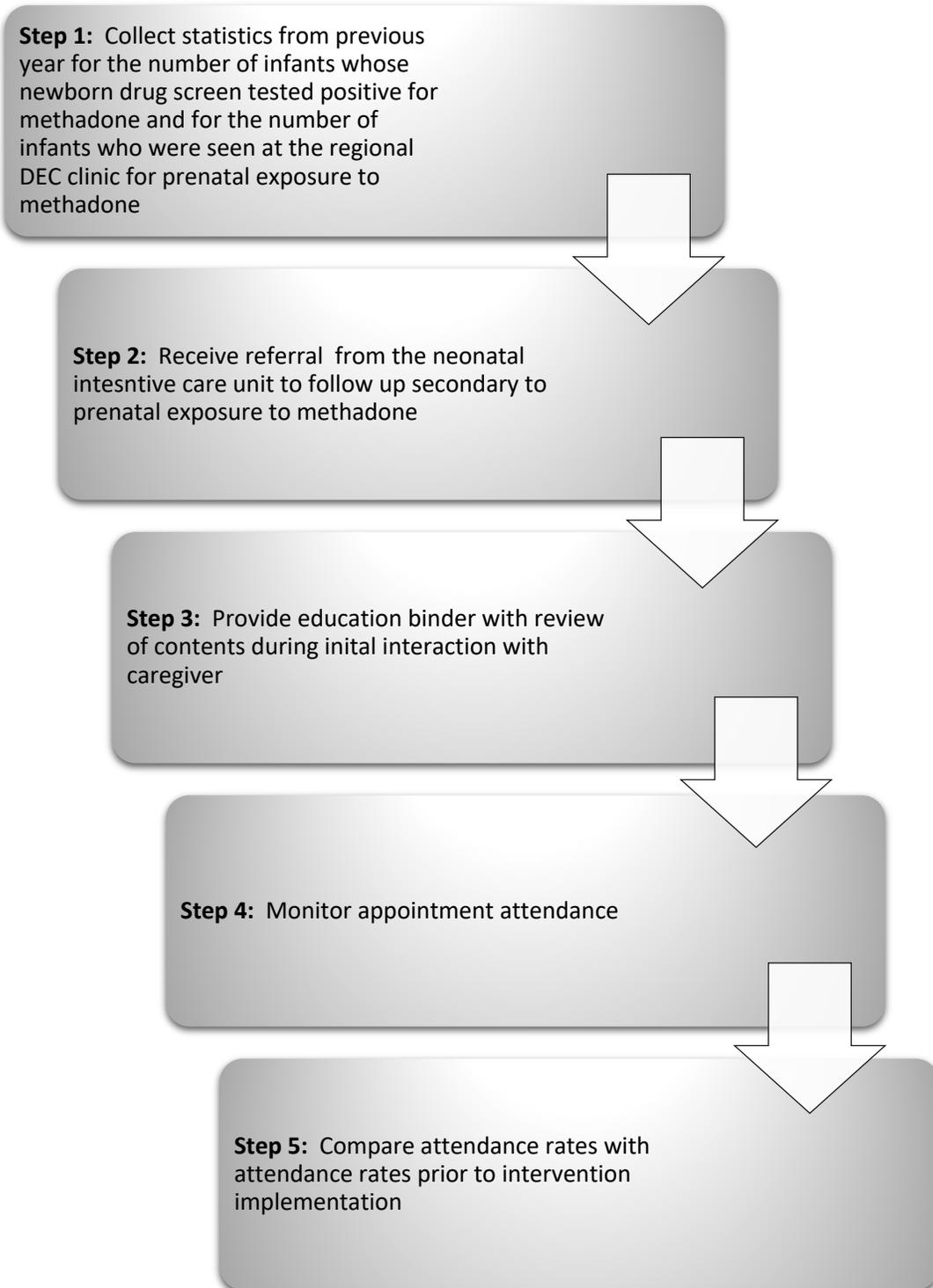
The Health Belief Model



Note. The Health Belief Model. Adapted from "Historical origins of the Health Belief Model," by I. Rosenstock, 1974, *Health Education Monographs*, 2(4), p. 334

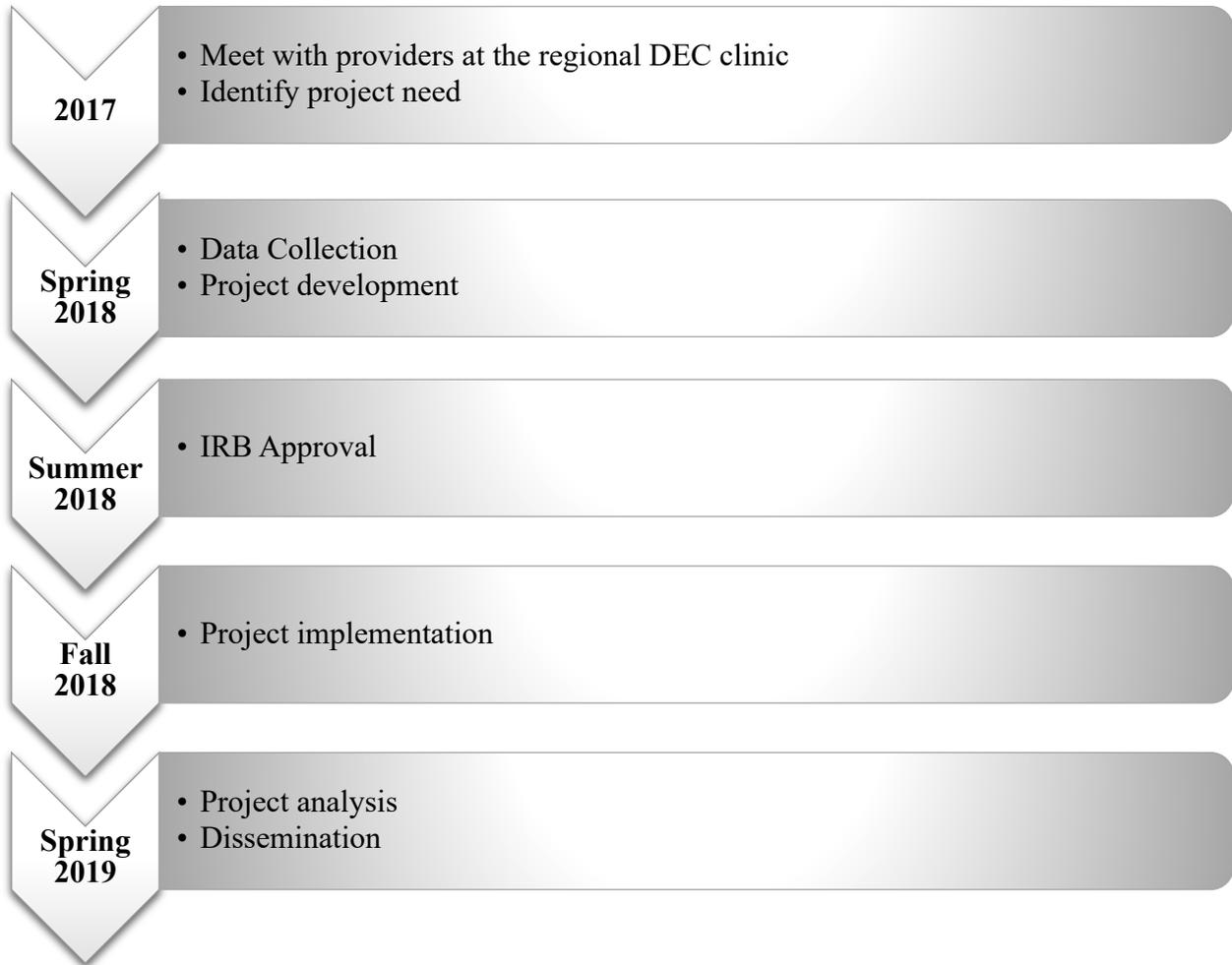
Appendix G

Intervention Flow Diagram



Appendix H

Project Timeline Flowchart



Appendix I

IRB Approval Letter

**Institutional Review Board
Human Research Protection Program**

September 6, 2018

Tria Doner

Dear Ms. Doner,

I have reviewed the Application to Conduct Research on Human Subjects, Waiver of Documentation of Informed Consent and Protocol for the following study:

Methadone Education - Educational Care Binder to Improve Appointment Attendance After Exposure to Methadone

This study has been approved by expedited review in accordance with federal regulation 45 CFR 46.110(b)(5) "Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)." All expedited reviews require notification to the full Institutional Review Board at the next convened meeting. The next IRB meeting will be October 11, 2018. *You need not be present at this meeting.*

This protocol has been assigned the following ID Number: **IM2018-074**. Please refer to this number in all correspondence regarding this protocol. Approval of a study should not be interpreted as a granting of any hospital privileges to any of the investigators participating in the study.

Your study has been approved from September 6, 2018 to August 31, 2019. The continuation review for this study will be scheduled August 2019. You will receive a continuation form to complete prior to this date. Please note: It is the principal investigator's responsibility to ensure the proper paperwork is submitted to the IRB Office prior to the study expiration date. Failure to comply with submitting materials prior to the deadline may result in investor non-compliance and the study may be suspended or terminated. If the study is suspended or terminated, all study related activity must cease and you will be required to present to the full convened IRB to reactivate the study.

If you choose to close the study prior to the continuing review date, please submit the Final Study Closure Report to the IRB office. This form can be found on the IRB website at www.unitypoint.org/irb.



is Fully Accredited by the
Association for Accreditation of Human Research Protection Programs, Inc.

Changes in the protocol may not be implemented without prior IRB review and approval, except when necessary to eliminate immediate hazard to research subjects.

Each investigator is responsible for notifying the IRB whenever approval of the study or investigator is withdrawn by the sponsor, FDA, or HHS. Additionally, each investigator shall notify the IRB in the event that the investigator discontinues the study at any time other than the scheduled completion date, and an investigator is required to report promptly to the IRB, within one working day, any fatalities and life-threatening or serious adverse events occurring in subjects enrolled in a protocol or variance from the approved protocol. At the conclusion of the study, the IRB may require such follow-up information and documentation of a completed or discontinued study as it may determine appropriate.

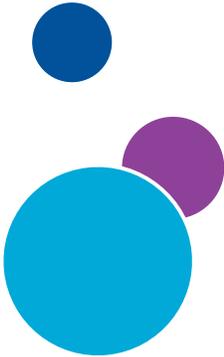
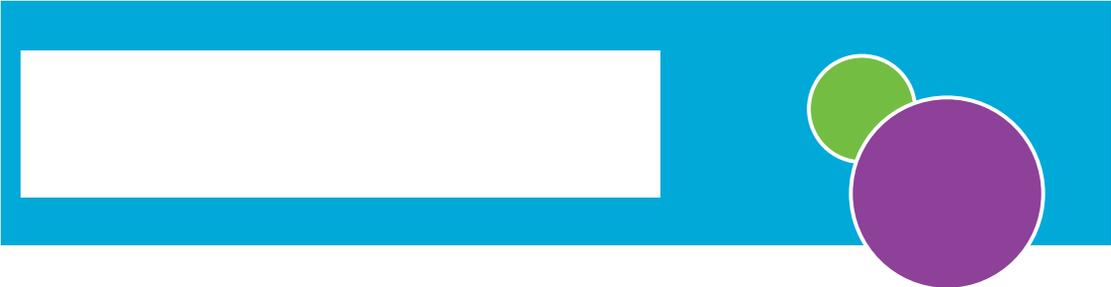
This IRB operates in accordance with all applicable federal, state and local laws and regulations. Please contact me if I can be of further assistance.

Sincerely,

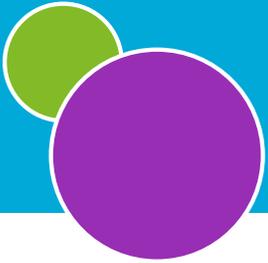
Expedited Review Committee Member

Appendix K

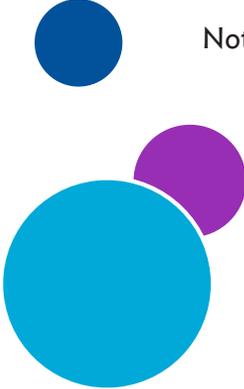
Educational Care Binder Inserts

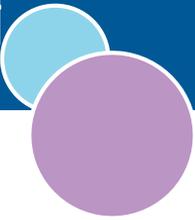


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Welcome to the 

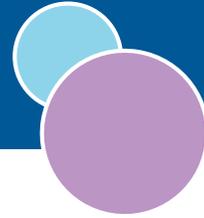
About Us

The mission of the _____ is to work as a team with experts in child health, development, and welfare to provide services and support to children which increase their resiliency and improve their health and well-being. To fulfill this mission, the _____ houses a Child Advocacy Center and three specialty clinics designed to meet the need of children and their caregivers.

Letting Childhood Begin

At the _____ we believe that every child deserves a happy and healthy childhood. We promise to provide services which help them get back on path to having one. The _____ is a unique community center designed to be child and adolescent friendly and trauma sensitive. Our staff are experts in child development and have a thorough understanding of how traumatic stress and Adverse Childhood Experiences may impact the health and well-being of children. With these principles in mind, our clinics work to increase a child's resiliency and improve their health and well-being.

What We Do



Drug Endangered Children Clinic

The Drug Endangered Children (DEC) Clinic serves children who have been exposed to drugs and/or alcohol. The clinic serves children of all ages to monitor their development and guide them in a healthy life.

Child Advocacy Center

The Child Advocacy Center provides a variety of services including forensic interviews and forensic medical examinations. Specially trained interviewers talk to children when there is an allegation of abuse or neglect. The multidisciplinary team works in collaboration with law enforcement and the Department of Human Services. Forensic exams are conducted by a pediatrician and a nurse practitioner and can sometimes be used in evidence collection.

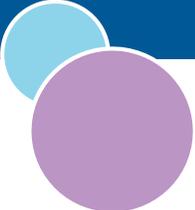
Growth and Nutrition Clinic

The Growth and Nutrition Clinic is a specialty clinic that helps families whose children are struggling with growth and weight gain. The clinic is run by a pediatrician, pediatric nurse, and a pediatric dietitian, and aims to make the growing health of your child a priority.

Foster Care Clinic

The Foster Care Clinic is a primary care clinic integrated with mental health services for children in foster care. We know these children may have special health care needs and this clinic has been designed specifically to assess and treat those needs. The clinic provides multiple services including medical care, behavioral health, school readiness, and care coordination for children, and education and support for caregivers.

Drug Endangered Children (DEC) Clinic



Why the Drug Endangered Children Clinic?

Children who are exposed to substances may have developmental, behavioral, or other medical concerns. Our team at the Drug Endangered Children (DEC) Clinic provide developmental assessments and follow-up for children who are prenatally or environmentally exposed to drugs to monitor their health and well-being and provide appropriate interventions when needed.

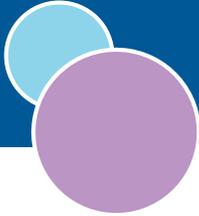
The DEC Clinic is dedicated to protecting children through multidisciplinary collaboration of services. This clinic provides services for infants and children who have been exposed to legal and illegal drugs prenatally or environmentally through a parent/caregiver's drug use or manufacturing. It is our goal to help each child and family heal and reach their maximum potential without labeling or judging. We support treatment and encouragement, not punishment or moral judgment for these families.

Upon assessment, arrangements, and referrals are made to connect the children and families with appropriate intervention and treatment services. We emphasize early identification and intervention for children exposed to drugs so that they can live a healthier life.

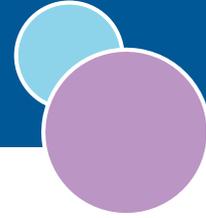
Services Provided

- Developmental assessment and followup for children who are exposed to alcohol and/or drugs
- Referrals for both the family and the child in various areas of need
- Education and advocacy for children and caregivers

Providers



Methadone



During pregnancy methadone passes from the blood to the baby. This means that methadone can affect the unborn baby as it is developing. This exposure can have long term effects as the baby grows.

Possible effects of methadone exposure

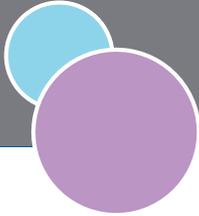
- Delayed milestones
- Slow growth
- Blurry vision
- Involuntary eye movements
- Lazy eye
- Short attention span
- Hyperactivity
- Impulsiveness
- Poor school performance
- Poor social skills
- Poor coordination

Following up with a specialist for infants exposed to substances like methadone is recommended to quickly recognize possible effects and connect infants and caregivers with the treatments and support that they need to be as healthy and successful as possible.

Benefits of follow up care at

- In depth developmental assessments to identify issues as early as possible
- Referrals to therapies and resources for infants and caregivers as needs are identified
- Education for caregivers to help the infant be as successful as possible

About Me



Child

Name: _____

Date of Birth: _____

Legal Guardian: _____

Address: _____

Daytime Phone: _____ Evening Phone: _____

Cell Phone: _____

Family Members

Mother: _____

Address: _____

Daytime Phone: _____ Evening Phone: _____

Cell Phone: _____

Father: _____

Address: _____

Daytime Phone: _____ Evening Phone: _____

Cell Phone: _____

Sibling: _____ Date of Birth: _____

Sibling: _____ Date of Birth: _____

Sibling: _____ Date of Birth: _____

Emergency Contact

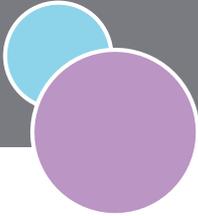
Name: _____

Address: _____

Daytime Phone: _____ Evening Phone: _____

Cell Phone: _____

My Care Team



Primary Care Provider

Name: _____

Address: _____

Phone: _____

Other Providers

Name: _____

Specialty: _____

Address: _____

Phone: _____

Name: _____

Specialty: _____

Address: _____

Phone: _____

Name: _____

Specialty: _____

Address: _____

Phone: _____

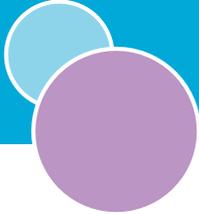
Dentist

Name: _____

Address: _____

Phone: _____

Appointments



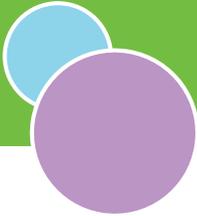
My Next Appointment is...

Date: _____

Time: _____

Provider: _____

Behavior/Symptom Journal



Use this space to write down behaviors or symptoms you are concerned about, such as not rolling over when you think they should, eyes not focusing right, or crying more than you think they should, and bring with you to share with your provider at your next visit

Behavior/Symptom	Date First Noticed	What Was Happening Before it	What Made it Better or Stop	What Made it Worse

Appendix L

Comparison Group Results Table

Participant	First Appointment	Second Appointment
Participant 1	Attended	Attended
Participant 2	Attended	Did not attend
Participant 3	Attended	Did not attend
Participant 4	Attended	Attended

Appendix M

Intervention Group Results Table

Participant	First Appointment	Second Appointment
Participant 1	Attended	Did not attend
Participant 2	Attended	Attended

Appendix N

Actual Project Cost Table

Tria Doner – Student Investigator				
Self-Funded				
Project Start Date October 2018				
Item	Cost/Unit	Quantity	Amount (\$)	Notes
Salary – Tria Doner, DNP Graduate Student	\$0.00		\$0.00	Student will not be compensated for time
Education Binder	\$2.50	10	\$25.00	1-inch binder
Color Copies	\$0.00	25	\$0.00	Copies include introduction to the clinic and providers, effects of methadone, benefits of follow up, and personalization forms
Print on Dividers	\$0.00	25	\$0.00	
Total			\$25.00	