ACE, Resilience, and Substance Use Disorder: Maternal and Baby Outcomes in the First Year of Life

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1. Objective/ Purpose

The purpose of this study is to understand the maternal factors that contribute to the health of an infant born to a mother with substance use disorder (SUD). We will evaluate whether or not the outcomes of maternal and baby health can be identified early through maternal screening tools, including the Adverse Childhood Experience (ACE) questionnaire and the 7Cs Resiliency Tool.

2. Hypothesis

Mothers with SUDs that have higher maternal ACE scores will have children with poor outcomes, including difficulty reaching developmental milestones, poorer adherence to vaccination schedule guidelines, and more frequent ER visits in the first year of life. However, high maternal resilience scores may counter the high ACE scores and allow for improvement of poor health outcomes in these populations.

3. Background

Adverse Childhood Experiences (ACEs) are traumatic or life-threatening events that occurred to an individual during the ages 0-17 and are measured with the ACE Score questionnaire. These experiences include being a victim of physical and sexual abuse, neglect, and exposure to household dysfunction such as parental substance abuse or incarceration[1]. Multiple studies have shown that the number of ACEs an individual experiences correlates with his or her risk in developing chronic health issues such as diabetes, asthma, and hypertension later in life [2-4]. In addition, ACEs correlate with a higher risk of engaging in risky behaviors such as substance use[5].
A recent survey conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA) showed that 5.4% of pregnant mothers had used illicit drugs including marijuana, opioids, and cocaine in the past month[6]. Moreover, ACE scores of pregnant women have been linked to poor coping mechanisms such as illicit drug use during pregnancy[7]. These scores also impact prenatal,

perinatal, and post-natal health[8]. For example, babies who were exposed to opioids in utero had significant associations with poorer health outcomes and delays in developmental stages[9]. Another study concluded that mothers suffering from substance use disorder engage in poor parenting practices such as “limited or absent parental monitoring and lower levels of parental involvement.”[10]
Currently, many medical practices are using ACE scores as a general screening tool to help identify health risks and provide individualized care and family support[11]. Recent studies show that identifying positive childhood experiences is important when evaluating the impact of ACEs. Protective factors, such as resilience, can offset the negative health impacts of trauma[12,13]. Described as good outcomes in the face of a threat to wellbeing[13], resilience can be quantified by using a questionnaire called the 7Cs tool[14]. The 7Cs tool, which examines an individual’s competence, confidence, character, connection, contribution, coping and control, is a valid method to measure resilience. Currently, the 7Cs tool is internally validated for adolescents that have experienced trauma, and it has shown a correlation between better outcomes with a higher resilience score despite having higher ACE scores.
Overall, there is limited information regarding ways to identify and determine the health impact of maternal resilience. More research is necessary to understand how ACEs and resilience affect postpartum outcomes in mothers with SUD and their child.

Significance of the Research

Currently, little research has been conducted to study the relationship between ACEs and maternal resilience and the health outcomes of mothers with SUDs and their newborn baby. Understanding factors that show a strong correlation with maternal and fetal health outcomes would allow health care providers to identify risks earlier, offer prenatal interventional care, and provide tailored resources for mothers and their infant.

4. Study Design

This is a prospective observational study that will require the initial administration of both the ACEs questionnaire and 7Cs resilience tool, followed by one year of chart reviews and/or phone calls to follow-up with patients regarding the identified outcome measures.

5. Proposed research Plan

A. Subjects

Number of subjects: 100

Inclusion criteria: Pregnant mother past her 1st trimester of pregnancy who is being seen at Cooper University Hospital Addiction Medicine clinic or Labor and Delivery or Maternal Fetal Medicine Unit. The subject is diagnosed with substance use disorder.

Exclusion criteria: Mothers under the age of 18.

Recruiting Methods: Subjects will be recruited through the Addiction Medicine clinic at Cooper Hospital. Staff at the clinic will ask any pregnant mothers, past their first trimester, if they are interested in participating in this study. Interested participants will be contacted by study co-investigators to learn more about the study. If all inclusion criteria is met, the pregnant woman will be invited to participate in the study.

Informed Consent Process: Prospective subjects will meet with either of the study co-investigators named earlier in the proposal. Additionally, prospective subjects may meet with the clinical psychologist on the study, Laura Park. All subjects will be given a copy of the informed consent to read along with the study co-investigators. Potential subjects will be invited to a private room away from distractions and will be allowed adequate lime to ask questions and read the consent forms.

Vulnerable Subjects: This study will include vulnerable subjects, namely pregnant women and their child.

Compensation to Subjects: No financial or other compensation will be offered to the subjects in exchange for participating in this study.

Treatment for Research-Related Injuries: No research-related injuries are anticipated in relation to participating in this study. If any research-related injuries are sustained during the course of this study, the subject may reach out to the research investigator or co-investigators to determine the appropriate course of action. While conducting ACEs and resilience interviews, re-traumatization will be a concern which would be handled by the current resources available through the Addiction Medicine clinic and Cooper Hospital.

B. Research Methods and Procedures

General description of methods and procedures: After consenting to participate in this study, pregnant mothers will be provided a modified survey based off of the Adverse Childhood Experiences (ACE)

questionnaire and 7C Resilience Tool. After giving birth, patient charts will be monitored for maternal commitment to treatment, child custody status, the number of times the child was admitted to the emergency room, adherence to recommended pediatric vaccination schedules, and infant developmental milestones. These measurements will be taken over the course of 1 year after child birth.

Summary of visit procedures: Pregnant mothers will meet with any of the co-investigators prenatally to complete the ACE questionnaire and 7C Resilience Tool. After the initial intake, outcome measures will be collected via chart review or verbally through phone call with the mother. Data will be collected at birth, 2 months, 4 months, 6 months, and 1 year after birth.

Procedures just for research purposes: The ACEs questionnaire and 7C Resilience Tool are not included in standard prenatal care and are solely being administered for research purposes. If the subjects were not enrolled in this study, the only difference in care would be the absence of either screening tool being administered prenatally.

How participation differs from standard of care/ study duration: As an observational study, participating subjects will be provided the appropriate standard-of-care.

Study Duration: Pregnant mothers will be enrolled between March 1, 2020 to August 1, 2020. All mothers will be followed for one year postpartum. The total duration of the project for the individual will be the duration of the pregnancy as well as the child's first year of life. This study will be conducted between March 1, 2020 - January 31, 2020.

<u>Data Analysis Plan, Statistical Tests, and Sample Size Rationale</u>

Outcome measures being followed at birth of baby, and at 2, 4, 6 and 12 months after birth:

1. Is the mother still parenting and have custody of the baby?
2. Is the mother receiving treatment for substance use disorder?
3. Has the baby reached expected developmental and health milestones after delivery?
4. How many Emergency Room visits did the baby have postnatally?
5. Does the child meet vaccination schedule as proposed by the CDC?

Sample size. The key outcomes of the study will include binary measurements (parenting, custody, continued treatment, etc.) measured at 2, 4, 6 and 12 months after birth. These outcomes will be related to the pre-natal scores of the ACE and 7C survey tools. Based on a repeated measures design, a sample size of 100 will provide >90% power to detect an odds ratio of 2 or greater for each standard deviation above the mean of the ACE scale (1-10) assuming a mean of 3.7 and a standard deviation of 2.7 and a response proportion of 0.50.

Data Analysis. The checking, assessment and analysis of the data will be carried out in a blinded fashion. Demographic and clinical characteristics will be presented using means with standard deviation for continuous variables and counts with proportions for categorical variables. The statistical analysis will be carried out using "intention-to treat" and "per-protocol" approaches. The primary outcomes (parenting, custody, continued treatment, etc.) will be analyzed using generalized estimating equations (GEE) appropriate for repeated measures over time. Odds ratios with 95% confidence intervals for the relationships of ACE and 7C with the clinical outcomes will be presented.

6. Risks and benefits

A. Potential Risks due to Study Participation: No study treatments will be included in this observational study. However, in some cases, re-traumatization is a possibility and necessary resources will be made available to the subject.

B. Minimizing Risks: Risks to subjects will be minimized by the study design, which is observational and not anticipated to be risky towards the mother or fetus. Subjects being seen at the Addiction Medicine clinic and Labor and Delivery Ward will have normal access to treatment and follow-up visits, which follows normal standard of care at Cooper Hospital.

C. Potential Benefits; Potential benefits of this study would be increased adherence to substance use disorder (SUD) treatment, appropriate follow-up with pediatricians per recommended vaccination schedule, and identifying risk factors during pregnancy to initiate early intervention practices. Society may benefit from this research by understanding the risks of ACEs and resilience scores of pregnant mothers suffering from SUD and how it affects the care of their newborn child. The findings of this

study may benefit the resources and management of mothers with SUD during pregnancy and postpartum.

D. Risk: Benefit Ratio: Due to the absence of risks associated with this study, the ratio of risks to benefits is reasonable to individual subjects and society.

7. Plans for Monitoring Subject Safety

Subjects are being enrolled in an observational study, there are no anticipated adverse events during the course of this study. However, in some cases, re-traumatization may be possible and necessary resources will be made available to the subject.

8. Procedures to Maintain Privacy and Confidentiality

All information obtained in this study will be strictly confidential, except, as may be required by law. Each mother and infant will be assigned a number and patient's name and identifying information with that number will be kept in a separate locked cabinet. We will use only the assigned number to the infants on the data sheet. All the files and records created for this study will be stored in Dr. Kushnir's office at 755 Dorrance and Cooper Hospital in a locked cabinet or in a computer with a password. Any publication resulting from this study will refer to the patient by a pre-assigned number. No published data will disclose the identity of any patient.

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