

**BABY AND ME, WITHOUT HEP C: AN EARLY INTERVENTION EDUCATION  
CAMPAIGN TO BETTER THE OUTCOMES OF HCV IN MOTHERS AND  
NEONATES**

by

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**ABSTRACT**

Hepatitis C infection is a growing public health concern, exacerbated by the opioid epidemic that continues to make headlines in Southwestern Pennsylvania and across the United States. With the primary means of transmission being blood borne from percutaneous exposure, the hepatitis C virus (HCV) is most commonly spread among injection drug users through unsafe injection practices. Although measures are being taken to aid individuals with substance use disorder (SUD) access efficacious treatments for cessation, such as Medication Assisted Treatment (MAT), few SUD treatment programs incorporate a hepatitis C education curriculum emphasizing how to prevent infection and transmission of HCV. A group of individuals that is overlooked when considering the long-term burden of HCV infection is pregnant women and their unborn babies, potentially because of the stigma around drug use and pregnancy. There is a need to intervene to improve birth outcomes and improve postpartum HCV treatment adherence in women with SUD.

The proposed public health intervention will incorporate an educational booklet that is based on the Information-Motivation-Behavioral skills (IMB) model. This self-guided booklet will be given to women at risk for pregnancy who are currently involved in SUD treatment in the Greater Pittsburgh Area, and will contain HCV prevention and treatment information, as well as a daily paper diary used in conjunction with their treatment to yield better outcomes because of

the behavioral motivation. The ‘Baby and Me, Without Hep C’ booklet program will be a low-cost way for already established pregnancy/SUD centers to potentially lessen the burden of HVC infection on mothers and babies.

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## PREFACE

I would like to extend my sincere thanks to my Essay Committee, Dr. Derrick Matthews and Dr. Martha Terry, for offering their unending support and guidance in assisting me to complete the Masters Essay as a part of the Master's of Public Health requirements. Although the journey was far from easy, Dr. Terry and Dr. Matthews were encouraging the entire time. The faculty and staff of the Graduate School of Public Health have been nothing short of extraordinary, and have significantly contributed to my unending passion for public health. As Dr. Seuss once said, "Unless someone like you cares a whole awful lot, nothing is going to get better. It's not."

## 1.0 INTRODUCTION

The increase in opiate abuse among all populations has caused great concern for special populations, such as pregnant women. One of the implications of pregnant women using opiates is the effect that it has on the unborn infant. In addition to putting the baby at risk for neonatal abstinence syndrome (NAS), a condition that an opiate addicted infant will experience after exposure to drugs in-utero, the baby is also at risk for contracting hepatitis C from an infected mother (“U.S. National Library,” 2015). With an estimated 5% risk of vertical transmission, HCV infection during pregnancy generates several concerns, including the effect of pregnancy on the course of chronic HCV infection, and the impact of maternal infection on pregnancy outcomes (Huges, 2017).

In the tri-state area of Pennsylvania, Ohio, and West Virginia, the opiate epidemic has hit relatively harder than in other areas of the United States. Because of the vast numbers of individuals with SUD, area health entities have begun incorporating and innovating SUD treatment into everyday practice. In 2014, the city of Pittsburgh opened a state-of-the-art center to treat pregnant women with opiate use disorder. The Pregnancy Recovery Center is located at Magee-Women’s Hospital of UPMC, and offers comprehensive care for women with opiate addiction by caring for both the developing fetus and the mother (Kreps, 2017).

Despite the urgent push for comprehensive care for individuals with SUD, the treatment of HCV as it relates to pregnancy and SUD has been neglected (Pergam, 2008). While substance

abuse treatment centers tailored for pregnant women provide many services to improve the outcomes for both mom and baby, they can benefit by having an additional service that encourages HCV infection prevention and treatment initiatives.

## **1.1 OPIOID EPIDEMIC AND INJECTION DRUG USE**

In the 1990s, a new approach was adopted in regard to pain management, allowing for more chronic pain sufferers to have access to opioid painkillers. Drugs once used only for cancer patients going through rigorous treatments were made available to anyone with pain and a prescription for opiates. Opioids reduce the intensity of pain signals reaching the brain and affect those brain areas controlling emotion (“Misuse of Prescription Drugs,” 2016). In turn, that lessens the effects of the pain. Many opiates affect the brain regions that are involved in reward, resulting in a euphoric response. Because of this phenomenon, many who abuse opioids may seek to intensify their experience by taking the drug in ways other than prescribed. Inevitably many turn to an even more potent and dangerous drug, heroin.

Both the Centers for Disease Control and Prevention (CDC) and Agency for Healthcare Research and Quality (AHRQ) agree that the opioid epidemic has caused over 500,000 preventable deaths since 2000 nationwide. Since the year 2002, heroin-related overdose deaths have increased 286 percent nationwide (“Today's Heroin Epidemic,” 2015).

In 2015, heroin was the most frequently identified drug in autopsies. Autopsy reports indicate that upwards of 55 percent of the 3383 drug related overdose victims had heroin in their system (“Today’s Heroin Epidemic,” 2015) Nearly 200 overdose deaths have been reported in 2016 in Allegheny County, Pennsylvania alone (Bowling, 2014). The statewide drug overdose

death rate in Pennsylvania is nearly twice that of the national overdose death rate (26 per 100,000 people vs 14.7 per 100,000 people) ("Today's Heroin Epidemic," 2015). Unlike other drug-related epidemics that North America has faced, the opioid epidemic has hit rural communities the hardest, further exacerbating the associated human suffering and productivity loss (Harrison, 2016). Although white males between the ages of 30 to 39 years old have the highest number of overdose related deaths in Pennsylvania, the rate of fatal overdoses among women is increasing quicker than that of the rate of men (Fucco, 2016). In addition to the immediate effects of opioid use on an individual, new data show that the rate of infants born with drug abuse-related problems, such as neonatal abstinence syndrome (NAS), has risen 250 percent from 2000 to 2015. In 2016 alone, 19.5 out of every 1,000 newborn hospitalizations are the result of the mother's painkiller or heroin use (Observer-Reporter, 2016).

Those addicted to opioid painkillers are 40 times more likely to become addicted to heroin than those not addicted to opioid painkillers. Fortunately, there is well-supported scientific evidence that individuals with SUD can be effectively treated with reoccurrence rates similar to those of other chronic illnesses like diabetes, asthma, and hypertension ("HHS takes strong steps," 2015). One of the more effective treatments for substance use disorder is medication assisted treatment (MAT), which typically involves a combination of synthetic opiates such as methadone, buprenorphine, or naltrexone with counseling, behavioral therapies, and harm reduction strategies ("Today's Heroin Epidemic", 2015). Mentioned earlier, the innovative recovery centers for pregnant women are utilizing MAT on an outpatient basis.

There are also several more unconventional approaches to helping those with SUD. Although not yet legal in many states, clean needle exchanges have arisen with the intentions of providing a safe place for drug users to obtain safe injection materials to lower the risk of

contracting needle borne diseases. Clean needle exchanges have in fact been proven to be an effective public health intervention that reduces the transmission of diseases by intravenous drug use, as well as not further encouraging the use of illegal drugs (“HHS takes strong steps,” 2015). Most needle exchange programs also offer additional services including HIV/AIDS counseling and other STD testing, as well as strategies and education materials for preventing sexually transmitted infections.

## **1.2 SUBSTANCE USE DISORDER IN PREGNANT WOMEN**

A study published in 2007 noted that in the United States, women are at the highest risk for developing some form of a substance use disorder during their reproductive years, particularly between ages 18-29 (Frances, 2008). Substance use before, during, and after pregnancy poses risks to the developing fetus and the newborn infant, as well as the mother. Women with SUD are typically at higher risk of sexually transmitted infections, such as HIV and HCV. Additionally, women with SUD typically have higher rates of unmet reproductive health needs, comorbid psychiatric illness, and postpartum depression (PPD) in comparison to women without SUD (Heil, 2011). Failure to complete the full course of substance use treatment is associated with poor adherence to prenatal care, poor prenatal nutrition, and the worsening or initiation of concomitant psychiatric illnesses (Benningfield, 2010). Pregnant women with SUD, as well as their children, are more susceptible to psychosocial problems than pregnant women without SUD. Childhood sexual abuse, intimate partner violence, posttraumatic stress disorder, and overall psychological distress are just a few of the concerns that women with SUD are more likely to have experienced

in their lifetime (Engstrom, 2012). All of those concerns can contribute to poor health and a compromised well-being in pregnant women with SUD.

### **1.3 HEPATITIS C VIRUS IMPLICATIONS**

Currently, approximately 3.7 million people living in North America have hepatitis C. The number of HCV-related deaths rose from 333,000 in 1990 to over 704,000 in 2013. This drastic increase reflects the high incidence of HCV through the mid-twentieth century, as well as the increase in parenteral procedures and injection drug use in the 1940s (Salvi, 2016). The estimated prevalence of HCV in pregnant women in the United States is 4% (Huges, 2017)

A blood borne disease, hepatitis C is a small, positive-strained RNA-enveloped virus that can enter the body through any perforation of the skin. Upon the virus entering the body, it travels through the blood and goes to the liver (“Addressing Viral Hepatitis,” 2011). The transmission and harboring of HCV are important in individuals with SUD because those individuals are more likely to be using unsterile injection materials and have underlying liver issues due to alcohol abuse (Takahashi, 2001). Although the primary means of HCV transmission is direct percutaneous exposure to infected blood, HCV may also be transmitted sexually. However, sexual transmission of HCV is much less likely than sexual transmission of other blood-borne viruses, like hepatitis B (HBV) and human immunodeficiency virus (HIV) (Terrault, 2002). Like most all other infections that can be transmitted sexually, HCV infection rates are higher in people who have more than one partner and highest in those co-infected with HIV (“Addressing Viral Hepatitis,” 2011).

Most people with a HCV infection are asymptomatic. The virus is not able to be detected in the blood for approximately seven to twenty-one days, and only 15 to 25 percent of infected

individuals are able to clear the infection. Of those who are unable to fight off the infection, 75-85% will end up with chronic hepatitis C. Disease progression is slow, presenting anywhere from 20-30 years after the initial infection, and typically in the form of severe liver damage (“Addressing Viral Hepatitis,” 2011). The only way to determine if an individual is infected with hepatitis C is by performing a nucleic acid test (NAT) for HCV RNA, which would allow one to see whether or not there are anti-HCV antibodies present (Thomas, 2011).

Hepatitis C is one of the more genetically diverse hepatitis virus strains, being classified into six different genotypic groups. This genetic variation amongst hepatitis virus strains is important to understand because certain treatments are significantly more effective on certain genotypes than on others (Simmonds, 2001). Although the cost of hepatitis C treatment is high regardless of the geographic location and genotype presence, the cost of genotyping for treatment alone presents an additional barrier to already disadvantaged areas. The most common genotype in North America is genotype 1, accounting for 75% of all infections (Messina, 2015).

The World Health Organization (WHO) argues that greater access to HCV testing and better surveillance are important steps to both increase the number of persons diagnosed with HCV, and to improve understanding the distribution of HCV infection in groups of increased risk (“Guidelines for the Screening,” 2016). In 2012, the WHO released recommendations for the prevention of HCV infection among people who inject drugs, which can be found in Table 1 below (“Guidance on prevention,” 2012).

**Table 1. WHO Recommendations for Prevention of HCV Infection Among People Who Inject Drugs**

1	Offer people who inject drugs the rapid hepatitis B vaccination regimen.
2	Offer people who inject drugs incentives to increase uptake and complete the hepatitis B vaccination schedule.
3	Implement sterile needle and syringe programs that also provide low dead-space syringes for distribution to people who inject drugs.
4	Offer peer interventions to people who inject drugs to reduce the incidence of viral hepatitis.
5	Offer opioid substitution therapy to treat opioid dependence, reduce HCV risk behavior and transmission through injection drug use, and increase adherence to HCV treatment.

HCV infection plays a significant role in adverse outcomes in pregnancies, for both mothers and babies. Infants born to women infected with HCV were more likely to be small for gestational age, have low birthweight, require admission to a neonatal intensive care unit, and require assisted ventilation. Maternal HCV infection is significantly associated with fetal growth restriction as well as low birthweight (Pergam, 2008). However, it is difficult to know for certain whether the increased risk of the above-mentioned fetal outcomes is due to the viral effect of HCV, or to the potential cofounders in women with SUD and HCV infection. These potential cofounders will be discussed in section 2.2.

In women who are HIV negative, the risk of vertical transmission, or the chance that the virus is passed from mother to child, is 5.8 percent. Maternal HIV coinfection is the most important risk determinant of vertical transmission of HCV (adjusted odds ratio, 2.56 [95% CI, 1.50-4.43]), with an estimated risk of 10.8 percent (Benova, 2014). Vertical transmission of HCV has been found to be a risk only for women with detectable HCV RNA during pregnancy, as opposed to detectable HCV antibody, but the level of HCV present in the blood has yet to be determined as a risk factor (Benova, 2014).

## **2.0 CURRENT PUBLIC HEALTH INTERVENTIONS**

The need to improve outcomes in people with SUD has become a public health priority. The subsequent sections outline SUD and HCV treatment among pregnant women.

### **2.1 SUBSTANCE USE DISORDER TREATMENT FOR PREGNANT WOMEN**

A widely accepted therapy for individuals with SUD is MAT. MAT is unique in that it combines behavioral therapy with pharmacotherapy, presumably bettering the outcomes for people with SUD (Substance Abuse and Mental Health Services Administration, 2011). Most all treatment plans emphasize the need for behavioral therapies, as they typically address the underlying causes for a person's substance use. To effectively treat SUD, strategies must be integrated with efforts to address substance use disorder and associated infectious diseases, such as HCV. Although MAT is considered as an effective, evidence-based treatment, it is important to note that it is not successful for all individuals.

Pittsburgh, Pennsylvania, is home to one of the first centers that focuses on both obstetrics and opiate dependence. Located at Magee-Women's Hospital of UPMC, the Pregnancy Recovery Center is a collaboration between four local Managed Care Organizations (MCOs) and the Allegheny County Office of Behavioral Health. The Pregnancy Recovery Center utilizes a newer pharmacotherapy called buprenorphine to help opiate dependent mothers. Buprenorphine has been found to yield overall better birth outcomes and less severe neonatal abstinence syndrome (NAS)

compared to the other opiate withdrawal drug, methadone (Jones, 2012). Although still effective, the use of methadone during pregnancy poses a risk because it can be abused.

Located in the Greater Cincinnati area, the Helping Opiate-addicted Pregnant women Evolve (HOPE) Program develops personalized care plans to reduce the risk of preterm birth and optimize pregnancy outcomes. The HOPE program provides pregnant women with the following:

- case management,
- social work support,
- referrals to available community support services,
- nutrition counseling,
- financial counseling,
- referrals to methadone maintenance treatment facilities/Subutex providers,
- ongoing follow up with MMT facility counselors,
- referrals to outpatient and inpatient treatment facilities,
- referrals to prenatal care,
- ongoing patient follow up at one of the local prenatal clinics, and
- prenatal care and follow up care for high risk pregnancy problems.

The HOPE Program uses outcome measures such as neonatal birth weight, compliance with prenatal appointments, and involvement in chemical dependency treatment programs to determine the effectiveness of the program (HOPE Program, n.d.).

## 2.2 HEPATITIS C SCREENING AND TREATMENT FOR PREGNANT WOMEN

Currently, the American College of Obstetricians and Gynecologists (ACOG) and the CDC recommend the pregnant women be screened based upon their risk of acquiring HCV. The standard screening test for HCV is an anti-HCV antibody test, which indicates whether the individual has an active HCV infection, the patient had a past infection that has resolved, or the result is a false positive (Trooskin, 2015). However, some researchers have suggested universal prenatal screening, regardless of what the woman’s risk for contracting HCV is (Huges, 2017). The strengths and limitations of universal screening are outlined later in section 2.3. The HCV screening recommendations of the ACOG and CDC are outlined in Table 2 below.

**Table 2. Women in Whom Prenatal Screening for Hepatitis C Virus is Recommended**

1	Women who ever injected illegal drugs (even once).
2	Users of intranasal illicit drugs.
3	Women ever on long-term hemodialysis.
4	Women with percutaneous/parenteral exposures in unregulated setting (for example, tattoos received outside of licensed parlors or medical procedures done in settings without strict infection control policies).
5	Recipients of transfusions or organ transplants before July 1992 and recipients of clotting factor concentrates produced before 1987.
6	Recipients of blood products from donor who later tested positive for HCV.
7	Women with History of incarceration.
8	Women seeking evaluation or care for sexually transmitted infection, including HIV.
9	Women with unexplained chronic liver disease (including persistently elevated ALT).
<i>Society for Maternal-Fetal Medicine. HCV in Pregnancy. Am J Obstet Gynecol 2017.</i>	

Although HCV viremia can be detected in the blood approximately three weeks after exposure, the actual diagnosis of HCV depends on the detection of anti-HCV antibodies, which do not typically present until two to six months after exposure (Workowski, 2015).

## **2.3 INFORMATION-MOTIVATION-BEHAVIORAL SKILLS MODEL OF RISK BEHAVIOR CHANGE**

The Information-Motivation-Behavior Skills (IMB) model has been used to design interventions that have ultimately improved medication adherence and clinical outcomes in HIV-infected persons. A study conducted at the University of Connecticut evaluated the effect of an AIDS risk reduction intervention on AIDS risk behavior in a college student population by using the IMB model to design, implement, and evaluate the intervention (Fisher, 1996).

The intervention consisted of three sessions, all conducted by health educators. In the first session, information about AIDS risk behavior that targeted information gaps was presented. In the second session, the motivation component, small group discussions were guided by peer educators, and then large group discussions guided by health educators followed by a screening of a movie (Fisher, 1996). The first two sessions aimed to change attitudes and norms regarding preventive behavior, as well as influence perceptions of support networks, and expectations for safer sexual behavior. The final session, comprised of the behavioral skills, taught students how to initiate and maintain safer sexual behavior, and on perceptions of self-efficacy and response efficacy.

To evaluate the effectiveness of the intervention, pre- and postmeasures consisted of self-administered scales designed to assess AIDS risk reduction information, motivation, behavioral

skills, and AIDS risk and AIDS preventive behavior (Fisher, 1996). One month after the intervention, the following were found to be increased at both the individual and group levels: AIDS risk reduction information, improved attitudes toward the performance of AIDS preventive acts, behavioral interventions to adopt preventive behaviors, perceptions of effectiveness of AIDS preventive behaviors being enacted, condom accessibility, safer sex negotiations, and condom use during sexual intercourse (Fisher, 1996). The use of an IMB model intervention also had a significant effect on follow-up HIV testing. In using the IMB model, one can identify modifiable and measurable determinants of behavior, providing an opportunity to improve the mechanisms that underlie decision making at both the individual and group levels (Campbell, 2000). The presence of both information and motivation is thought to lead to behavior skills being acquired, ultimately leading to behavior change. Because of its success in AIDS risk reduction, the IMB model can be used as a guide for the design, implementation, and evaluation of risk reduction interventions targeted at the needs of specific populations (Fisher, 1996).

## **2.4 DISCUSSION**

In general, the effective coordination of care is an essential part in the quality of healthcare. Although there are organizations that emphasize such coordination and the use of evidence-based care, some SUD treatments have limited resources, ultimately preventing this coordination. From a historical standpoint, SUD treatment is provided on an ‘as needed’ basis, meaning that a person usually does not pursue treatment until they experience a negative episode relating to their drug use (Institute of Medicine, 2006). Additionally, there are no concrete or universal measures of

success when it comes to SUD treatment, making outcome metrics difficult to capture across all of the different treatment facilities.

The ongoing debate as to whether or not all pregnant women should be screened for HCV poses a significant public health consideration as it weighs the potential cost of the screens with the logistics of linking women to the indicated care. In identifying HCV infection early in pregnancy, or even before pregnancy, measures can be taken to properly manage and monitor the status of the liver, while also preparing to care for an infected neonate (Ly, 2017).

Until 2011, the standard pharmacotherapy for HCV infection was a combination of pegylated interferon (PEG-IFN) and Ribavirin. However, both of these drugs have side effects and contraindications that advise against use in pregnant women. Ribavirin is an FDA classified Category X drug because of embryocidal and teratogenic effects observed in animals. Because of this, Ribavirin is not recommended for women of child bearing age (“EASL Clinical Practice,” 2011). Since the discovery of the adverse effects of Ribavirin in pregnancy, new pharmaceuticals have been developed and approved for HCV treatment, but there are still no studies available that show the effects on pregnant women. Of the newer medications known as direct-acting antivirals (DAA), the medication with the best outcomes in animal studies is Sofosbuvir. Sofosbuvir works by fully inhibiting one of the HCV polymerase active sites, thus blocking viral RNA synthesis (“Sofosbuvir summary,” n.d.). Sofosbuvir has the potential to become the standard-of-care for women of childbearing age with HCV because of its safety and effectiveness in animal trials.

### **3.0 PROPOSED INTERVENTION**

Based upon current research, there are mutual understandings and agreements in the medical and scientific communities that HCV prevention, treatment, and management in pregnant women with SUD is lacking. With that, proposed is an education campaign for pregnant women with SUD that utilizes the IMB model in the form of self-report journals to provide women with the education and motivation to change their behavior. The goal of the education campaign is to change women's behaviors to prevent HCV infection, improve birth outcomes, and better the outcome of HCV treatment postpartum.

### **3.1 STUDY POPULATION**

The target population for the education campaign is women of childbearing age seeking treatment for SUD. Because this campaign is aimed at the prevention and treatment of HCV, both women with and without HCV will be engaged. As mentioned above, women of childbearing age, particularly between the ages of 19-29, are at the highest risk of getting an HCV infection. Because this education campaign is aimed at improving the outcomes of HCV infection, there will not be many exclusionary criteria. Women entering residential alternatives to incarceration are also eligible to participate, with the permission of their treatment case worker. During the 18-month pilot, 200 women total are to be engaged by receiving self-report journals.

### 3.2 STUDY SETTING

The Greater Pittsburgh area has several state-of-the-art services for individuals with SUD. Given the treatment clinics, mental health support, and inpatient facilities, there are many opportunities to integrate a unique addition in the Greater Pittsburgh area. This pilot study will not be housed in one particular location, rather it will be a collaboration among different providers with the oversight of a project coordinator. Because there is no central location, and the “Baby and Me” journals will be completed by the participants on their own time, it is up to the project coordinator and care specialists (role to be explained further in section 3.4) to keep track of adherence to completing the journals.

As mentioned, Magee-Women’s Hospital of UPMC’s Pregnancy Recovery Center was created in conjunction with four area managed care organizations (MCOs), including Community Care Behavioral Health Organization, UPMC for You, Gateway Health, and United Healthcare for Families and Communities, providing pregnant women with SUD the opportunity to begin treatment with buprenorphine on an out-patient basis, all while integrating it into their obstetric care (Kreps, 2014). Women in the Pregnancy Recovery Center will fit the inclusion criteria because of their concomitant SUD diagnosis and pregnancy. Collaborating with the Pregnancy Recovery Center can help mothers remain HCV free through the pregnancy, or better the birth outcomes of an HCV positive woman.

Women will also be recruited from the numerous SUD centers in the Greater Pittsburgh Area, including but not limited to, Confidential Outpatient Addiction Treatment Center of Pittsburgh, Recovery Pathways, Trinity Wellness Services, South Hills Recovery Project, Journey Healthcare, Community Psychiatric Centers Professional Mental Health Services, Right Track Addiction Services, and New Life Renewal Services. Physicians who prescribe buprenorphine

independently can also recommend this to their eligible female patients to participate in this educational campaign.

In addition to recruiting from SUD treatment centers and buprenorphine prescribers, a mass email will be sent to all obstetric and gynecological providers within the greater Pittsburgh Area. To prevent health coverage limitations, this pilot study does not have any direct affiliation with a medical system.

### **3.3 STUDY AIMS AND GOALS**

The ultimate aims of the pilot study are to change women's behaviors to prevent HCV infection, to improve birth outcomes, and to better the outcome of HCV treatment postpartum.

The goals of the educational campaign are the following:

- Women of child bearing age seeking SUD treatment have increased knowledge of HCV transmission risks;
- Women of child bearing age seeking SUD treatment have increased understanding of recommendations to improve birth outcomes in HCV positive women;
- Women of child bearing age seeking SUD treatment are willing to seek HCV treatment postpartum (if indicated);
- Women with SUD are empowered to work with their health care providers to establish a plan of care to achieve the best possible outcomes for themselves and their neonates;
- Women with SUD will decrease engagement in riskier behaviors that may result in HCV infection;

- Pregnant women with SUD in the greater Pittsburgh area have improved health outcomes;
- Pregnant women with SUD in the greater Pittsburgh area have improved HCV outcomes;
- Neonates born to women with SUD in the greater Pittsburgh area have improved health outcomes; and
- Neonates born to HCV positive women in the greater Pittsburgh area have improved health outcomes.

### **3.4 PILOT STUDY**

In the pilot of the educational campaign, mixed methods will be used to engage with at least 200 women of childbearing age who are diagnosed with SUD and at risk of HCV in the greater Pittsburgh area. Behavioral responses will be collected by means of self-report data. Quantitative birth outcomes will also be measured. Further outlined later in this section, an educational self-report journal will be completed by the target population in efforts to capture behaviors that can influence SUD and HCV infection outcomes. By utilizing a mixed methods approach influenced by the Information-Motivation-Behavioral Skills model, it is expected to yield positive outcomes in regards to HCV education and prevention because the participants may answer more honestly.

### **3.4.1 TRAINING AND RECRUITMENT**

The first step of the “Baby and Me, Without Hep C” campaign is getting IRB approval. Because personal patient health information will be shared, it is assumed that the IRB needs to approve of the self-report journals and recruitment materials. During this approval period, overall recruitment for providers will also begin. This will include hiring program personnel. The program personnel will be responsible for establishing relationships with the community providers (such as the MAT clinics, probation officers, and obstetric providers), and training those personnel on how to distribute the self-report journals to eligible women.

For providers, participation in the pilot campaign requires minimal effort. Providers will be enticed to participate because all of the education materials distributed are from pre-existing documents and recommendations. All of the documents utilized are open access, and any references with copyrights will be appropriately acknowledged. By doing this, not ‘reinventing the wheel,’ providers should be at ease that these are already valid materials and that they do not have to invest in anything other than time to pass the documents out to participants. Essentially, all the community partners/stakeholders will be responsible for is passing out flyers and self-report journals to eligible women. Questions and concerns from the participating sites will always be welcomed by the care coordinators, program coordinators, and program director. The purpose of the ease of use is to be able to build upon the program after establishing relationships.

### **3.4.2 PARTICIPANT RECRUITMENT AND MATERIALS**

Upon developing relationships with the participating providers, the second step of the education campaign will be to identify and recruit eligible women for the campaign. Over a 12-month

recruitment period, self-report journals will be distributed to 200 women seeking SUD treatment within the Greater Pittsburgh Area. Over the 12-month recruitment and data collection period, the program personnel will be in contact with the distribution sites, as well as the patients, to answer any questions that may present.

As for recruitment, all eligible women will be handed a flyer about participating in the campaign. Putting the information on a flyer allows the woman to be in charge of taking the initiative to pursue participation, rather than being influenced by the provider. If a woman indicates that she would like to participate, the provider will distribute the self-report journal, and notify the program coordinator of the potential participant's locator information within 24 hours. Within three business days of the woman expressing interest, program personnel will contact her via her preferred method to further explain the purpose of the 'Baby and Me, Without Hep C' campaign, as well as address any questions she may have. The woman will be informed that she can contact the program personnel at any point during her participation if she were to have any questions.

The self-report journals will act as an educational booklet, as well as a diary for women to feel more empowered and motivated during their SUD treatment to stay HCV free, or to empower them to pursue HCV treatment postpartum if indicated. The journals will be distributed in print, but can also be accessed and completed electronically as a PDF. The journals will be composed of the following sections:

1. **Hepatitis C Education-** The purpose of the HCV education section is to empower to woman to pursue HCV screening throughout her pregnancy. The HCV education section will consist of patient focused education materials directly from the CDC and NIH National Institute of Diabetes and Digestive and Kidney Diseases. The information will

be thorough enough for women to understand the severity of hepatitis C, while easy enough to understand so that the woman is not overwhelmed. At the end of the Education Section, a competency survey can be found. This competency survey should be completed by the participating woman.

2. **Prenatal Preparation-** This section of the booklet will explain the risks that HCV poses for pregnancy, both for mother and baby. This section will reiterate the importance of safe injection practices and further encourage SUD treatment. Communication with the woman's obstetrician will also be emphasized in this section.
3. **Postpartum Care-** this section will provide resources for women to pursue HCV treatment postpartum, if indicated. A list of providers who treat HCV will be found here, and can be personalized by the participant, or medical provider, with appointment and follow-up information.<sup>1</sup>
4. **Diary-** This section of the booklet will be used to capture the woman's entire experience, including SUD treatment, prenatal care, antenatal care, postpartum care, and HCV education segment. The diary portion will encourage the mother to change her behaviors through the course

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<sup>1</sup> Upon the design of this campaign, extensive information about the treatment and management of HCV was going to be included in this section. However, after beginning to develop the program and complete further research, it was determined that the journal would best serve as a tool to motivate women at risk for pregnancy and HCV to prevent infection and pursue treatment, if need be. By doing this, the woman will not be overwhelmed with too much information that she may not be able to fully understand.

of her SUD treatment to not only better the outcomes of her treatment, but also to better the outcomes of her pregnancy when the time comes.

5. **Emergency contact information-** Because many women experiencing SUD also have disadvantaged living situations, a list of providers, from food services to crisis relief centers, will be provided at the end of the booklet.
6. **Neonate outcomes-** This section will not be filled out by all participants. Because the inclusion criteria being women of child bearing age, and not necessarily just pregnant women, there will also be women who never are pregnant during this pilot recruitment.
7. **Evaluation surveys-** At the end of booklet, participants will be asked questions relating to whether or not they learned anything during the education campaign. The responses for the questions will be on a Likert scale.

### **3.4.3 DATA COLLECTION**

Data collection and evaluation will occur on a rolling basis and will end exactly 12 months after the 200<sup>th</sup> individual engages by receiving access to a journal. One-hundred twenty women are expected to complete the journals in their entirety and submit them. Upon the completion of each individual self-report journal, the woman is to contact the associated program personnel to arrange pick-up. If the woman is pregnant, she will also have the option to report birth outcomes in the

‘Neonate Outcomes’ section of the journal. The purpose of capturing the birth outcomes is to eventually compare them with an adjusted control that did not receive educational intervention.

During provider recruitment, providers and office staff will be given the opportunity to submit observation forms that capture the following metrics: overall ease of program integration into office flow, and overall impact of program among patients. Similarly, as a part of the self-report journals that the participants receive, the female participants will also have the opportunity to submit experience forms that capture the following metrics: ease of joining program, overall impact of program on SUD diagnosis, overall impact of program on HCV diagnosis, increase in SUD knowledge, increase in HCV knowledge. Table 3 below outlines the observation forms, from both providers and participants, that may be submitted at any time to showcase the impact of the program. The purpose of allowing the participating women to speak with program personnel is to empower them to pursue further care of HCV (if indicated), and to continue preventing HCV infection. By using ordinal scales to determine the degree to which the providers and participants feel a certain way, the program personnel will be able to immediately see whether or not the program is being received well at any given location.

**Table 3. Observation Forms for Providers and Participants**

Provider Observation Form “Baby and Me: Without Hep C”						
	1: Strongly Agree	2: Agree	3: Neutral	4: Disagree	5: Strongly Disagree	N/A
I feel that the program is easy to integrate into our office flow...						
Comments:						
I feel that the program has a positive impact on the participating patients...						
Comments:						
Participant Observation Form “Baby and Me: Without Hep C”						
	1: Strongly Agree	2: Agree	3: Neutral	4: Disagree	5: Strongly Disagree	N/A
I feel that the program was easy to join...						
Comments:						
I believe that participating in this program has positively affected my SUD diagnosis...						
Comments:						
I believe that participating in this program has positively affected my HCV diagnosis...						
Comments:						
This program has increased my knowledge on SUD...						

<b>Table 3 Continued</b>						
Comments:						
This program has increased my knowledge on HCV...						
Comments:						

The timeline for the ‘Baby and Me, Without Hep C’ campaign is illustrated in the appendix.

### 3.5 DATA ANALYSIS

Data analysis will be conducted on a rolling basis, with an inductive approach. First, all open-ended entries in the journal will be transcribed, coded, and sorted into related categories. The categories will be examined, and if relationships presented, they will be noted and evaluated. The purpose of this program is not to prove that the IMB model provides improved health outcomes, but rather, the information gathered will be used to determine whether or not the IMB model can be used to improve health outcomes. MAXQDA, a software program designed to facilitate and support qualitative, quantitative, and mixed methods research projects, will be used to cross-examine relationships and to determine if there are any significant findings. MAXQDA was chosen as the data analysis database because it focuses on mixed methods research, linking qualitative text analysis and quantitative methods (“MAXQDA:...,” n.d.). Trained project personnel will run the data analysis to determine if there are any recurrent themes in the narratives.

Although women with SUD may share some fundamental aspects of their experience with SUD, it is expected that the open-ended portions will still be vastly different. All of the open-ended portions of the diary will be examined to determine if there is any type of trends in reporting (i.e.,

reporting disadvantaged living situations, abusing painkillers, etc.). The decision to use qualitative data was made to fully capture exactly what the woman wants to say, and to see exactly how their life factors are influencing their health. The qualitative, open-ended portions of the journal are being utilized in place of in-person interviews to save on time of the providers. The use of self-reported journals are being used under the premise that women are going to feel more empowered to complete them, and complete them honestly. The women who will be participating are already pursuing SUD treatment, so that alone suggests that they may be more willing to further engage in a program as such.

The entire journal will have Likert based responses to determine competencies influenced by the IMB model, and to determine whether or not the program goals were met. The competency surveys will then be compared to the evaluation surveys at the end of the journals. How measurements are to be assessed are outlined in Table 4 below.

**Table 4. Assessment of Measurements**

<b>Measures of Information</b>		
<b>Goals</b>	<b>Location in program</b>	<b>Data type</b>
<b>Women of child bearing age seeking SUD treatment have increased knowledge of HCV transmission risks.</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Hepatitis C Education</b> section.</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>
<b>Women of child bearing age seeking SUD treatment have increased understanding of recommendations to improve birth outcomes in HCV positive women.</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Prenatal Preparation</b> section.</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>
<b>Measures of Motivation</b>		
<b>Women of child bearing age seeking SUD treatment are willing to seek HCV treatment postpartum (if indicated).</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Postpartum Care</b> section.</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>
<b>Women with SUD are empowered to work with their health care providers to establish a plan of care to achieve the best possible outcomes for themselves and their neonates.</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Hepatitis C Education</b> section.</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>
<b>Measures of Behavior</b>		
<b>Women with SUD will decrease engagement in riskier behaviors that may result in HCV infection.</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Hepatitis C Education</b> section.</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>
<b>Pregnant women with SUD in the greater Pittsburgh area have improved health outcomes.</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Neonate Outcomes</b> section.</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>
<b>Pregnant women with SUD in the greater Pittsburgh area have improved HCV outcomes.</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Neonate Outcomes</b> section.</li> <li>OB/GYN reporting</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>
<b>Neonates born to women with SUD in the greater Pittsburgh area have improved health outcomes.</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Neonate Outcomes</b> section.</li> <li>OB/GYN reporting</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>
<b>Neonates born to HCV positive women in the greater Pittsburgh area have improved health outcomes.</b>	<ul style="list-style-type: none"> <li>Competency survey in <b>Neonate Outcomes</b> section.</li> <li>OB/GYN reporting</li> </ul>	<ul style="list-style-type: none"> <li>Ordinal</li> <li>Open-ended</li> </ul>

The information captured in the education campaign journals will inform women, motivate them, and have them make better behavioral choices to improve SUD and HCV outcomes.

#### 4.0 STRENGTHS AND LIMITATIONS

There are several strengths to this proposed educational campaign. First and foremost, participation requires minimal effort by providers, enticing them to engage with eligible women and distribute self-report journals to them. Second, by utilizing self-report journals, women may feel more in charge of their care, and therefore may answer more honestly. However, considering the diaries are self-report, they also may be wary of judgment or discrimination, and may not answer truthfully. Because the education campaign is targeting women of child bearing age, women may feel that they could be treated negatively (if pregnancy results) while pursuing SUD treatment.

One limitation that is discussed in the assumptions portion of the logic model is that there may not be sufficient interest amongst eligible women or amongst treatment providers. To address this, care coordination specialists can encourage potential providers by ensuring that there is minimal effort required on their part. As for gaining interests of the target population, one way to encourage participation is to reiterate that they are already involved with a treatment structure and that their participation in the education campaign yields virtually no risks to them.

Although SUD and HCV infection is a structural problem, an individual-level intervention was implemented for the Baby and Me: Without Hep C program with the hopes that each woman would feel empowered to take charge of her care. By directly educating each individual, it is hoped to yield better outcomes. With that, the individual-level approach could also act as a major limitation by not motivating the participants enough, like a group-level intervention might have.

The Baby and Me: Without Hep C program is designed to require little funding and time commitment from all parties involved. With that, it is thought that the program will be sustainable

because of its 'hands off' design. However, this could also allow for program aspects to be neglected and not be utilized to its full potential, no longer being sustainable.

## 5.0 CONCLUSION

Despite the urgent push for comprehensive care for individuals with SUD, the treatment of HCV as it relates to pregnancy and SUD has notably been neglected. The intended goal of the ‘Baby and Me, Without Hep C’ campaign is to better the outcomes for both mothers and babies, and by targeting women of child bearing age with SUD. Self-efficacy plays a large factor into health outcomes, so in order to produce the best possible outcomes for mother and baby in the case of HCV infection, the participating women will be educated and motivated to pursue treatment and/or prevention, before, during, and after pregnancy. By integrating this campaign with a woman’s SUD treatment, it is showing that her whole well-being is being cared for.

**APPENDIX: SUPPLEMENTAL TABLE**

**Table 5. Timeline**

<b>Activity</b>	<b>Involvement</b>	<b>Time</b>
<b>A. Training and Recruitment</b>		
Hire Key Personnel	Program director, program coordinator, care coordinator specialists, data analysts	Month 0 - Month6
Self-Report Journal Compilation (print and electronic)	Program director, program coordinator	Month 0 - Month 6
IRB Approval	Program director, program coordinator, IRB	Month 0 - Month 6
<b>PILOT STUDY BEGINS</b>		
Recruit Providers	Program director, program coordinator, care coordinator specialists, providers	Month 6 – Completion
Distribute Recruiting Materials to Providers	Program director, program coordinator, care coordinator specialists, providers	Month 6 - Completion
<b>B. Participant Recruitment</b>		
Distribute Recruiting Flyers to Participants	Program director, program coordinator, care coordinator specialists, providers, women of child bearing age with SUD	Ongoing
Distribute Self-Report Journals to Participants	Providers, care coordinator specialists	12 month duration
<b>C. Data Collection and Analysis</b>		
Collect Data	Care coordinator specialists, providers	Ongoing basis from start of journal distribution
Analyze Data	Care coordinator specialists, data analysts	Ongoing basis from return of journals
<b>D. Results</b>		
Disseminate Findings	Program director, program coordinator, care coordinator specialists, providers, women of child bearing age with SUD, stakeholders	Upon completion of final engaged participant

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